2024

Enhancing Organisational Performance through Patient-focused Learning Excellence in the Biopharmaceutical Industry

Lori Richter
Technological University Dublin, Ireland, lori.richter@tudublin.ie

Enhancing Organisational Performance through Patient-focused Learning Excellence in the Biopharmaceutical Industry

Lori Richter, B.S Microbiology

College of Science and Health,

School of Chemical and Biopharmaceutical Sciences

A thesis submitted to Technological University Dublin in fulfilment of the requirements for the award of Doctor of Philosophy (PhD)

Supervisors: Professor Anne Greene & Dr Nuala Calnan

February 2024

Volume 1

“Education is the acquisition of the art of the utilisation of knowledge”

– Alfred North Whitehead (Whitehead, 1929).

ABSTRACT

Drug shortages, quality defects and challenges regarding innovation within the biopharmaceutical industry pose significant risks to patient safety and organisational performance. These problems persist despite the many scientific, technological and economic advances over the past several years in a well-funded, high-revenue industry operated by highly qualified personnel. Evidence suggests that the industry has yet to fully realise the potential for building organisational capabilities to enable learning from mistakes to enhance performance outcomes.

This research study explored how biopharmaceutical companies can learn from their mistakes and embrace a culture of learning in order to reduce quality defects and drug shortages by deliberately and continuously innovating to improve operational performance and reduce patient risk.

The research unfolded in four phases. Phase I involved a comprehensive literature review and the development of an initial concept for a Patient-focused Learning Excellence Model (PFLEx). Phase II engaged industry experts through a podcast series, *Risk Revolution*, to gather insights into learning within the biopharmaceutical sector. The research uncovered barriers to adopting organisational learning within the industry. The PFLEx prototype emerged as an output of this phase of research.

Phase III employed a qualitative case study approach to evaluate and test the PFLEx prototype, resulting in its refinement as PFLEx 1. Phase IV involved an expert focus group to critically evaluate PFLEx 1 and enhance it, leading to the final PFLEx 2 model.

The final 3D PFLEx model emerged as a transformative framework, integrating design elements, theoretical frameworks, instructional design and development processes, and deployment practices. The aim was to shift from compliance-focused training to learning excellence programmes centred on patient safety and continuous improvement.

Key outputs from the research included the definition of a learning culture in the biopharmaceutical industry, determining enabling behaviours, creating the Adult Learner Effective cGMP Training Tool (ALECT) and developing the Patient-focused Learning Excellence Model (PFLEx).

PFLEx was aimed at enhancing patient outcomes, reducing risks and sustaining operational excellence by fostering a culture of continuous learning and innovation. Future work could involve conducting in-depth case studies and providing guidance for different organisational maturity levels to ensure effective implementation.

The 3D PFLEx model has positioned learning as a dynamic contributor to organisational resilience, innovation, and improved performance, aiming to assist biopharmaceutical organisations in reducing drug shortages and quality defects by achieving continuous improvement and patient-focused learning excellence.

DECLARATION

I certify that this thesis which I now submit for examination for the award of Doctor of Philosophy (PhD) is entirely my own work and has not been taken from the work of others, save and to the extent that such work has been cited and acknowledged within the text of my work.

This thesis was prepared according to the regulations for graduate study by research of the Technological University Dublin (TU Dublin) and has not been submitted in whole or in part for another award in any other third-level institution.

The work reported on in this report conforms to the principles and requirements of the TU Dublin guidelines for ethics in research.

TU Dublin has permission to keep, lend or copy this report in whole or in part, on condition that any such use of the material of the report be duly acknowledged.

15 February 2024

Lori Richter **Date**

ACKNOWLEDGEMENTS

The researcher would like to express her heartfelt gratitude to the dedicated and insightful supervisors, Dr. Anne Greene and Dr. Nuala Calnan, whose unwavering support, guidance and expertise have shaped this thesis. Their mentorship and constructive feedback were significant in enriching this academic journey.

The researcher would also like to thank her esteemed colleagues in the PRST programme. The collaborative environment was a source of inspiration and motivation. The invaluable discussions, shared insights and collective commitment to academic excellence enhanced the quality of this research.

Thanks to the researcher's family for their resolute support throughout the academic journey.

This thesis is a testament to the collaborative spirit and collective effort of an incredible community of scholars, mentors and loved ones, making it a fantastic academic adventure.

GLOSSARY OF TERMS AND LIST OF ABBREVIATIONS

ALECT = Adult Learner Effective cGMP Training

AR = Augmented Reality

CEB = Corporate Executive Board

CFR = Code of Federal Regulation (US)

CG&T = Cell and Gene Therapy

cGMP = Current Good Manufacturing Practices (denotes the expectation of continual learning and current standards)

CMCQA = Chemistry, Manufacturing and Controls Quality Assurance

CMO = Contract Manufacturing Organisation

CO = Contract Organisation

EMA = European Medicinal Agency

EU = European Union

FDA = Food and Drug Administration (US regulatory body)

FDASIA = Food and Drug Administration Safety and Innovation Act

GMP = Good Manufacturing Practices

GxP = Used to denote all good practices in the pharmaceutical life cycle (e.g., GCP Good Clinical Practice; GDP Good Distribution Practices, etc.)

HPRA = Health Products Regulatory Authority

ICH = International Council on Harmonization

ILT = Instructor-led Training

IMP = Investigational Medicinal Product

IVT = Institution of Validation Technology

KM = Knowledge Management

KSA = Knowledge, Skills, Abilities

L&D = Learning and Development

LNA = Learning Needs Assessment

MMR = Mixed or Multi-methods Research

MRA = Manufacturer-Registered Authorisation

OJT = On-the-job Training

OOS = Out of Specification

PGEU = Pharmaceutical Group of the European Union

PQS = Pharmaceutical Quality System

PRST = Pharmaceutical Regulatory Science Team

QRM = Quality Risk Management

QP = Qualified Person

R&U = Read and Understand

RA = Risk Assessment

RP = Responsible Person

SME = Subject Matter Expert

SOP = Standard Operating Procedure

vILT = Virtual Instructor-led Training

VR = Virtual Reality

WHO = World Health Organization

3pVRMO = Third-party Vendor Risk Management Oversight

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1: INTRODUCTION AND CONTEXT

> *Patients deserve to receive every dose of every medicine they need, every single day. (Ranmarine, 2021)*

Pharmaceutical quality is achieved by assuring that every dose of a drug on the market is safe, effective and free of contamination and defects (UD FDA CDER, 2022). The assessment of quality for each drug marketing or licensing application includes a detailed assessment of both the drug substance and drug product, as well as the proposed manufacturing process, facilities and workforce, and the overall control strategy set out by the organisation seeking the license. Each site involved in the manufacture and distribution of a drug must adhere to current good manufacturing practice (cGMP) requirements, which define the minimum manufacturing standards to legally market drug products. The US Food and Drug Administration (FDA) and other global regulatory agencies perform routine facility evaluations and surveillance, including facility inspections, to provide assurance that manufacturing sites comply with cGMP. This regulatory oversight is intended to provide patients and consumers with confidence in every dose of medicine they receive.

The 2022 Quality Management Maturity white paper from the Centre for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality (OPQ) at the FDA highlights the post-approval challenges that can arise, resulting in supply disruptions which put a patient's access to their medicine at risk:

> *Patients and consumers also deserve confidence in the availability of their medicines. Their access should not be impeded by drug shortages or supply disruptions. (US FDA CDER, 2022)*

The white paper clearly states that compliance with the cGMPs alone does not eliminate this risk:

> *Simple adherence to cGMP standards does not indicate, for example, that a firm is investing in improvements or deploying statistical process control to prevent supply disruptions. (US FDA CDER, 2022)*

According to recent research conducted at TU Dublin, the increasing complexities affecting the landscape within which the biopharmaceutical industry operates have led to the "wicked problem of ongoing drug shortages, quality defects, products recalls and a lack of innovation" (Ranmarine, 2021). This "wicked problem" presents a challenge to ensuring patients reliably receive every dose they need, every day. In 2019, Dr Janet Woodcock, then director of the Centre for Drug Evaluation and Research (CDER) at the FDA, outlined the potentially devastating impacts of drug shortages as "a critical health care issue that reduces treatment options, limits access to medications, and can threaten the well-being of patients in need of important therapies" (Woodcock, 2019).

In identifying the underpinning reasons for these drug shortages, the 2019 report *Drug Shortages: Root Causes and Potential Solutions* (US FDA, 2019) indicated that 62% of drugs that were in short supply between 2013 and 2017 were associated with *manufacturing or product quality problems* (e.g., substandard manufacturing facilities/processes or quality defects in the finished product). These quality problems necessitate remediation, which can take time (waiting for the available resources within

the manufacturing facilities) to address, causing interruptions in production schedules and contributing to drug shortages.

More recently, the 2022 drug shortages report to the US Congress by the FDA noted that

> *Shortages continue to pose a real challenge to public health, particularly when the shortage has involved a critical drug to treat cancer, to provide parenteral nutrition, or to address other serious medical conditions, such as a shortage of antibiotics. In the past year, FDA has seen manufacturers in the United States and abroad continue to experience quality issues as well as struggle with capacity constraints. (US FDA, 2022)*

The problem of drug shortages extends beyond US borders; it is a global healthcare problem. A Pharmaceutical Group of the European Union (PGEU) survey completed in 2022, involving 29 European countries, including EU members and Turkey, Kosovo, Norway and North Macedonia, reported that almost a quarter of those countries had more than 600 drugs in short supply, and 20% of those surveyed reported 200-300 drug shortages. More seriously, four countries reported that these shortages had been linked to patient deaths (PGEU, 2022).

The US Homeland Security and Governmental Affairs report on drug shortages from 2023 summarises the impacts:

> *Drug shortages are increasing, lasting longer, and impacting patient care: Between 2021 and 2022, new drug shortages increased by nearly 30 percent. At the end of 2022, drug shortages experienced a record five-year high of 295 active drug shortages. While the average drug shortage lasts about 1.5 years, more than 15 critical drug products have been in shortage for over a decade. Shortages continue to have devastating consequences for patients and health care providers, including medication errors and*

> *treatment delays, and in some cases, have led to doctors having to ration lifesaving treatments. (HSGAC, 2023)*

To identify the root causes of the problem, the 2019 US FDA Drug Shortages report warns that organisations built on a foundation of basic cGMP requirements, coupled with a lack of continual improvement, *will* result in drug shortages (US FDA, 2019). Conversely, the report points out that organisations that strive to build capabilities to detect and address vulnerabilities, coupled with a continuous improvement culture, will result in a mature quality system that *significantly reduces* the risk of drug shortages (US FDA, 2019).

This point was also highlighted by Fugate in his 2018 review of industry trends:

> *Right now, it [the data] is saying that we are doing the same things wrong, year after year. We can improve, and we must. It just takes time to mentor and develop the workforce to resolve the root causes of these observations (Fugate, 2018).*

The data is clearly telling us that the problems of drug shortages, quality defects and lack of innovation are persistent and entrenched, despite the many scientific, technological, and economic advances over the past several years, in a well-funded, high-revenue industry, operated by highly qualified personnel. The evidence supports the hypothesis that the opportunity to build the organisational capabilities required to learn from mistakes and improve performance outcomes has not yet been fully realised within the biopharmaceutical sector. This research study seeks to examine this hypothesis, and Chapter 1 sets out the context within which the study was undertaken.

1.1 Drug Shortages: A Wicked Problem

Ten years ago, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) concluded that the objective of the reliable supply of safe, effective, high-quality medicines for patients has yet to be accomplished and that the issue of drug shortages was a cause for concern. The ICH Q12 Concept Paper acknowledges that "several gaps exist which limit full realisation of intended benefits" (ICH, 2014).

Vinther was among the first to contend that the persistent issue of drug shortages is in fact a "wicked problem", introducing the term in an article published in the PDA letter (Vinther, 2016). Rittel and Webber characterised a wicked problem as

> *A problem which is highly resistant to solutions, which are highly complex and cannot be well-defined, do not have easily defined solutions, and cannot be solved by any one group of people. (Rittel & Webber, 1973)*

For more than a decade, multiple researchers from the Pharmaceutical Regulatory Science Team (PRST) based at TU Dublin, Ireland, have examined how this "wicked problem" poses risks for patients and ongoing challenges for organisations. This research includes work by Dr Kelly Waldron (2018) and Dr Ghada Haddad (2019) with respect to quality risk management (QRM). It also incorporates work by Dr Paige Kane (2018) and Dr Martin Lipa (2021) in relation to knowledge management (KM) and by Dr Nuala Calnan (2014) with respect to the importance of nurturing and supporting a culture of excellence within organisations. These researchers found that without leadership investment in the behaviours that contribute to a culture of excellence coupled with the

effective use of QRM and KM, the Pharmaceutical Quality System (PQS) cannot be effective, and it is therefore not possible for organisations "to maximise benefits from continual improvement and innovation" (ICH Q10, 2008).

1.2 Learning from Our Mistakes

Following on from the body of PRST research, this researcher contends that a key contributor to this wicked problem is that the biopharmaceutical industry has a fundamental problem of not learning from its mistakes. This researcher proposes that a lack of responsiveness to learning and the ineffective use of organisational knowledge present real risks to patients and have negative consequences for organisational performance. Evidence presented in relevant literature shows (as outlined in more detail in Chapter 2) that while many industries have successfully adopted operational excellence and quality maturity principles and tools, the pharmaceutical sector has been slower to capitalise on these learnings (McKinsey, 2014; MDIC, 2015). In 2017, Yu and Kopcha from the US FDA reinforced and extended the FDA's vision for pharmaceutical quality by challenging the industry to achieve continuous improvement and operational excellence capability to better ensure reliable supply and minimise the risk to consumers (Yu & Kopcha, 2017).

Garvin notes that any organisation seeking to enhance its capability requires "a distinctive mind-set, tool kit, and pattern of behaviours" (Garvin, 1993). This distinctive mindset is one that encourages those working in the company to learn from their mistakes by recognising the value of *productive failure* as opposed to *unproductive*

success. Garvin defines a *productive failure* as one that leads to new information and understanding, adding to the body of knowledge within the organisation, whereas an *unproductive success* occurs when something goes well but nobody knows how or why (Nadler, 1989). As early as 1990, Peter Senge outlined in his work *The Fifth Discipline* the potential benefits associated with creating a learning organisation. These learning organisations, which are led by *learning leaders*, drive continuous improvement, create growth opportunities, retain talented staff, increase collaboration and seek to build both business value and longevity (Gibbs, 2020; Senge, 2006). This research study explores how biopharmaceutical companies can address one important aspect of this "wicked problem" by learning from their mistakes and embracing a culture of learning. This may serve to reduce the risks patients are exposed to from quality defects and drug shortages by innovating to improve operational performance.

1.3 Training Compliance Versus Learning Excellence

The biopharmaceutical industry is required to train and qualify staff to ensure the biopharmaceutical product is compliant and manufactured according to specifications. This researcher proposes that the current training and education available for relevant personnel in the biopharmaceutical industry is heavily focused on fulfilling current good manufacturing practice (cGMP) regulatory compliance requirements and does not support the actual use of that knowledge though the development of individual competencies and organisational capabilities in risk-based decision making, critical thinking and the underpinning proactive behaviours necessary to build a culture of learning.

cGMP regulations (as outlined by the Regulatory Health Authority, as detailed in Table 1.1) stipulate specific requirements related to the qualification of personnel, training and performance monitoring. This establishes the minimum expectations from the regulators with respect to training. As stated by Jim Vesper, "personnel should be appropriately trained or otherwise qualified in the procedures and methods they use and the tasks they perform" (Vesper, 2018).

Regulatory Health Authority	Compliance Requirement
US FDA	Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs (US FDA 21CFR211.25). Each person responsible for supervising the manufacture, processing, packing or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess (US FDA 21CFR211.25). Personnel *(a) General.* Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed. (b) *Training.* Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented. (1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs. (2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions (21CFR820.25).
Health Canada	Ensure all personnel conducting GMP activities are able to understand the written procedures for those activities (Health Canada, C.02.006 5(e)). Provide training before implementing new or revised standard operating procedures (SOPs). Maintain records of training. Give specific training to personnel working in areas where highly active, toxic, infectious, or sensitising materials are handled. Ensure access to relevant information (e.g., safety data sheets) (Health Canada, C.02.006 5(e)).
EU	The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product (European Commission, EU 2.10).

Regulatory Health Authority	Compliance Requirement
	Besides the basic training on the theory and practice of the quality management system and Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept (European Commission, EU 2.10).

Table 1.1: Biopharmaceutical industry regulations related to training and qualifications

The regulatory requirements are clear. Biopharmaceutical companies must provide an appropriate level of knowledge, skills and abilities (KSAs) for the employee to perform their job duties and meet their responsibilities to provide safe and efficacious products to patients. This researcher proposes that assuring the availability of skilled workers who meet the minimum compliance-focused training requirements may satisfy global health authority expectations, but this does not result in organisations which are capable of learning from their experiences. Nor does it ensure the timely and effective dissemination of that learning to respond to emerging economic conditions or technological advances which best meet patients' needs and business needs (Choo, 1996; Ingelgård et al., 2002; Senge, 2006).

As defined by Rashid K Al-Abri and Intisar S Al-Hashmi in *The Learning Organisation and Health Care Education*,

> *A learning organisation encourages its members to improve their personal skills and qualities, so that they can learn and develop. They benefit from their own and other people's experience, whether they are positive or negative. In a learning organisation, there are more opportunities to be creative and this helps ensure that any individual will be able to cope rapidly with a changing environment and move freely within the organisation. (Al-Abri and Al-Hashmi, 2007)*

This ability to “cope rapidly with a changing environment” is a critical differentiator for successful organisations today. Supply chains are more complex, while business networks are more fragmented, and the impact of globalisation exerts increasing pressure on businesses. The need to embed these learning organisation principles within the biopharmaceutical industry is greater than ever before. With tight labour markets, there is increasing pressure to retain talent and knowledge to enhance understanding of the dynamic environment in which companies function. A culture that values learning and continuous improvement is necessary to survive in this competitive landscape (Powar, 2010). As the biopharmaceutical industry seeks to invent, innovate and improve, its mission must not only be to hire and develop *technically* capable people, but it must value and ensure that they have the freedom to learn and share what they have learned within a growth mindset environment (Bersin, 2013). In an environment of patient-focused learning excellence, the mindset is grounded in people learning for the purposes of innovating and improving the patient experience.

Patient-focused learning excellence in the pharmaceutical industry refers to a commitment to understanding and meeting the needs of patients through continuous learning and improvement. This approach involves actively seeking feedback from patients, caregivers and healthcare professionals to enhance products, services and support by considering how the manufacturing processes and products impact on patients' well-being, safety and overall experience. For example, a pharmaceutical company might engage in patient-focused learning excellence by collaborating with patient advocacy groups and healthcare providers to gather insights and feedback on

clinical trial design and support programmes. Another example could be continuously improving manufacturing processes to minimise the risk of defects and contamination, which could adversely affect patients' health. By prioritising patient-focused learning excellence, pharmaceutical companies can improve organisational performance, foster patient trust by reducing risk and, ultimately, improve patient outcomes.

1.4 Training Versus Learning – A Key Distinction

A useful distinction between training and learning is presented in *Learning and Development in Organizations*, where Garavan et al. (2020) provide two simple definitions that highlight a clear difference between the two approaches.

> ***Training:*** *Formal and planned efforts to ensure that employees acquire KSAs to enhance performance in their current role.*
>
> ***Learning:*** *A process through which employees acquire KSAs that involve unconscious learning processes, including awareness, reflection and experience.*

These different approaches are further examined and summarised by the researcher in Table 2.3 (Chapter 2).

Vesper notes that it has become commonplace within many biopharmaceutical organisations to change the name of their traditional training departments to incorporate the word “learning” (Vesper, 2018). This indicates that there is at least an awareness of the need to transition from “training” to “learning”, but to be effective, this must also be accompanied by a more fundamental change in philosophy. Vesper proposes that this awareness offers the prospect of positive implications for future employee development within the biopharmaceutical industry (Vesper, 2018). For this

researcher, understanding the distinction between training and learning, and how the two can work together to develop the necessary KSAs, is a crucial first step for an organisation that desires to pursue a strategy of patient-focused learning excellence.

1.5 Researcher Introduction and Positionality

The researcher brings over 25 years of biopharmaceutical experience gained in various roles and organisations across the industry. Starting her career as a technician at a biologics company that produced monoclonal antibodies on a large scale, and given the complexity of the work at hand, she began to develop a passion for learning in this area. As the researcher moved on to a manufacturing site quality assurance (QA) role, reviewing batch records, managing deviations and change control, as well as preparing product batch lots for release to the market, an interest in continuous improvement and root cause analysis emerged. Subsequent years spent as a quality assurance investigator, assessing critical failure events, determining root causes and the necessary corrective actions, reinforced this learning mindset.

A global quality role in the quality risk management function of a multinational biopharmaceutical company led the researcher to develop training courses to educate colleagues across the company network in relation to managing risk. Through this, the researcher developed a passion for training and the sharing of knowledge to improve processes and overall performance. This drove the researcher to learn more about adult learning theory, the most appropriate ways to share knowledge (whether tacit or explicit) and how to measure the effectiveness of knowledge transfer. This led to

curiosity about the foundations of learning principles to address common challenges and build improvements within the biopharmaceutical industry. Subsequently, this learning journey led directly to the exploration of learning organisations as the pathway to reducing risk for the patient and enhancing business outcomes.

1.6 Focus of This Research Study

The research hypothesis for this study is as follows:

> *The current training and education for personnel based in the biopharmaceutical industry is focused on fulfilling regulatory compliance requirements. These compliance-focused training programmes do not adequately develop capabilities in critical thinking, risk-based decision making, reflection and associated proactive behaviours necessary to build the types of learning organisations which support the development of individual competencies and build organisational capabilities.*

Exploration of this hypothesis led to the development of a theoretical framework which underpins this study and is presented in more detail in Chapter 3. Ultimately, the research question explored within this study asks the following:

> *Can companies learn from their mistakes to reduce risk and improve overall operational performance by pursuing a strategy of patient-focused learning excellence?*

1.7 Purpose of the Research and Thesis Structure

The goal of the research is to develop a practical patient-focused learning excellence (PFLEx) model driven by enlightened leaders who sponsor, nurture and sustain a learning culture within their organisation. The intention is that this practical model can be used within the biopharmaceutical sector to develop structured learning and development (L&D) programmes that encourage learning from mistakes, reducing risk and seeking

opportunities to improve organisational performance. The evolution of the design and development of the PFLEx Model has occurred across four phases of this research study (Research Phases I-IV) and is depicted in Figure 1.1.

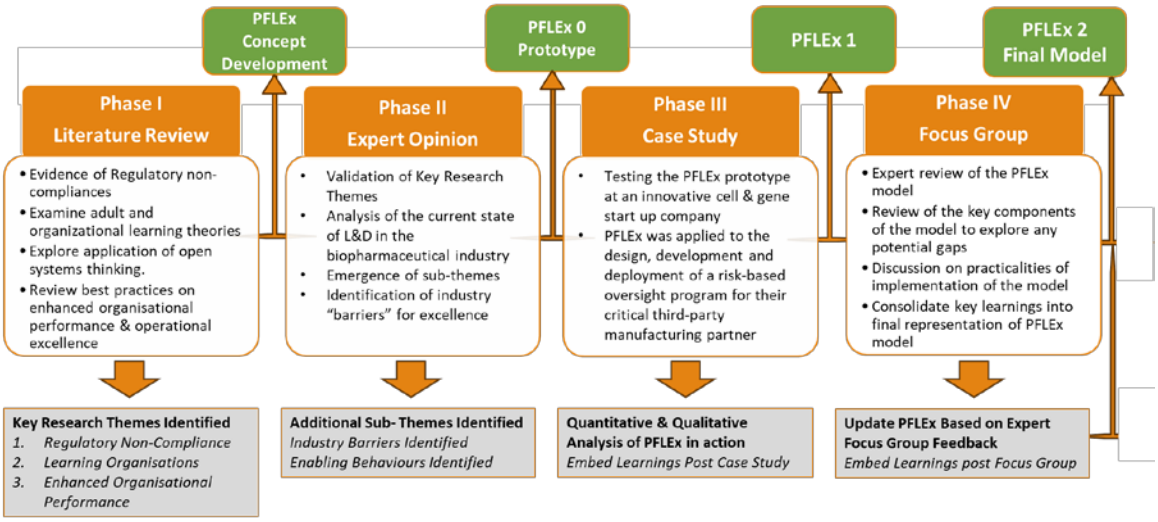


Figure 1.1: Evolution of the design and development of the Patient-focused Learning Excellence PFLEx Model across Research Study Phases I-IV

The first phase (Phase I) consisted of a detailed literature review which documented evidence of regulatory non-compliance, examined adult and organisational learning theories, explored open systems thinking and reviewed best practices on organisational performance and operational excellence (presented in Chapter 2). From this phase of the study, three key research themes were identified, as follows:

1. **Regulatory non-compliance** – evidence of the problem
2. **Learning organisations** – opportunities to address the problem
3. **Enhanced organisational performance** – how to measure and sustain L&D *effectiveness*

Arising out of this phase of study, the PFLEx concept was developed, and Phase II of the research solicited expert opinions to validate the key research themes identified and to analyse the current state of L&D in the biopharmaceutical sector (presented in Chapter 4). From this phase, two additional key sub-themes emerged:

1. Industry barriers to learning
2. Enabling behaviours for learning

Arising out of Phase II of the study, a PFLEx 0 Prototype Model was developed, which was tested via an industry case study, affording the researcher the opportunity to carry out quantitative and qualitative analyses of the prototype in action (presented in Chapter 6). This analysis led to the development of the PFLEx 1 Model, which was subsequently evaluated by an expert focus group (presented in Chapter 7). Based on the learnings from this focus group evaluation, PFLEX 2, the final model, was developed (presented in chapter 8). Chapter 9 summarizes outputs and impact of the research, followed by conclusions and recommendations for future work presented in the final chapter, Chapter 10.

CHAPTER 2: LITERATURE REVIEW

Before commencing an exploration of the theoretical and practical perspectives in the field of learning and development (L&D), the researcher set out to identify evidence that organisations within the biopharmaceutical industry do not learn from their mistakes. This involved an analysis of the publicly available regulatory non-compliance data, which is presented in Section 2.1, below. Figure 2.1 illustrates the journey of the literature review, including how each topic commenced with a broader exploration and followed on to address the specifics relevant to the biopharmaceutical industry. The illustration also depicts how the literature review underpinned the outputs of the research, linking this to the subsequent chapters of this thesis.

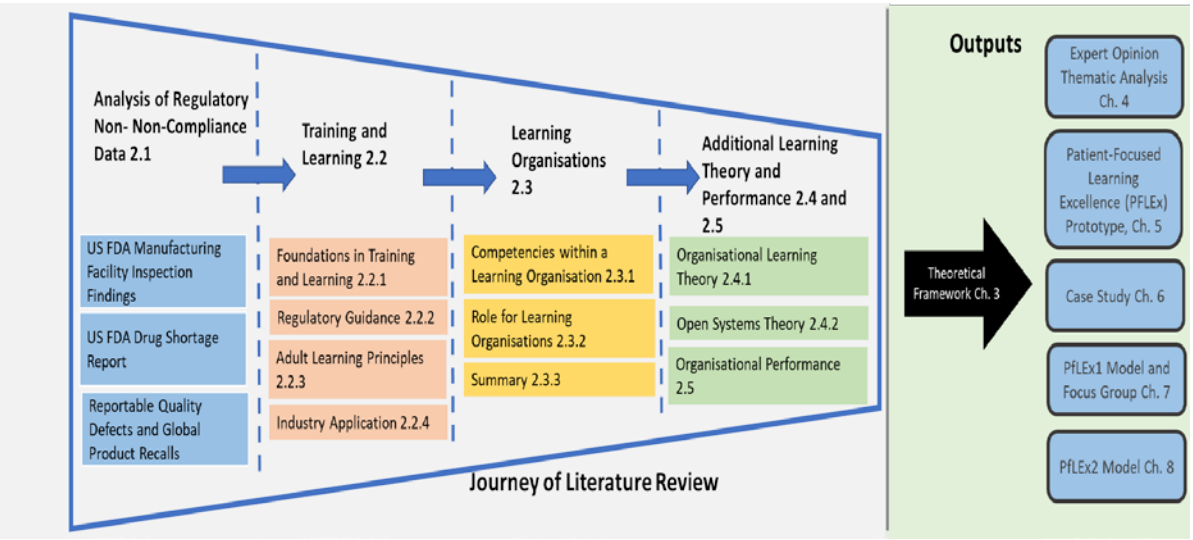


Figure 2.1: Journey of the literature review

2.1 Evidence of the Problem – An Analysis of Regulatory Non-compliance Data

To examine the problem, we must firstly address the regulatory context within which manufacturers of regulated medicinal products operate. Current good manufacturing practice (cGMP) describes the minimum standards that a "medicine's manufacturer must meet in their production processes" (EMA, 2023). All manufacturers of medicines, no matter where in the world they are located, must comply with cGMP. The cGMP regulations require that medicines

- are of consistent high quality
- are appropriate for their intended use
- meet the requirements for marketing authorisation or clinical trial authorisation

(EMA, 2023)

cGMP regulations also stipulate minimum requirements related to the qualification of personnel, training and performance monitoring, including the observation that personnel should have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the operations that the employee performs (US FDA 21CFR211.25).

A high-level review of three key publicly available data sources indicated that manufacturers' internal pharmaceutical quality management systems can and do fail to ensure that only high-quality products are supplied to patients. Three of the data sources reviewed included the following:

1. US FDA Manufacturing Facility Inspection Findings
2. *US FDA Drug Shortage Report*
3. Reportable Quality Defects and Global Product Recalls

To seek evidence of weaknesses within pharmaceutical manufacturing organisations, the researcher accessed the US FDA Drug Manufacturer Inspection Observations from 2014-2020 (US FDA, 2021). This data is based on the findings of US FDA field inspectors during routine inspections at biopharmaceutical manufacturing and distribution facilities. Table 2.1 reflects the top three defect categories found by the FDA during on-site inspections over the seven-year period examined are as follows:

- procedures not followed
- lack of scientifically sound laboratory controls
- ineffective investigations of discrepancies/failures

2014	2015	2016	2017	2018	2019	2020
Procedures not in writing, fully followed	Procedures not in writing, fully followed	Procedures not in writing, fully followed	Procedures not in writing, fully followed	Procedures not in writing, fully followed	Procedures not in writing, fully followed	Procedures not in writing, fully followed
Scientifically sound laboratory controls	Scientifically sound laboratory controls	Scientifically sound laboratory controls	Scientifically sound laboratory controls	Scientifically sound laboratory controls	Investigations of discrepancies, failures	Investigations of discrepancies, failures
Investigations of discrepancies, failures	Investigations of discrepancies, failures	Investigations of discrepancies, failures	Investigations of discrepancies, failures	Investigations of discrepancies, failures	Scientifically sound laboratory controls	Scientifically sound laboratory controls
Absence of written procedures	Procedures for sterile drug products	Absence of written procedures	Absence of written procedures	Absence of written procedures	Absence of written procedures	Absence of written procedures
Written procedures not established /followed	Absence of written procedures	Environmental monitoring system	Written procedures not established/followed	Cleaning/ Sanitising/ Maintenance	Cleaning/ Sanitising/ Maintenance	Equipment design, size and location

Table 2.1: Top three US FDA drug manufacturer inspection observations from 2014-2020

It is fair to assume that in each of these top three failure cases, the personnel involved in these activities would most likely have had a job description outlining their roles and responsibilities. It is also reasonable to expect that they had a compliant training record to indicate that they were "trained" on the execution of the manufacturing procedures, the utilisation of laboratory controls and the deviation investigation processes for which they were responsible.

A second key source of data which highlights organisational weaknesses within biopharmaceutical organisations is the US FDA *Drug Shortages: Root Causes and Potential Solutions* report (US FDA, 2019), which provides details of drugs that are experiencing a supply disruption. The data presented in this report is strikingly similar to the field inspection failure events discussed above. In this report, the US FDA analysed

163 drugs that were in short supply during the five-year period between 2013 and 2017. They determined that 62% of these shortages were associated with “manufacturing or product quality problems” (US FDA, 2019). The report concludes that an organisation which builds a foundation of basic cGMP requirements coupled with a lack of continual improvement *will* result in drug shortages. On the other hand, the report points out that those organisations that strive to build capability to detect and address vulnerabilities, coupled with a continuous improvement culture, result in a mature quality system that “significantly reduces the risk of drug shortages” (US FDA, 2019).

In the third data source, which examined pharmaceutical product recall events, evidence indicates that recalls are increasingly common within the biopharmaceutical industry (Waldron, 2018). Research data analysed in 2018 by Waldron indicates that a failure which requires a product recall from markets increases the threat of a supply disruption for patients based in those markets. Although the product recall removes the risk of exposing a patient to a defective medicine, it can expose patients to another risk in terms of loss of access to their usual medication or having to seek access to alternative therapies.

Waldron’s research examined the top causes of pharmaceutical product recall events in both the US and Ireland (markets for which data was publicly available) for each year over the period 2006-2013; the analysis in Table 2.2 shows that the same categories of quality failures appeared time and again over the eight-year period reviewed. These included the following:

- lack of sterility
- cGMP compliance deviations
- out-of-specification (OOS) issues
- packaging and labelling issues
- contamination concerns
- cold chain distribution problems

		Contribution Rank (percentage of total quality-related recall events in noted calendar year)		
Year	Country	1	2	3
2013	US	Lack of sterility assurance / sterility failure (49.8%)	Out of specification (OOS) release specification (10.9%)	cGMP deviations[33] (9.3%)
	Ireland	Lack of sterility assurance (19.8%)	cGMP deviations (18.5%)	OOS stability specification (17.3%)
2012	US	Lack of sterility assurance / sterility failure (29.5%)	OOS release specification (11.6%)	cGMP deviations (10.5%)
	Ireland	Contamination issue (29.2%)	OOS stability specification (20.8%)	Incorrect or inadequate labeling (15.3%)
2011	US	Cross contamination (47.9%)	Microbial contamination (non-sterile products) (13.7%)	cGMP deviations (10.5%)
	Ireland	Cold chain failure (33.0%)	Damaged product (18.7%)	OOS release specification (13.8%)
2010	US	Cold chain failure (25.8%)	cGMP deviations (18.4%)	OOS stability specification (12.1%)
	Ireland	Packaging or labeling issue (41.0%)	Damaged product (15.4%)	Cold chain failure and cGMP deviations (tie; 11.5% each)
2009	US	cGMP deviations (84.9%)	OOS release specification (6.5%)	OOS stability specification (2.5%)
	Ireland	Packaging or labeling issue (42.2%)	Lack of sterility assurance (20.0%)	OOS release specification (15.6%)
2008	US	cGMP deviations (50.6%)	OOS release specification (17.7%)	Incorrect or inadequate labeling (8.6%)
	Ireland	Packaging or labeling issue (70.6%)	OOS release specification (8.8%)	OOS stability specification (5.9%)
2007	US	Incorrect or inadequate labeling (57.2%)	OOS release specification (13.5%)	OOS stability specification (12.6%)
	Ireland	Packaging or labeling issue (27.6%)	Cold chain failure (25.0%)	Lack of sterility assurance (17.1%)
2006	US	Incorrect or inadequate labeling (59.9%)	OOS release specification (9.5%)	cGMP deviations (8.2%)
	Ireland	Packaging or labeling issue (35.9%)	Lack of sterility assurance (20.5%)	OOS release specification and Particulate or other contamination (tie; 10.3% each)

Table 2.2: Top three US and Irish recall categories, 2006-2012 (Waldron, 2018)

The analysis of these three sources indicates to the researcher that despite the many scientific, technological and economic advances over the past several years, in a well-funded, high-revenue industry operated by highly qualified personnel, the opportunity

to build the organisational capabilities required to learn from mistakes and continuously improve performance outcomes has not yet been fully realised.

2.2 A Review of Training and Learning

To commence this phase of the literature review, it is helpful to firstly establish a common understanding for some key terminology. There are distinct differences in approach and outcomes between the concepts of *training* and *learning* that need to be defined up front in this research study.

2.2.1 Theoretical Foundations in Training and Learning

To better understand this distinction, the researcher turned to Thomas Garavan (Professor of Leadership Practice in Cork University Business School, and a world-leading expert in leadership development, learning and development and human resources development) to commence the review of research in the field of training and learning. In his book *Learning and Development in Organizations*, which covers many different industries, there is a useful distinction between training and learning presented. Garavan et al. (2020) provide two simple definitions that offer a clear difference between the two approaches. These are summarised by the researcher in Table 2.3.

Term	Definition	Common Features
Training	Formal and planned efforts to ensure that employees acquire KSAs to enhance performance in their current role.	• Useful for the shorter term and for a more practical purpose. • Focus is on KSAs required to carry out a job to the optimal level of performance. • Takes place on the job, off the job in a classroom or online. • Typically, it is related to a specific current job or role within an organisation. • Important for imparting technical or mechanical knowledge.
Learning	A process through which employees acquire KSAs that involve broader sources of knowledge and unconscious learning processes, including awareness, reflection and experience.	• Learning involves a longer-term change in KSAs that enhances the potential of individuals to grow, develop and perform effectively in tasks and job roles. • Learning is an active process that requires active participation or involvement by learners. • Effective learning requires both ongoing evaluation of progress and feedback. • The emotions of learners are a particularly important component of the learning process.

Table 2.3: Training versus learning

Understanding this distinction between training and learning, and how the two can work together to develop the necessary KSAs, is a crucial first step for an organisation that desires to pursue a strategy of patient-focused learning excellence. To better understand another often-used concept, that of organisational learning, the researcher drew resonance and inspiration from one of the grandfathers of organisational development, the Harvard Business School emeritus professor and learning organisation guru Argyris, who stated that

> *The inability to uncover errors and other unpleasant truths arises from **faulty organisational learning**. Such habits and attitudes, which allow a company to hide its problems, lead to rigidity and deterioration. (Argyris, 1977)*

Given the evidence of recurring quality failures reviewed in Section 2.1, the researcher proposes that biopharmaceutical organisations should be relentless in their pursuit of

organisational learning excellence to avoid what Argyris describes as “errors and unpleasant truths”. In his recent book, Garavan et al. also provide a brief history of the discipline of learning and development (L&D) which proved useful as a summary of the literature on the topic (Garavan et al., 2020). Garavan classified the evolution of L&D in organisations into five phases, which are summarised in Table 2.4.

Phase 1: Classroom and OJT / 1930+	Phase 2: e-Learning and Digitisation / 1980+	Phase 3: Blended Learning / 2005+	Phase 4: Social Learning / 2010+	Phase 5: Personalised Learning / 2015+
Formal training in classroom settings. Focus on training design and transfer of training. Use of on-the-job training (OJT) and training in context.	Use of technology to deliver training in organisations. Emergence of computer-based training and e-learning to deliver learning to large groups. Use of augmented reality (AR) and virtual reality (VR).	Emphasis on mixing classroom learning with online elements to create blended L&D solutions. Use of learning management systems (LMSs) to manage the learners and their learning. Use of webinar platforms to deliver their training.	Emergence of the social web. Use of social media to allow learners to interact with each other in online courses. Social learning in the context of the workplace.	Emphasis on the customisation and individualisation of L&D. Learning advisors and personal learning toolkits. Individual takes a key role in organising and managing his or her own development.

Table 2.4: A brief history of L&D in organisations (adapted from Garavan et al., 2020)

This brief history of learning and development across various industries gave the researcher a better understanding of the evolution of the discipline of learning and of which approach might be best to apply in the industry case study summarised in Chapter 6.

2.2.2 Regulatory Guidance on Training and Learning

As this work is focused on the biopharmaceutical industry, it is important to note that within this highly regulated sector, a fundamental element of any employee training programme is assuring compliance with the Regulatory Health Authority requirements.

One such requirement can be seen in the US FDA Code of Federal Regulations (CFR), part 211.25:

> *Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. (US FDA, 2018)*

Regulatory Health Authorities are not only interested in how a biopharmaceutical product is manufactured, but also in who is performing each of the critical operations. Other similar expectations, listed here, are based on a variety of cGMP regulatory guidelines from the US Food and Drug Administration (FDA), Health Canada, European Medicines Agency (EMA), the World Health Organisation (WHO) and the International Conference on Harmonization (ICH). Collectively, these regulatory guidelines have been assessed by Vesper and Sandle in the book *cGMP in Practice: Regulatory Expectations for the Biopharmaceutical Industry* (Vesper & Sandle, 2018), and they are summarised by the researcher in Table 2.5.

	Summarised Regulatory Requirement
1	There are an adequate number of qualified people to perform the required tasks safely and effectively.
2	Tasks, roles and responsibilities are defined in the job descriptions and organisational charts.
3	Personnel are trained and/or otherwise qualified in the procedures and methods they use, and in the tasks they perform.
4	Personnel learn the cGMP concepts and regulations that apply to what they do.
5	Key personnel (including consultants and contractors) have the professional, educational and experiential credentials required.

	Summarised Regulatory Requirement
6	The learning programme is defined by a procedure and learning plan; learning events like training and assessment results are documented, and their effectiveness is evaluated.
7	Learning events are conducted by qualified personnel.
8	Supervisors and management have training that is appropriate to their functions.

Table 2.5: Summary of biopharmaceutical industry learning/training regulatory requirements

These requirements have led to an emphasis being placed, by both the industry and the regulators, on ensuring there is documentary evidence of how staff are qualified and how qualified the trainers themselves are to educate others in certain operations (Welty, 2009), rather than an emphasis on demonstrating the effectiveness of knowledge transfer and learning.

Many cGMP training programmes contain a basic curriculum outline of expected educational components that must be met by the employee (Gallant, 2018), which dictates that personnel have demonstrated proficiency with the relevant industry regulations and how this affects the day-to-day activities in which they are engaged (Vesper & Sandle, 2018). As the regulatory and technology landscape evolves, employees are typically required to record attendance at refresher training to ensure their knowledge is aligned with the current cGMP environment (Welty, 2009). Scheduling attendance at, and maintaining training records of, these events often take up a large share of the L&D Department resources.

2.2.3 Adult Learning Principles and Best Practice

To better understand current biopharmaceutical industry training and learning practices, the researcher next explored best practice in adult learning. The research examined how the biopharmaceutical industry trains its staff today and how this

compares with best practice on how adults learn and apply new skills. This phase of the research led to a series of three peer-reviewed articles published by the researcher through the Institute of Validation Technology (IVT) network in 2019 and 2020:

- Understanding Adult Learning Principles, cGMP Training Modalities, and the Biopharmaceutical Regulatory Landscape (Richter & Greene, 2019a)
- Applying Adult Learning Principles in cGMP Training (Richter & Greene, 2019b)
- Building Effective cGMP Training Designed for the Adult Learner (Richter & Calnan, 2020)

The questions explored in this series of articles include the following:

1. In determining the training modality for cGMP training programmes, do companies evaluate adult learning theories in their approach?
2. Are companies effective with regard to the transfer of knowledge and mastering of skills for employees?
3. Why do organisations still routinely receive Regulatory Health Authority observations that impugn the knowledge, skills and abilities of their employees?
4. Are companies more focused on documenting training programmes than nurturing a culture of learning?

This review provided the researcher with a foundation in adult learning theory, training methodologies applied in the biopharmaceutical industry and best practices for assessing learner needs in deploying an effective learning programme. Copies of the published articles are presented in volume 2 of this thesis.

A summary of the research into *Adult Learning Principles* led the researcher to identify three key concepts, as follows:

1. Incorporating the needs of the adult learner is integral to effective learning.
2. Current training modalities in use in the biopharmaceutical industry do not always accommodate the needs of the adult learner.
3. Basic human neurological processes should be considered to enhance the learning experience.

These key concepts are explored in more detail below.

***Key Concept #1:* Incorporating the needs of the adult learner is integral to effective learning**

Knowles identifies that incorporating the needs of the adult learner into L&D programmes can lead to more engaged, motivated and effective adult learners (Knowles, 1980). By respecting the adult learner's autonomy, building on their experiences and making learning relevant to their lives, L&D programmes become more impactful and effective in achieving educational goals. See Table 2.6 for a summary of adult learner needs.

Needs of the Adult Learner	Description
Adult learners are aware of self	Adults have moved away from thinking that was framed by those around them or the parents who raised them. They are aware of who they are and what they are seeking from their education. Because of this, adults need to have some autonomy in their learning by having a say in the content of their learning, or they will lose interest.
Past experiences are critical	Adults bring a wealth of experiences and knowledge with them to a course. They have built skills and knowledge that the instructor will need to explore or utilise when teaching them potentially new concepts or advanced concepts of what they

Needs of the Adult Learner	Description
	already know. If the instructor does not consider this, the adult learner may reject a new concept that conflicts with something they already know or practise.
Adults are purpose-driven in their learning	In an adult's quest for knowledge, they are seeking information that either feeds into a hobby they enjoy or meets a requirement or expectation for a job they occupy or are seeking to obtain in the future. Their learning must be goal-orientated and must achieve the purpose they are seeking to achieve. They must be able to take away an applicable skill that will help them progress further in their job or hobby.
Adults have a readiness to learn	The adult learner is there of their own accord or due to a request from their employer. They understand the global landscape and can appreciate the importance of a course within that space. They will be vocal with feedback and discerning in their taste regarding the instructor and the material.
Adult learners have internal motivation	Adults are motivated to learn based on the purpose which they see the education as serving. They will want experiences within the course that contain exercises and scenarios to apply the concepts in real life. This will keep them engaged as a learner and coming back for more.
Mistakes are valuable	Because adult learning theory focuses on experiential learning, mistakes are important learning opportunities that must not be overlooked. Examples and workshops that enable the learner to make mistakes in a safe environment, and learn how to correct those mistakes, are considered valuable learnings for future use in the workplace. Taking away the key elements of how to address mistakes or avoid mistakes allows the learner to apply them to situations that may arise in the future.
Adult learners want an active role in curriculum development	Adult learners must be a dynamic part of curriculum development so that they are empowered and motivated. To be a part of the development of material and content, it is important to collect feedback via interviews or surveys with key stakeholders. Survey information must be collected at the end of each session when teaching the course, to ensure key improvements are identified and implemented. During the course, instructors must be open to flexibility in lessons to allow the adult learners to sometimes determine how the day will progress and facilitate discussions required to grasp the material and its practicality.

Table 2.6: Needs of the adult learner (adapted from Northern Arizona University, 2018, and Knowles, 1980)

These seven needs of the adult learner were carefully integrated into the development of the Patient-focused Learning Excellence (PFLEx) Model and evaluated in practice during the case study in Chapter 6.

Key Concept #2: Current training modalities in use in the biopharmaceutical industry do not always accommodate the needs of the adult learner

Many training modalities fall short of considering the adult learners' needs in the L&D programme design. This was observed by the researcher when assessing the "typical case" training modalities through philosophical dialogues held with biopharmaceutical industry learning experts during the *Risk Revolution Podcast* series, co-hosted by the researcher. Six "typical case" training modalities identified by the experts as being in use within cGMP training environments were evaluated through the lens of a specific example and evaluated against criteria based on use, benefit and challenges. The results are summarised by the researcher in Table 2.7.

"Typical Case" Modality	Use	Benefits	Challenges
Read and Understand (e.g., a Standard Operating Procedure or Instruction)	• Introduce a concept and/or the instructions for completing a task • Pre-work to prepare learners for an instructor-led course • Preparation for an on-the-job training session	• Pace is set by the learner • Learning can occur any time of the day and at any location	• Questions can go unanswered without an instructor • Engagement is based on the individual learner • Practical application is non-existent • Learner must be able to access documentation
E-learning (Vesper, 2015)	• To provide training that needs to be deployed at a global level (policy or SOP overview) • Training that can be completed in a short window of time	• Learners enjoy flexibility, access and convenience in courses that can be taken and delivered from any location • Online learning expands access and extends the reach to a global audience • Learning is open 24 hours per day, seven days per week • Visual elements (as opposed to text) can improve knowledge retention • Can be tailored to allow learners to select alternative paths of learning based on their prior experience and knowledge	• Course design must be well thought-out, and different strategies must be employed for teaching, engagement and assessment • Learning happens continually in the asynchronous environment • Creating an environment for a sense of community for other learners • Learners who are new to the online environment or who have lower motivation and drive may fall behind

"Typical Case" Modality	Use	Benefits	Challenges
		• Learners can use the learning immediately if the course is designed to access "just enough" to operate	• Static PowerPoint slides with voice-over may not be engaging • Material can be challenging to update depending on voice-over and video modifications that need to be made
On-the-job Training (OJT) (Hands-on Training) (Jacobs et al., 1992)	• Used to teach hands-on/manual skills that a learner may need to demonstrate in order to show appropriate mastery, in a one-on-one situation with an instructor, before being allowed to perform independently, due to their criticality to the manufacturing process or the potential safety risk to the employee	• Minimises impact on product quality or employee safety with oversight • Builds a relationship between the trainer and the learner, increasing engagement • Improved return on investment, long-term employee retention and job performance in comparison to instructor-led training • Passing of tacit knowledge from senior staff to junior staff	• Requires the learner to perform GMP operations with oversight from a trainer • Requires additional personnel to provide hands-on training to learners • Variability in how trainers determine skill mastery among learners
Virtual reality and augmented reality (VR/AR) (Collins et al., 2020; See et al., 2018)	• Training on processes that are critical to operations (an aseptic technique in cleanroom operations, lab testing, gowning, etc.)	• Training sessions can occur without impacting on the production line, product quality, the availability of equipment or room use (such as cleanrooms) • Learner can be challenged with various scenarios and can practise problem solving and/or troubleshooting without any impact on production • Learner can practise often without impact to the production line • Information retention increased	• Technology can be expensive • Training sessions must have a facilitator and scheduled times for the availability of technology • Suitable only for specific knowledge transfer • Still requires a transition from virtual/augmented reality to a real GMP environment. Some AR/VR technology is still not accurate in depicting the exact movements and tracking of the operations • Must be a distraction-free environment
Instructor-led training (ILT) (classroom style)	• Instructor-led courses are often chosen to train learners on a	• Interaction and engagement can be seen	• Scalability – always requires the instructor to be present

"Typical Case" Modality	Use	Benefits	Challenges
(Robertson, (2022)	concept or approach that may be new to the company, in which learners may have many questions. The instructor's presence may be beneficial in managing the change or launching the new process	from all learners in the classroom • Provides the right environment and resources to interact with an instructor to ask questions • Builds relationships with other learners who are learning and growing together • Provides the appropriate environment to manage a major change in policy or a process that may invoke many questions by learners, then can be easily addressed with an instructor present	• Large class sizes limit one-on-one interactions with the instructor • Learners must move through the material together, which does not allow for a personalised learning path • Lectures can become long, causing learners to become disengaged
Work-based Learning (Brodie, 2007)	• Work-based learning can be used by companies to identify future talent by bringing students into the work environment as interns or in mentorship programmes. Biopharmaceutical companies will work with specific universities to develop internship programmes that are focused on areas within the industry that partner technical skills with focused study areas.	• Learners can practically apply in the workplace techniques and theory learned in a classroom environment • Biopharmaceutical companies can identify talent during internships who can be pursued after the learners complete their education • New tools and methods being taught in university can be learned and applied in the industry • Universities can take the information from interns after their work-based learning experience and apply it to the curriculum to ensure alignment with the industry	• Identifying areas within the organisation where work-based learning can be practically applied and can bring benefit to the company • Can disrupt the business, as time must be committed from a skilled employee to train the learners • Matching skill level with the learners' tasks

Table 2.7: "Typical case" learning modalities in biopharmaceutical cGMP training programmes

While *blended learning* was not identified as a "typical case" by the experts sampled, it is often used in the biopharmaceutical industry, with a combination of read-and-understand, e-learning and instructor-led training, and it does have its benefits (Guzer &

Caner, 2014). More recently, many companies within the industry have also employed *communities of practice* (CoPs) that use social learning networks, which have been proven to be effective for sharing best practices and offering a route for continued learning within the organisation (Wenger, 2000). This phase of the research created a deeper understanding of the importance of selecting the training modality best suited to addressing the adult learner's needs for each L&D application under consideration, and it informed the case study design, as detailed in Chapter 6.

Key Concept #3: Basic human neurological processes underlying how adults learn should be considered to enhance the learning experience

Malcolm Knowles, often referred to as the "father of adult education", found that adult learning is most effective when it follows certain key principles. "When trainers follow these principles, they greatly enhance the learning experience for participants" (Knowles, 1990). Edgar Dale first quantified the effectiveness of knowledge transfer for active and passive learning processes in a model known as the Cone of Experience (Janoska, 2017). This model has subsequently been widely adopted by the learning research and practitioner community.

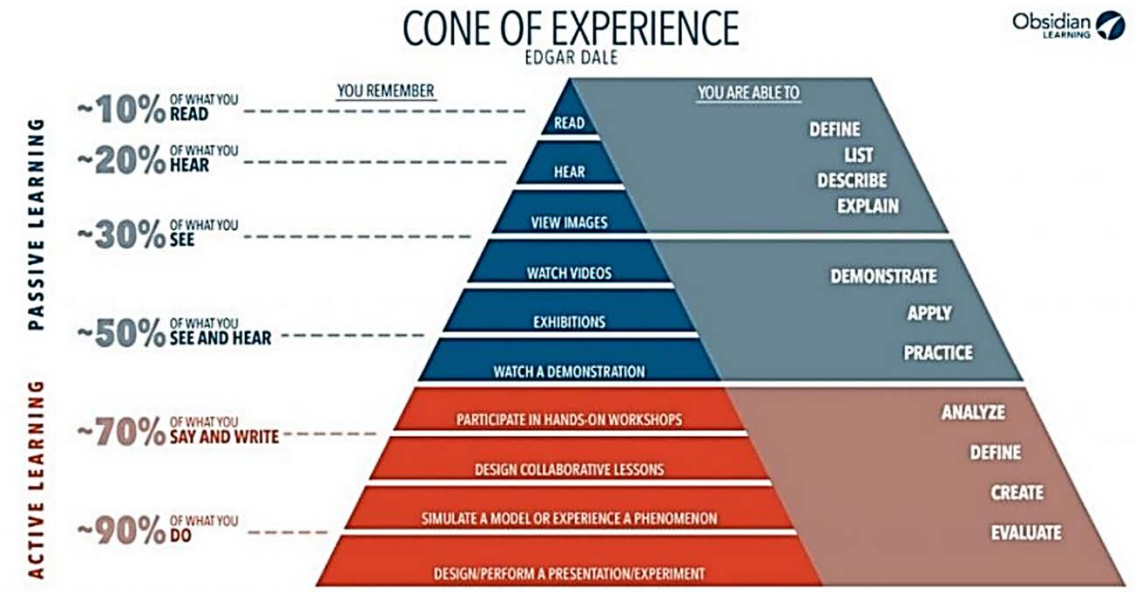


Figure 2.2: Cone of Experience (Janoska, 2017)

For adult learners to retain what they learn, they need to engage in both active and passive learning modalities (i.e., they need to **hear** a lecture or discussion, **see** a demonstration or visual aids, **discuss** the material with peers or trainer and have an opportunity to **practically apply** the new knowledge and skills by "learning by doing", in order to more effectively bridge the *knowing-doing* gap (Pfeffer & Sutton, 2000). In summary, an *experiential learning environment* must be designed that encourages seeing, hearing, observing and practising, as well as tapping into emotions to best enable the learning and retention of new knowledge, skills and abilities. Confirming the value of designing an *experiential learning* experience for the adult learner, Kolb proposes that effective learning is only determined to have occurred when a person progresses through a four-stage "learning-by-doing" cycle.

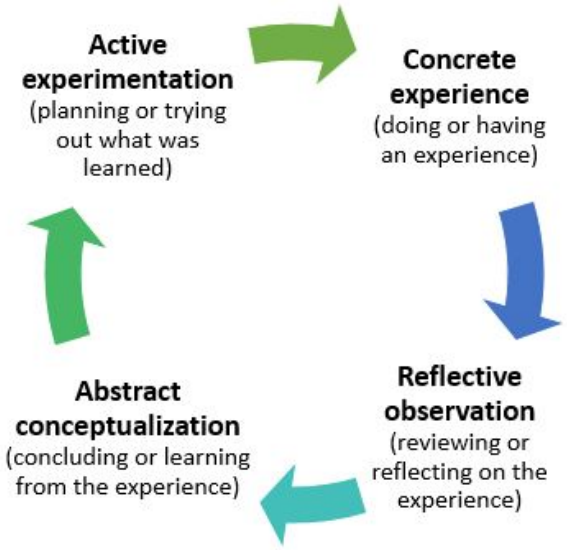


Figure 2.3: Kolb's Learning Process Cycle (Kurt, 2020)

With Kolb's Cycle, it is important to understand that the cycle may need to be repeated a number of times to ensure effective knowledge transfer. The learner must also be encouraged to reflect on and challenge the learning by asking questions and receiving active coaching from the instructor to cement the learning.

A practical output from this phase of the research led the researcher to develop a risk-based learning needs assessment tool that considers the adult learner's needs when designing and developing the curriculum and modalities for a learning event. The *Adult Learner Effective cGMP Training* (ALECT) Tool offers a structured process for instructors/designers to incorporate adult learning principles and an experiential learning cycle when designing and deploying learning events. The next section of this literature review examines in greater detail how *learning organisations* nurture a learning culture.

2.3 A Review of Learning Organisations

A learning culture is defined by the Corporate Executive Board (CEB) as

> *A culture that supports an open mindset, an independent quest for knowledge, and shared learning directed toward the mission and goals of the organisation. (Srinivasan & Kurey, 2014)*

As described in Chapter 1, learning organisations also drive continuous improvement, grow and retain talented staff, increase collaboration and build both business value and longevity (Gibbs, 2020; Senge, 2006). However, these organisations are still the exception rather than the rule. Recent research found that only 10% of organisations have managed to create an environment which could be described as a learning organisation, with just 20% of employees routinely demonstrating effective learning behaviours at work (Bersin et al., 2018). Bersin's research represents organisations across many industries and indicates that there is a real opportunity for growth in this area for the biopharmaceutical industry. This researcher proposes that biopharmaceutical companies that embrace learning organisation principles could deliver gains on innovative product pipeline development, operational excellence and market success, ultimately bringing great benefits to both the company and its patients. Encouragement for continuous learning modelled by senior leadership, establishing direct links to the learner's role within the organisation and to the overall company strategy can create fertile ground for a learning culture to thrive. (Richter & Calnan, 2020)

It has proved challenging over the years to establish a common definition of the key attributes of a learning organisation. An examination of the work of organisational

theorists who have studied learning for over three decades has highlighted the variations in thinking among scholars and practitioners. Learning organisations take immense time to establish and grow but do result in enhanced knowledge sharing and improved performance to the business. A variety of theories related to learning organisations are summarised in Table 2.8 as potentially applicable to biopharmaceutical organisations.

Characteristics of Learning Organisations	Reference
"In a learning organisation, employees continually create, acquire, and transfer knowledge—helping their company adapt to the unpredictable faster than rivals can"	Garvin et al., 2008
"Learning organisations create a culture that encourages and supports employees' lifelong learning, critical thinking and risk-taking from new ideas; allows employee mistakes and appreciates their contributions; learns from experience and experiment; spreads/disseminate new knowledge throughout the organisation so that they are integrated into everyday activities"	Halmaghi, 2018
"Organisational learning occurs through shared insights, knowledge, and mental models [… and] builds on past knowledge and experience—that is, on memory"	Stata, 1989
"Organisational learning is a process of detecting and correcting error"	Argyris, 1977
"An organisation where people continuously learn and enhance their capabilities to create. It consists of five main disciplines: team learning, shared vision, mental models, personal mastery and systems thinking"	Senge, 2006
"For knowledge work to flourish, the workplace must be one where people feel able to share their knowledge! This means sharing concerns, questions, mistakes, and half-formed ideas"	Edmondson, 2018

Table 2.8: Key characteristics of learning organisations

Many of the characteristics listed here are particularly relevant to address the complexities faced by employees within the biopharmaceutical industry today.

Reflecting on the literature published on learning organisations, the researcher observed considerable alignment with the principles of continuous improvement and operational excellence, encompassing the philosophies of Juran, Deming, Shewhart and Crosby throughout the 1900s. The application of operational excellence programmes continues to be popular today, as organisations strive to better themselves and secure a position

ahead of their competitors (Samman & Ouenniche, 2016). Some human resource development (HRD) scholars (Callahan & de Davila, 2004) have concluded that elements of both learning organisations and performance management are equally important and necessary for organisations to thrive. To successfully deploy continuous improvement programmes, lean processes and tools, Korte states that learning organisation characteristics are necessary to shape the underpinning culture (Korte, 2012). Failed continuous improvement programmes far outnumber successful programmes, because most companies have failed in their commitment to learning. This is indicated in the *Harvard Business Review* article "Building a Learning Organization", by Garvin et al. (2008):

> *In the absence of learning, companies and individuals simply repeat old practices. Change remains cosmetic, and improvements are either fortuitous or short lived.*

Practical approaches to enhancing the commitment to learning examined by other members of the TU Dublin PRST research team, particularly in relation to the transfer of tacit knowledge or "know-how", has demonstrated the important role that practices such as after-action reviews and lessons learned can play in creating learning opportunities between employees to solve problems and improve performance (Lipa, 2020a). The next section of this literature review explores the key competencies that an organisation needs to develop in order to be considered a learning organisation.

2.3.1 Key Employee Competencies within a Learning Organisation

Based on the work of Garvin (1993), the researcher developed Table 2.9 to summarise the key employee competencies which support and sustain the development of a learning organisation.

An Employee within a Learning Organisation
Systematically solves problems
Experiments with new approaches
Learns from their own experience and history
Learns from the experiences and best practices of others
Transfers knowledge quickly and efficiently throughout the organisation

Table 2.9: Key employee competencies within a learning organisation (adapted from Garvin, 1993)

Strategies to target and nurture these key learning organisation competencies within the development of patient-focused learning excellence programmes have been carefully considered by the researcher in the development of the PFLEx Model.

2.3.2 The Role of Learning Organisations in the Biopharmaceutical Industry

Examining the key characteristics and employee competencies of learning organisations for specific points of relevance with regard to the biopharmaceutical industry proved fruitful. Maintaining constant vigilance to prevent harm to our patients can be challenging to sustain without embracing continuous improvement and a culture that encourages open, curious, knowledge-seeking practices.

As noted earlier in this thesis, the heavily regulated biopharmaceutical industry is required by a range of regulatory guidances to embrace learning. Yet, a 2010 Pharmafield article questioned whether the biopharmaceutical industry is ready and

willing to learn. The article, entitled “Is the Pharma Industry Willing to Learn?”, identified that building learning organisations requires excellent communication, relationship building, conflict resolution, time and total commitment, along with ongoing formal workshops to ensure success (Pharmafield, 2010). Porter goes further by highlighting that the biopharmaceutical industry often “trains to compliance” by meeting the tactical skills needed to perform a task, without considering the long-term implications of inadequately providing an environment whereby it is safe to learn from mistakes and ask questions when unsure (Porter, 2017). Garvin, in a *Harvard Business Review* article entitled “Is Yours a Learning Organisation?”, presented a useful questionnaire which can be used for assessing learning within an organisation (Garvin et al., 2008). The assessment outlined factors that are essential for organisational learning and adaptability, across three key pillars:

1. a supportive learning environment
2. concrete learning processes and practices
3. leadership behaviours

Each pillar established criteria in further detail (Tang, 2020), and these criteria have been carefully considered in the design of the Patient-focused Learning Excellence (PFLEx) Model (Chapters 5-8). Garvin concluded his article by outlining four distinguishing attributes of a supportive learning environment, as shown in Figure 2.4.

Figure 2.4: Attributes of a supportive learning environment (diagram created by researcher)

Without feeling safe, people in the workplace will not challenge their peers or authority figures, nor will they offer an alternative viewpoint compared to others. Conversely, if people are comfortable expressing their thoughts, as well as appreciating the opinions of others, they will have the courage to take risks and explore unknowns. Their ability to think critically and analytically can be encouraged further in a supportive learning environment where time for reflection is allowed (Tang, 2020). These key attributes have been incorporated into the PFLEx Model design.

2.3.3 Summary of Learning Organisations

The need for learning organisations is greater today than ever before, as the challenge to maintain competitiveness in a complex global environment is intense. Organisations need to acquire knowledge quickly and be prepared to constantly adapt their understanding of the dynamic environment in which they function. This can only be

made possible through an environment that supports and nurtures continuous improvement and ongoing learning.

2.4 A Review of Additional Learning Theories

The literature review now explores two additional important theories:

1. Organisational learning theory
2. Open systems theory

These two theories, combined with the *adult learning theory*, provide the foundation for the theoretical framework of this research, presented in Chapter 3. Care should be taken not to confuse the characteristics and competencies necessary to build and sustain what is described as a learning organisation with the theoretical framework that underpins how organisations learn, described as organisational learning theory.

2.4.1 A Review of Organisational Learning Theory

Organisational learning theory is a large and varied topic with influences ranging from sociology to psychology, philosophy and business management, among others (Edmondson & Moingeon, 1998). It is commonly described as “a process of developing, retaining, and transferring knowledge within an organisation” (Argyris & Schon, 1978), and is therefore closely aligned with current knowledge management principles. Crossan and Maurer emphasise that organisational learning occurs as a result of experience, and an organisation is said to have learned from an experience when there is a change in the organisation's behaviour or performance (Crossan & Maurer, 2011).

According to Fiol and Lyles, organisational learning is defined as:

> *The process of improving actions through better knowledge and understanding (Fiol & Lyles, 1985).*

For this research, the work of several influential organisational learning theory leaders was reviewed, including that of

- **Argyris and Schön:** Key premise: we learn from our mistakes.
- **Levitt and March:** Key premise: organisational learning is routine-based, history-dependent and target-oriented.
- **Fiol and Lyles:** Key premise: organisational memory exists.

Argyris and Schön

A common organisational learning theory developed by Chris Argyris and Donald Schön holds that we learn from our mistakes. They suggested that learning takes place through the process of detecting and correcting errors. For example, when one performs a task and the actual outcome is not what one expected, one (or one's team) will investigate what happened and correct the mistakes as needed. This process of interacting with fellow colleagues is the process by which learning occurs within the organisation.

Single-loop and double-loop learning

Argyris and Schön propose that when something goes wrong, people tend to look for another strategy that will address the error while working within what they have defined as their governing boundaries or operating rules. These rules will not necessarily be questioned, but rather will bind the thinking of the person in their quest to correct the

error (Argyris & Schön, 1974). This is known as *single-loop learning*. Another approach to correcting the error would be to question the rules themselves, to subject them to critical thinking (Argyris, 1977). This is known as *double-loop learning.* Argyris and Schön provide an example to explain this thinking in the context of organisational learning (Argyris & Schön, 1978):

> When the error detected and corrected permits the organisation to carry on its present policies or achieve its presents objectives, then that error-and-correction process is single-loop learning. Single-loop learning is like a thermostat that learns when it is too hot or too cold and turns the heat on or off. The thermostat can perform this task because it can receive information (the temperature of the room) and take corrective action. Double loop learning occurs when error is detected and corrected in ways that involve the modification of an organisation's underlying norms, policies and objectives.

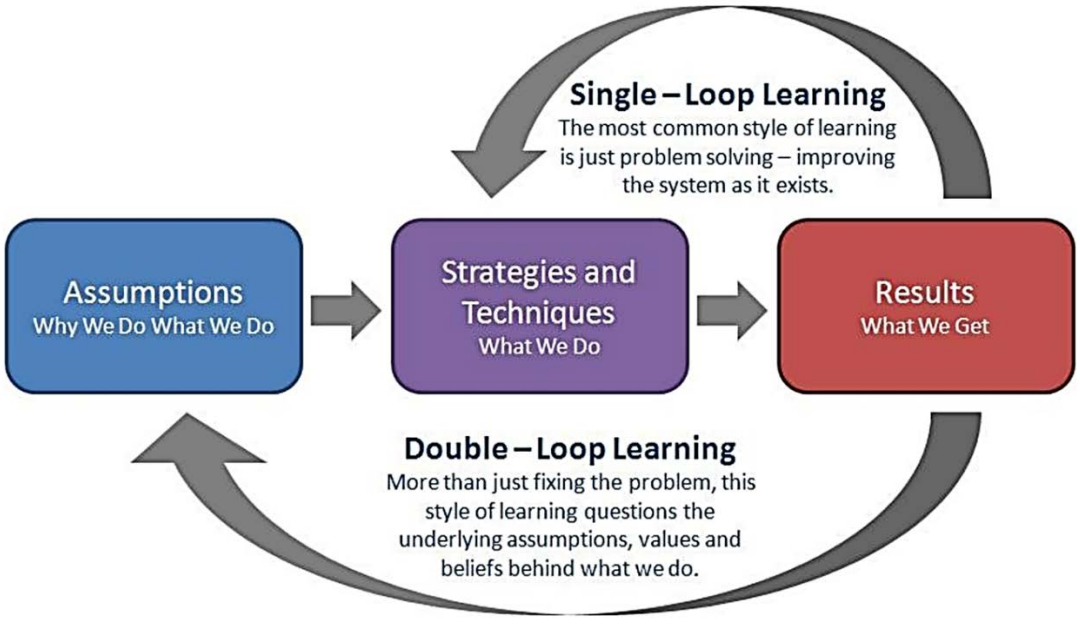


Figure 2.5: Single- and double-loop learning (Bryant, 2020)

According to Argyris, the environment required to cultivate double-loop learning must be one where

> *To question someone else's reasoning is not a sign of mistrust but a valuable opportunity for learning. (Argyris, 1991)*

Single-loop learning is present in organisations where the emphasis is on improving existing approaches rather than rethinking an existing framework (Usher & Bryant, 1989). Double-loop learning occurs when one challenges the underlying goals and strategies to determine if they may be improved. Edmondson and Moingeon caution that double-loop learning is often inhibited within organisations, particularly when it is most needed. The underlying theory, supported by years of empirical research, is that the reasoning processes employed by individuals in organisations inhibit the exchange of relevant information in ways that make double-loop learning difficult – and all but impossible in situations in which much is at stake. This creates a dilemma as these are the very organisational situations in which double-loop learning is most needed. (Edmondson & Moingeon, 1999)

Argyris argues that double-loop learning is most necessary if organisations are to make informed decisions in swiftly moving environments and complex, uncertain times (Argyris 1985).

Levitt and March

Levitt and March examined organisational learning based on behavioural studies and made three significant observations.

- Their first observation is that **behaviour in an organisation is heavily based on routines** (Levitt & March, 1988). Therefore, the actions of an organisation often stem from referencing procedures rather than determining actions based on logical choices.
- The second observation is that **organisational actions are history-dependent** (Levitt & March, 1988). In other words, routines are based through a lens of past actions more than with a lens of what the future holds. With this perspective, an organisation may only make incremental changes in response to feedback regarding past deliverables. These "rearview" routines are then encoded into their learning philosophy, which becomes deeply ingrained into the organisation and can even survive the turnover of key individuals.
- The third observation is that **organisations are orientated towards targets** (Levitt & March, 1988). However, this can lead to a very binomial evaluation of success and failure. When targets are missed, individuals continue to rely on and apply routine-based historical learning, regardless of whether they have ever experienced the original historical event themselves (Levitt & March, 1988).

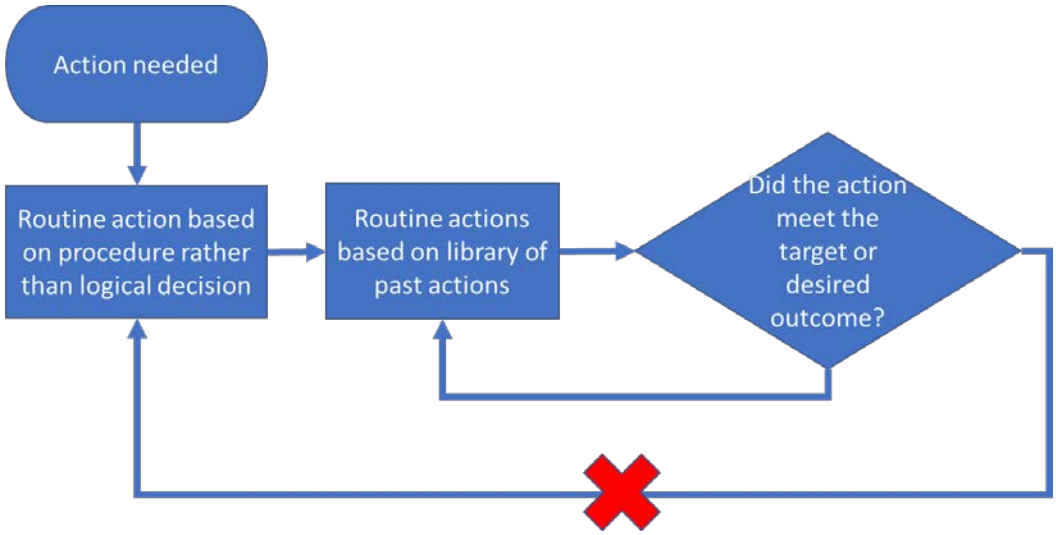


Figure 2.6: Levitt and March's model of organisational learning (created by researcher)

The challenge that Levitt and March highlight is that organisations stop seeking alternative actions once they have built a significant library of experience based on their known routines (Edmondson & Moingeon, 1998). This can create obstacles in relation to adapting to the ever-changing global economy and can lead to the belief that one organisation's processes are superior to those of others. Without the ability to seek out new approaches or continuously improve processes, the organisation will continue to suffer through inferior processes due to this mindset (Levitt & March, 1988). The researcher has observed these challenges first-hand within biopharmaceutical organisations that rely on historical, compliance-based routines and struggle with continuous improvement and learning from mistakes.

Fiol and Lyles

Fiol and Lyles identified four factors that affect the probability that learning will occur:

- A corporate culture conducive to learning
- A strategy that allows flexibility
- An organisational structure that allows both innovation and new insights
- An environment to cultivate these behaviours.

Fiol and Lyles emphasise that these four factors have a circular relationship with learning in that they create and reinforce learning and are themselves created by learning (Fiol & Lyles, 1985).

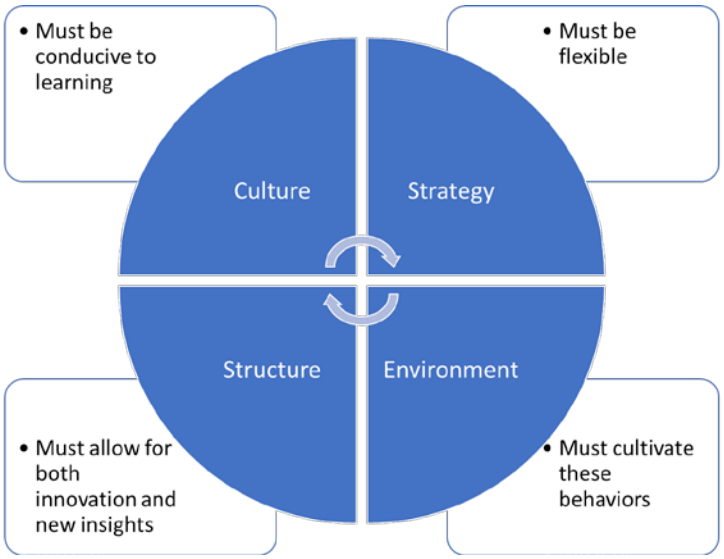


Figure 2.7: Fiol and Lyles's model of organisational learning (created by researcher)

Essentially, Fiol and Lyles's theory is that organisational learning is a process of "improving one's action through better knowledge and understanding as an individual within the construct of the organisation" (Fiol & Lyles, 1985). This ultimately contributes to the "organisational memory". This organisational memory enables the company to utilise the strengths and knowledge of the individuals to meet the goals presented to the

group while reducing the demand on any particular individual within the collective group (Jackson et al., 2005). In this way, no individual within the group will be exploited for their individual knowledge, because the organisational memory and its members will have access to this knowledge as a collective (Jackson et al., 2005).

2.4.1.1 A Summary of Organisational Learning Theory

Although individual learning is important to organisations, organisational learning is not just the accumulation of each member's learning (Fiol & Lyles, 1985). Individuals may share their learnings amongst the members of the organisation, but organisations create learning infrastructure and systems that are transferred by way of organisational historians and the rules or norms of the organisation (Levitt & March, 1988). Hedberg states that although organisational learning occurs through individuals, it is inaccurate to assume that organisational learning is a cumulative result of all individual learning (Hedberg, 1981). Organisations have memories, and the individuals may contribute and build their worldviews around it, but it is the organisation's memory that is preserved and that perpetuates its own rules, norms and values over time (Hedberg, 1981).

The examination of organisational learning theory supports the proposition put forward by the researcher that if an L&D programme is carefully designed to enhance the learning experience for individuals to learn from their mistakes, opportunities exist to enhance the organisational memory and capabilities, thereby improving organisational performance while reducing the opportunity for repeated errors.

2.4.2 Open Systems Theory

Examining the roles of culture, strategy and structure in creating an optimal learning environment brings us to open systems theory. Having an “open system” means that all organisations have the same characteristics or attributes as other living organisms. Katz and Kahn (1966) describe an organisation as comparable to a living organism, which by its very nature is an open system. As an open system, an organization must adapt, work within its environment, and co-exist harmoniously with external stakeholders, responding to changes, feedback, and evolving dynamics to thrive and achieve goals effectively. Katz and Kahn developed a framework for open systems theory that encompasses the following:

- Energetic inputs into the organisation
- The transformation of those inputs within the system
- Energetic outputs
- Recycling

Garavan et al. (2021) took these concepts from Katz and Kahn, and put together a framework of open systems concepts related to learning, establishing the following principles:

- The first principle of open systems theory relates to *congruence* or the fit between the components of the system, and it requires understanding about the fit between the external and internal context and the training processes.

- The second principle of open systems theory emphasises the concept of *adaptation* and suggests that scholars should investigate the extent to which training adapts to changes in external inputs.

- The third principle of open systems theory proposes the concept of *internal interdependence*, or the interconnectedness of system components. This is linked to how performance is connected with investment in training.

- The fourth principle of open systems theory highlights the concept of *emergence*, which relates to the outputs of the interactions of different components within the learning system.

- The fifth principle of open systems theory is the concept of *equifinality*, which means that the same end objective can be achieved through various different means.

- The final principle of open systems theory is the concept of *feedback loops,* where company performance outcomes for training will influence future training investments.

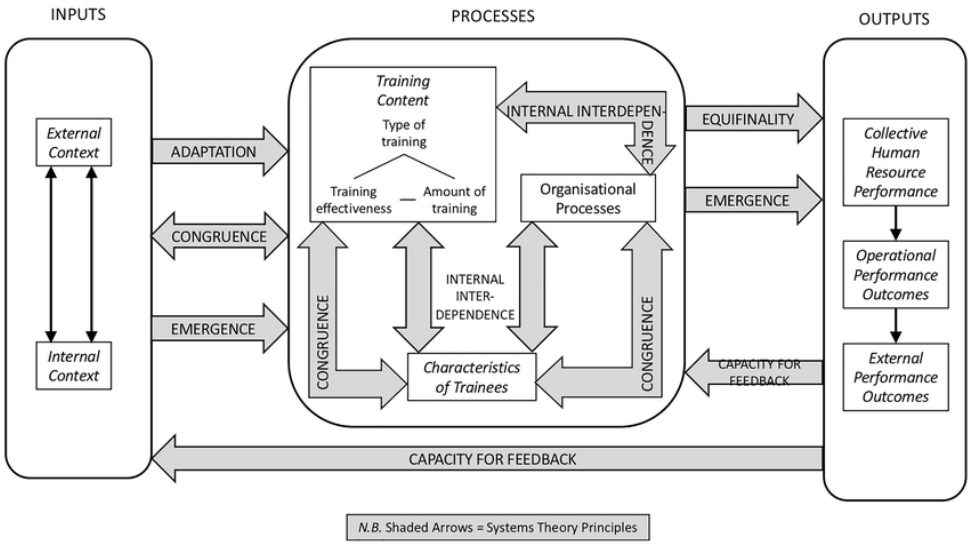


Figure 2.8: Map of Open Systems Theory for Training and Performance (Garavan et al., 2021)

2.4.2.1 Summary of Open Systems Theory

Open systems theory is explored within learning and development research to evaluate the value of training investment in providing a positive impact on organisational performance measurements (Garavan et al., 2021). Although these six principles prove valuable for investigating the performance outcome of a training intervention, for the purpose of this research, open systems theory is used to focus on the design of effective feedback loops and their potential to impact on leadership decisions related to future training investments. The next section of this literature review considers the field of organisational performance.

2.5 A Review of Organisational Performance

This section will explore how training is linked to improved organisational performance and will address the most appropriate metrics to demonstrate this.

2.5.1 Connecting Training with Organisational Performance

Tharenou et al. (2007) state that training has a positive influence on organisational performance, while Garavan et al. (2020) outline several definitions of how training is linked to organisational performance. Below is a list of how training impacts organisational performance.

- Training enhances employees' KSAs for current and future roles, which results in enhanced organisational performance (Kim & Ployhart, 2014). This was further demonstrated by a study performed to measure performance before and after the recession of 2007-2009, which suggested that investing in staffing and training pre-recession generated slack resources that helped firms buffer and more quickly recover from the recession (Kim & Ployhart, 2014).
- Secondly, training enables the development of a greater depth of KSAs, enabling employees to be more flexible and to perform different tasks more effectively (Somaya et al., 2008), leading to enhanced organisational performance. This ability to be more flexible positively impacts on innovation and productivity. This was observed through the work of Somaya et al. by assessing employee movement between competing firms and the positive impact that could be observed with respect to relationships between the firms and knowledge sharing (Somaya, 2008).

- Thirdly, training can cultivate a greater depth of skills and allow for the specialised knowledge of employees to build core competencies internally, thereby staying ahead of the competition (Coff, 1997).

Garavan et al. argue that unique, valuable and rare human capital developed through both internal training and general training leads to higher organisational performance. In addition, there are theoretical arguments suggesting that higher-quality training will have a greater impact on performance than the quantity of training provided. A study performed in Europe by Aguinis and Kraiger (2009) investigated the relationship between training and organisational performance by distributing a survey to 457 small and medium-size businesses in the United Kingdom, the Netherlands, Portugal, Finland and Spain. Organisational performance was measured by (a) *effectiveness* (i.e., employee involvement, human resource indicators and quality) and (b) *profitability* (i.e., sales volume, benefits before interest and taxes, and a ratio of benefit before taxes/sales). The results indicated that some types of training activities, including on-the-job training and training inside the organisation using in-house trainers, were positively corelated with most dimensions of effectiveness and profitability (Aguinis & Kraiger, 2009).

Another example presented by Arguinis and Kraiger studied 78 Spanish firms with more than 100 employees. This study related each organisation's training policies (denoted by functions assumed by the training unit, the goals of the training unit, the nature of training and how training is evaluated) with four types of organisational-level benefits:

employee satisfaction, customer satisfaction, owner/shareholder satisfaction and workforce productivity (i.e., sales per employee). The results suggested that training programmes orientated toward human capital development directly correlated with employee, customer and owner/shareholder satisfaction, as well as with objective measures of business performance (i.e., sales per employee) (Aguinis & Kraiger, 2009).

To appropriately measure the effects of organisational learning theory on a biopharmaceutical organisation, it is important to carefully identify the most appropriate organisational performance measures to be evaluated. The next section will explore measures used within the biopharmaceutical industry and how these demonstrate enhanced organisational performance. The researcher has focused on the most appropriate metrics based on the problem statement and hypothesis.

2.5.2 Measuring Organisational Performance within the Biopharmaceutical Industry

Within the biopharmaceutical industry, it is well understood that a robust pharmaceutical quality system (PQS) provides the necessary oversight and assurance within the manufacturing and quality control processes to ensure that patients are provided with medications that are safe, effective and reliably produced to a high level of quality (Friedli et al., 2017). Therefore, to measure the performance of a biopharmaceutical organisation, it is relevant to measure the performance of the PQS as an indicator of organisational performance.

The Office of Pharmaceutical Quality (OPQ), established in 2015, has made it a priority to ensure that pharmaceutical products available to the American public meet high

quality standards throughout their product life cycle. The FDA Quality Metrics initiative, which stems from the FDA Science and Innovation Act (US Congress, 2012), was created to develop and implement industry reporting of a set of standardised manufacturing quality metrics. The implementation and analysis of these metrics should provide industry and regulators with the capability to understand quality issues at a manufacturing facility and to better predict potential quality issues. This, in turn, should provide patients with the satisfaction that regulatory oversight and industry vigilance is focused on maintaining safe, reliable and efficacious products.

As part of this initiative, the FDA awarded a research grant to the University of St. Gallen to help establish the scientific basis for such metrics. For the University of St. Gallen team, *operational excellence* is a concept which directs an organisation towards continuous improvement. They consider this to involve a balance between cost, quality and time, with a focus on ensuring the patient's needs are met. For the University of St. Gallen team, operational excellence is not only about performance, but also about the way an organisation achieves superior performance and about how it continuously improves itself (Friedli et al., 2017). This view of operational excellence directly supports the identification of the measurements needed to support the research hypothesis for this study.

Figure 2.9, below, provides a structured and holistic depiction of the St. Gallen *Pharmaceutical Production System Model,* showing key *Metrics* and *Enablers*. The model includes the US FDA Quality Metrics, as well as additional data points collected across

the industry to measure performance (Friedli et al., 2017). These performance measures are directly linked with the *effectiveness and efficiency* of the PQS at a manufacturing site. The effectiveness and efficiency of the PQS, in turn, speak to the health of the continuous improvement culture and how it meets the needs of the patient. These are relevant performance measures to tie to this research for the purpose of measuring organisational performance with respect to organisational learning. This research focuses on measuring improved performance as a result of training interventions and organisational learning, by examining the *PQS effectiveness metrics, operational stability and the engagement metrics* (Tables 2.10, 2.11 and 2.12). These performance measures are representative of the performance of the people and processes within the PQS, and they align well as a measure of the success of the training interventions which may be deployed to improve such operations.

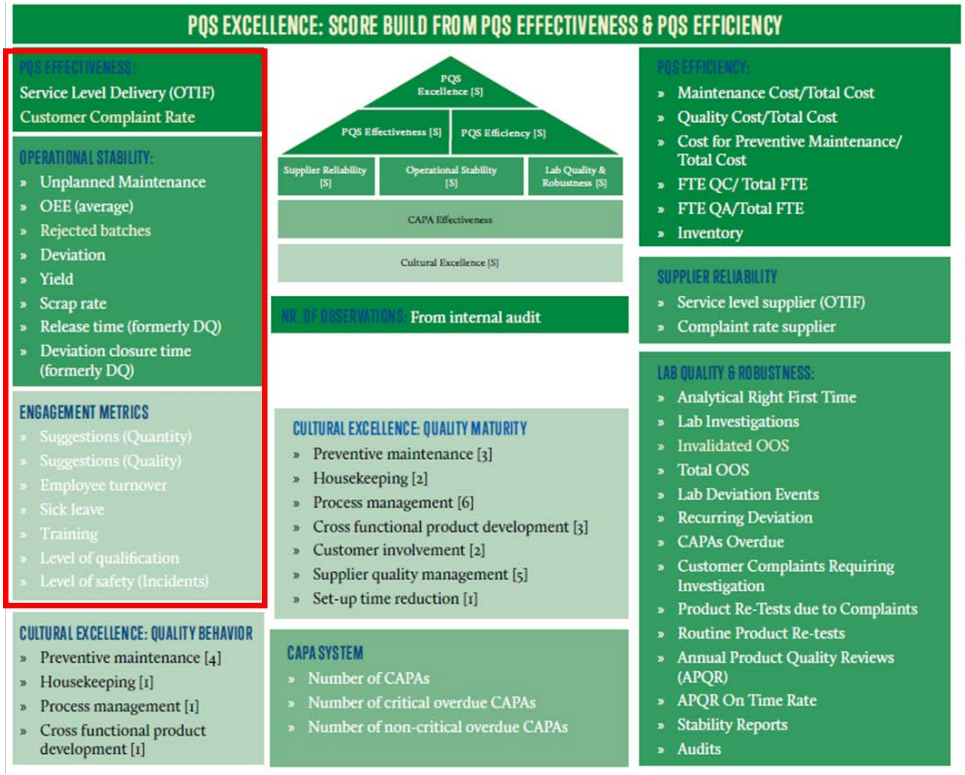


Figure 2.9: St. The Gallen pharmaceutical production system model with metrics and enablers

Metric	Description
Service Level Delivery (OTIF)	Perfect order fulfilment (the percentage of orders shipped in time from the site (+/- 1 day of the agreed shipment day), in the right quantity (+/- 3% of the agreed quantity) and right quality) to the customer.
Customer Complaint Rate	Number of justified complaints as a percentage of all customer orders delivered.

Table 2.10: PQS effectiveness

Metric	Description
Yield	Real achieved output in pharmaceutical production (input minus material losses, weighting, sediments, etc.)
RFT	Total number of batches produced without document errors or exception reports as a percentage of the total number of batches produced
Rejected batches	Number of rejected batches as a percentage of all batches produced
Scrap rate	Average difference between 100% and real achieved output in packaging operations
Complaint rate (supplier)	Number of complaints as a percentage of all deliveries received (from the supplier)
Release time	Average time from sampling to the release of finished products, including all waiting times
Deviation closure time	Average deviation closure time, in days

Table 2.11: Operational stability definitions

Metric	Description
Training	Number of training days per employee (all kinds of training off the job and on the job) in the last year
Level of Qualification	Number of workers with prior work-related qualification/education as a percentage of the total number of workers at the site
Suggestions (Quantity)	Average number of suggestions per employee in the last year

Table 2.12: Engagement metric definitions

The researcher has chosen these organisational performance metrics for the remainder of this study. It is acknowledged that these metrics are adopted at various levels of maturity across the industry, and do not necessarily represent every company or how they measure performance. Nevertheless, the chosen metrics connect with the research problem statement and research question, and they will be used to measure organisational performance when required by the study. Chapter Three provides an overview of the theoretical framework and research methodologies underpinning this study.

CHAPTER 3: RESEARCH DESIGN METHODOLOGY AND METHODS

The purpose of this chapter is to outline the research design, methodology and methods used in this study. This includes the researcher's worldview and insider perspective, the research questions and the associated methodology and methods applied, the research timeline, along with ethical and privacy considerations.

3.1 Introduction

In Chapter 2, the current problems relating to pharmaceutical product quality issues were discussed, including the increase in compliance actions, product recalls and quality defect reports for medicines in the marketplace. These issues are indicative of the organisational performance challenges that impact on the biopharmaceutical industry's ability to meet patients' needs. While there are multiple opportunities to improve organisational performance, this research aims to address learning as one key aspect which can meaningfully impact on organisational performance. The goal of this research is to develop a practical **Patient-focused Learning Excellence (PFLEx) Model** driven by enlightened leaders who sponsor and sustain a culture of learning within their organisation. The research began with a literature review, presented in Chapter 2, that underpinned the research design and informed the methods selected, which are discussed in this chapter.

The research is primarily a qualitative study using mixed methods of inquiry, with the aim of developing a deep understanding of the problem under review and the key

aspects of human behaviour that enable learning excellence within an organisation. The research study is presented in four phases (I-IV), as follows:

1. Phase I – Literature Review
2. Phase II – Expert Opinions
3. Phase III – Case Study
4. Phase IV – Focus Group

3.2 Developing the Research Questions and Hypothesis

The original title of the research proposal, developed in 2019, was as follows:

> Development of an Education Programme that Provides the Quality Risk Management (QRM) Competencies Needed to Realise the Benefits of QRM Implemented in the Biopharmaceutical Industry

This initial research proposal focused on the implementation of the International Conference on Harmonization (ICH) Q9 Guideline: Quality Risk Management (QRM), published in 2005 for the biopharmaceutical industry (ICH Q9, 2005). ICH Q9 detailed the quality risk management expectations for the biopharmaceutical industry to protect the quality of the product and ensure safety to the patient. This represented a paradigm shift from rule-based compliance to a risk-based view of compliance (Waldron et al., 2014). Over the intervening years, companies established tools, processes and training, yet the industry continued to struggle with implementation, as was evident from a range of articles published throughout the years highlighting challenges with regard to QRM implementation (Brady, 2015; Vesper & O'Donnell, 2016; Waldron, 2018). Then, in 2013,

the World Health Organisation (WHO) introduced Technical Report Series No. 981, Annex 2 WHO Guideline on Quality Risk Management, which stated the following:

> *Resources can be focused on risks to patients through the Manufacturers' evaluation of quality risk through science-based decisions linked ultimately to protection of the patient by ensuring the quality, safety and efficacy of the product*

and

> *Training of relevant personnel in industry, international Medicines Regulatory Authorities (MRAs) and universities in QRM principles and applications is essential for its effective implementation. Industry employees should understand what QRM is, possess the skills necessary to apply it properly, and have access to appropriate resources to enable the effective practice of the QRM principles […] The success of QRM depends on the education and training of management and employees to understand the importance of QRM in producing and supplying safe pharmaceuticals. (WHO, 2013)*

These quotes showcase not only the importance of risk management in protecting the patient, but also how critical it is that the necessary skills be transferred through robust education and training. This is essential in providing safe and efficacious pharmaceuticals to the targeted patient population.

As the researcher narrowed her focus, another TU Dublin PhD student completed research entitled

> Quality Risk Management: The Development of a Role-Based Competency Model for the Biopharmaceutical Sector.

This proposed a role-based competency model to fulfil the requirements within a QRM programme (Haddad, 2019). These events stimulated this researcher's interest in

looking deeply at the training programmes needed to support the development of the QRM competencies identified.

Thus, an original research hypothesis for this research was proposed:

> There is not adequate training and education of relevant personnel in the biopharmaceutical industry, regulatory authorities, and universities to build the competencies needed to realise the benefits of a quality risk management programme as outlined in ICH Q9.

As the researcher continued to gather knowledge and information regarding the training and education needed to realise the benefits of ICH Q9, the research hypothesis evolved over time and emerged with a more specific approach. The researcher developed additional interests regarding learning and development, which drove the evolution of a secondary hypothesis, still focused on QRM competencies:

> The current training and education available for relevant personnel in pharmaceutical and biopharmaceutical industries, regulatory authorities and universities does not support the development of competencies in risk-based decision-making, critical thinking and underpinning behaviours necessary to realise the benefits of an effective quality risk management programme as outlined in ICH Q9.

Additional research to understand the attributes and culture needed to enhance the capabilities of critical thinking and risk-based decision making led to the deeper exploration of learning organisations. As the literature review progressed, the

researcher started to see the connection between learning excellence and understanding risk, a connection that ultimately leads to a higher level of protection for the patient. Seeing the connection led to a third and final hypothesis:

> The current training and education for personnel based in the biopharmaceutical industry is focused on fulfilling regulatory compliance requirements. These compliance-focused training programmes do not adequately develop capabilities in critical thinking, risk-based decision making, reflection and associated proactive behaviours necessary to build the types of learning organisations which support the development of individual competencies and builds organisational capabilities.

This hypothesis also led to the development of a series of research sub-questions:

1. In determining the training modality for the cGMP training programme, do companies evaluate adult learning theories in their approach?
2. Are companies effective with regard to the transfer of knowledge and mastering of skills in employees? If that is the case, why do we still experience Regulatory Health Authority observations that essentially impugn the knowledge of the companies' employees?
3. Are companies developing training programmes or learning cultures?
4. Does the biopharmaceutical industry have barriers in its learning culture, within the subconscious of the industry, which are preventing the development of

adaptive and innovative learning organisations needed to address the 21st-century industry challenges they face?

5. Can a biopharmaceutical company improve organisational performance by adopting adult learning principles and concepts from organisational learning theory and open systems theory?

Examining these various research questions led the researcher to a final overall question which ultimately became the research question explored within this study:

> Can companies learn from their mistakes to reduce risk and improve overall operational performance by pursuing a strategy of patient-focused learning excellence?

Thus, as the study evolved, the need for a practical Patient-focused Learning Excellence (PFLEx) Model driven by enlightened leaders who sponsor, nurture and sustain a learning culture within their organisations became the goal of the research.

3.3 Theoretical Framework for the Research

The theoretical framework for research provides an anchor for the literature review, the research methods and analysis (Maxwell, 2004). Once the theoretical framework is set, the researcher can develop the hypothesis and research question, design the research methodology and assess the data and outputs. The researcher must stay grounded within the theoretical framework, which acts as the guiding source for the research journey.

An enhancement of this process involves *theoretical triangulation*, which is the combination of multiple theories or hypotheses when researching an event or occurrence (Denzin, 1970; McMillan & Schumacher, 2006) within the same study. This triangulation helps to bring additional validity, but also expands the understanding of a complex topic (Yeasmin & Rahman, 2012). The intent is to conduct the research study with multiple views and questions to ponder, to either support or refute findings. In theoretical triangulation, the perspectives or hypotheses may be related or may have opposing points of view, depending on what the researcher is seeking to accomplish (Denzin, 1970). Theoretical triangulation may also be used to test various theories by analysing information from the same data set through different perspectives or lenses (Boyd, 2000). For the purpose of this research, Figure 3.1 showcases the triangulation of three specific theories of study within the learning ecosystem selected to guide this research study. These areas are

1. Adult learning theory
2. Organisational learning theory
3. Open systems theory

Theoretical triangulation was selected as an approach because a large portion of the research in this study is based on qualitative research involving both expert opinions and a case study methodology. It is therefore important that several sources are used to validate the corroboration of data and common themes within the outcomes (Yin, 2018).

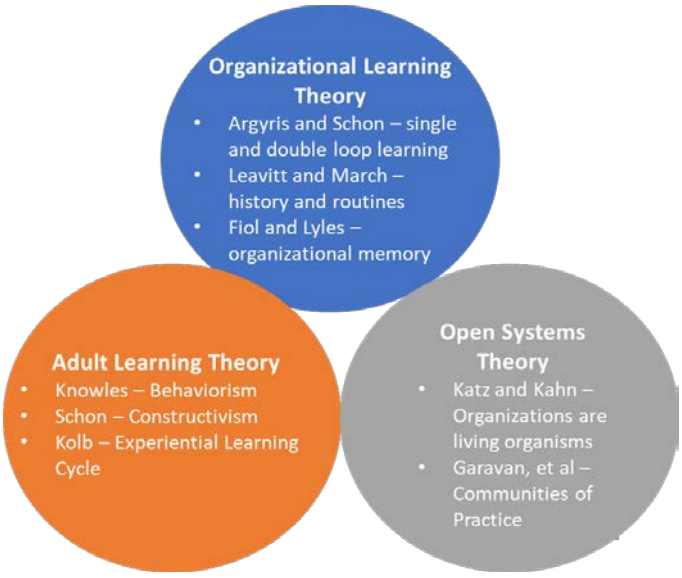


Figure 3.1: Triangulation of the theoretical framework

The theories highlighted in the theoretical framework for this research were reviewed in detail in the literature review (Chapter 2) and are summarised in Table 3.1. The expert opinions were evaluated through these theories (Chapter 4). These theories were considered during the design of the case study (Chapter 5). The insights and conclusions from the case study were evaluated through these theories (Chapter 6), and they formed the basis of the design for the **Patient-focused Learning Excellence Model**, which is summarised in Chapter 8.

Theory	Description
Adult Learning Theory	Adult learners are aware of self
	Past experiences are critical; experiential learning; reflecting on lived experiences and formulating these experiences into knowledge that is stored in memory and then transferred to new situations
	Adults are purpose-driven in their learning
	Adults have a readiness to learn
	Adult learners have internal motivation
	Mistakes are valuable
	Adult learners want an active role in curriculum development
	Learning from mistakes

Theory	Description
Organisational Learning Theory	Looking for an alternate strategy to address when something goes wrong (within the governing rules) (single loop)
	Correcting an error by challenging the rules themselves and employing critical thinking (double loop)
	Organisations lean on information from history and routines which are then encoded into their learning philosophy
	Organisational learning is the process of improving one's actions through better knowledge and understanding as an individual within the construct of the "organisational memory"
Open Systems Theory	Feedback loops within OST provide information regarding company performance outcomes of training and influence future training investments, impacting organisational performance.

Table 3.1: Theoretical framework areas of focus

3.4 Research Study Design, Methodology and Methods

Based on the research questions, a qualitative, mixed methods approach was determined to be the most suitable methodology for this study design. This research methodology design seeks to build upon the information collected at each previous stage and to inform each subsequent stage in the process. These stages of exploration build up into what Saunders refers to as an onion structure, as shown in Figure 3.2 (Saunders, 2019).

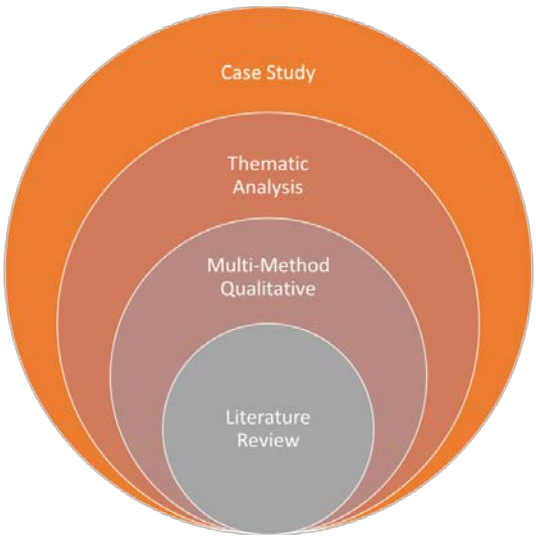


Figure 3.2: Saunders research methodology

Teddlie and Tashakkori refer to mixed methods or multi-methods research (MMR) as methodological eclecticism, noting that the researcher "knowledgeably" (and often intuitively) selects the best techniques available to answer the research questions that frequently evolve as the study unfolds" (Teddlie & Tashakkori, 2010). Certainly, in the case of this researcher, both knowledge and intuition played a part in the selection of the methods used, purposefully selecting events for industry and regulator engagement, nominating topics to explore and capturing inputs from purposive samples of experts during podcast development and at large-scale conference events. The choice of MMR as the methodology for this study was an obvious decision, where the research questions and the methods deemed most appropriate to provide "mutual illumination" to these questions drove the four-phase research process.

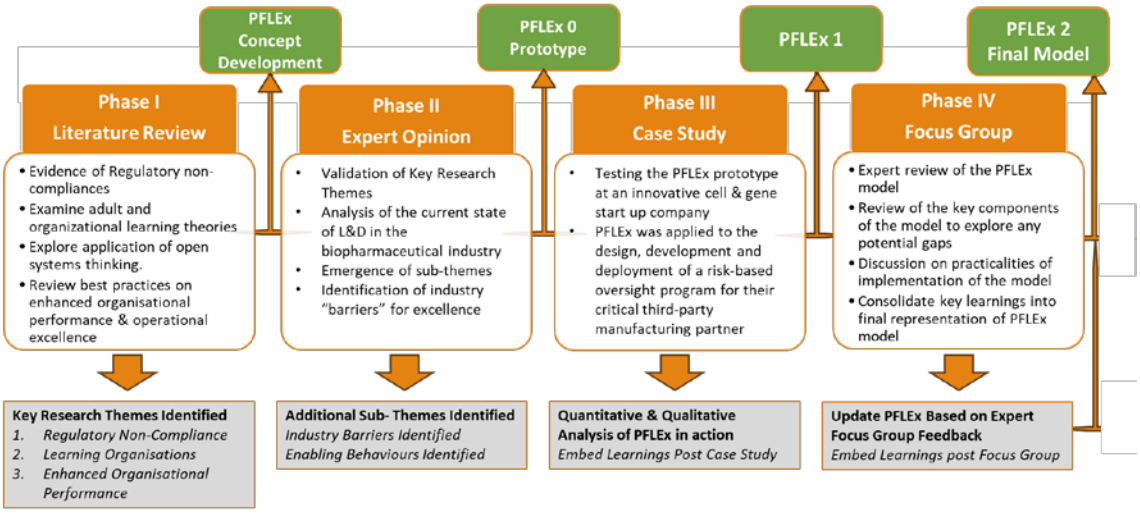


Figure 3.3: Evolution of the design and development of the Patient-focused Learning Excellence PFLEx Model across Research Study Phases I-IV

Phase I

Phase I of the research study involved a deep review of the literature presented in Chapter 2 of this thesis. The review commenced by examining evidence of the problem with an analysis of regulatory non-compliance. The rest of the literature review sought insights from the body of knowledge related to the triangulated theoretical framework underpinning the research. The development of the initial prototype for a **Patient Focused Learning Excellence Model** (PFLEx) emerged from the literature review.

Phase II

Phase II of the research study was designed to solicit expert opinions on the current situation regarding "learning" in the biopharmaceutical industry, how it "learns from its mistakes" and to further explore the emerging PFLEx concept. Through the medium of modern media technology and the necessity to find novel ways to make personal connections with others in the industry network during the global COVID-19 pandemic, an opportunity arose for the researcher to co-host a monthly industry podcast entitled *Risk Revolution*, broadcast through the US-based IVT Network, commencing in September 2020. The researcher co-hosted several sessions throughout 2020 and 2021, enabling the collection of biopharmaceutical industry expert opinions to further understand the problem statement.

In his book *Think Again* (Grant, 2021a), Adam Grant urges experts to seek feedback and rethink their approaches to topics that they consider within their expertise (Grant, 2021a). Grant advises us not to become too set in our ways, but to constantly seek out

new ways or new information that could be used to drive innovation. Seeking out innovative risk management approaches is what the researcher, as co-host, set out to do with the *Risk Revolution* podcast series, bringing together guests from across the industry with a variety of subject matter expertise. The podcasts were leveraged to elicit expert opinion on a range of topics directly relevant to the industry and the research at hand. Each podcast episode featured on or more experts from the biopharmaceutical sector, sharing a wealth of knowledge and evidence regarding recurring failures to address common critical risks within the industry. Guest selection for the podcast involved identifying experts from a homogeneous purposive sample; i.e., focused on one particular subgroup in which all the sample members are similar, in terms of their particular occupation, level of experience and recognised expertise.

Purposive sampling, also known as judgment, selective or subjective sampling is a sampling technique in which the researcher relies on his or her own judgment when choosing members of a population to participate in the study. Purposive sampling is a non-probability sampling method. Elements selected for the sample are chosen by the judgment of the researcher. Researchers often believe that they can obtain a representative sample by using sound judgment, which will result in saving time and money (Black, 2010).

Details of Phase II of the research are presented in Chapter 4 of this thesis. Analysis of the data and opinions from Phase II led to the development of the PFLEx 0 prototype. Chapter 5 of this thesis discusses the development of PFLEx 0 prototype.

Phase III

Phase III of the research study was a case study designed to evaluate and test the PFLEx 0 prototype. This type of qualitative case study approach has been described by Creswell as an exploration of a "bounded system" or "case over time" through detailed, in-depth data collection involving multiple sources of information, each with its own sampling, data collection and analysis strategies (Creswell & Poth, 2018). The case study is determined by the size of the bounded case or the intent of the analysis (Creswell & Poth, 2018). While, at times, qualitative case study research has not been recognised for its full potential, researchers have used the approach to contribute to the knowledge of individuals, groups, processes and relationships (Yin, 2018). Qualitative case study researchers Stake, Merriam and Yin contend that the case study approach allows for a holistic understanding of a phenomenon within real-life contexts from the perspective of those involved (Boblin et al., 2013). As Stake writes, "case study is the study of the particularity and complexity of a single case, coming to understand its activity within important circumstances" (Stake, 1995). Case studies have been described as best suited to research that asks "how" and "why" questions (Yin, 2018).

The researcher took into consideration other research methods prior to selecting the case study approach. As the researcher sought to answer "how" and "why" research questions and did not require control over behavioural events, the case study was identified as the preferred method, compared to experimentation, surveys or archival analytics to allow for exploration (Yin, 2018). Chapter 6 of this thesis discusses in further

detail the case study, the output of which was a further update to the model and the development of PFLEx 1. Chapter 7 of this thesis discusses the revision of the PFLEx 1 model.

Phase IV

Phase IV of the research study was an expert focus group which critically evaluated PFLEx 1 and gave insights and improvement suggestions which led to the final iteration of the PFLEx model. Chapter 8 of this thesis discusses in detail the focus group and the development of the final PFLEx 2 model.

3.5 The Researcher's Worldview and Insider Perspective

3.5.1 The Researcher's Worldview

It is necessary for any researcher to be conscious of how they view the world, notice and process information, formulate positions, communicate these positions and employ a variety of other processes. Otherwise, the researcher would risk being blind to their assumptions and biases. There are entire fields of study for such philosophical concepts, including definitions of ontologies and epistemologies. Ontology involves the study of "being", and it is concerned with "what is known", including the nature of existence and the structure of reality (Crotty, 1998). Epistemology involves a way of looking at the relationship between the knower and the known (Guba & Lincoln, 1994) and how we know what we know (Crotty, 1998).

Reflecting on the literature review in relation to ontology, the researcher proposed *realism* as the ontological stance for this study. Robson informs us that realism has a

long tradition in the philosophy of science, including social science, for which it is an attractive approach (Robson, 2002). Furthermore, it facilitates an approach that takes note of the perspectives of participants, which was a key method of knowing and meaning generation for this study. The researcher's epistemological belief was that reality is known through using the many tools of research that reflect both objective and subjective evidence (Creswell & Poth, 2018). A worldview is defined by Guba as "a basic set of beliefs that guide action" (Guba, 1990). Creswell uses the term worldview to describe four general philosophical orientations about the world and the nature of research that a researcher brings to a study (Creswell & Creswell, 2020). These are widely discussed in the available literature and are shown below in Table 3.2.

Postpositivism	Constructivism
• Determination • Reductionism • Empirical observation and measurement • Theory verification	• Understanding • Multiple participants' meanings • Social and historical construction • Theory generation
Transformative	**Pragmatism**
• Political • Power and justice oriented • Collaborative • Change-oriented	• Consequences of actions • Problem-centred • Pluralistic • Orientated towards real-world practice

Table 3.2: Four worldviews (Creswell & Creswell, 2020)

The researcher most closely associated with the worldview of *pragmatism*, with a problem-centred study orientated toward real-world practice. This worldview was reinforced throughout this study, including the desire to deliver meaningful and useful outcomes as a result of this research. Thus, the study was aimed at solving the problem of the lack of adoption of learning organisation principles within the biopharmaceutical

sector, taking a pragmatic approach focused not on the research methods, but on the research problem, and developing practical solutions to address it. Pragmatism is concerned with applications and solutions (Patton, 1990); this was the primary objective of the researcher, to move the industry forward by understanding the current state and delivering solutions to educate and demonstrate what is possible.

Creswell and Creswell note that mixed methods research is particularly well-suited for a pragmatic worldview, as the researcher can adapt the methods to the most appropriate means in order to characterise the problem and the solution (Creswell & Creswell, 2020). Further detail on these methods is presented in Section 3.4 of this chapter.

3.5.2 The Researcher's Insider Perspective

Following a 25-year career within the industry, including many years in managing risk, developing and delivering training content, the researcher acknowledges her insider's perspective and the challenges that can present when undertaking insider research. The term "insider research" is used to describe research projects where the researcher has a direct involvement or connection with the research setting (Robson, 2002, as cited in Rooney, 2005). Research undertaken with an "insider perspective" can be seen as having both advantages and disadvantages. The disadvantages highlighted by Rooney include the following:

- Will the researcher's relationships with subjects have a negative impact on the subject's behaviour in such a way that they behave in a way that they would not normally?

- Will the researcher's tacit knowledge lead them to misinterpret data or make false assumptions?
- Will the researcher's insider knowledge lead them to make assumptions and miss potentially important information?
- Will the researcher's politics, loyalties or hidden agendas lead to misrepresentations?
- Will the researcher's moral/political/cultural standpoints lead them to subconsciously distort data?

As pointed out by Rooney, some argue that insiders have a level of skills and knowledge which to which the outsider does not have access (Tedlock, 2000). It is also argued that interviewees may feel more comfortable at talking openly if he or she is familiar with the researcher or their background (Tierney, 1994). Insider research has the potential to increase validity due to the added robustness, honesty, depth and authenticity of the information acquired (Rooney, 2005). Armed with this knowledge, the researcher sought to take account of the advantages and manage the risks related to the disadvantages.

There were several advantages arising from the researcher's deep knowledge of the area, access to information and extensive industry expert networks. The researcher has first-hand leadership experience in the field under study due to her career development during this doctoral research. This role included responsibility for the management of the Quality Systems Team and oversight of corporate risk management, training and continuous improvement functions at an innovative biopharmaceutical company. Being

an “insider” has also granted the researcher the ability to reach out to international regulators and seek feedback and guidance across the industry.

Ever mindful of the disadvantages, the researcher and the academic supervisory team paid particular attention to monitoring and managing the research risks that can arise by

- seeking multiple perspectives and guidance from several sources of information on the subject under research, through academia, regulatory bodies and industry during interactions, purposive sampling and philosophical discussions
- assessing the quality of the qualitative data and related data analytics by comparing results from various sources through the literature, expert opinions and case studies, focusing on cross-checking assumptions and assessing patterns or trends for validity

Although the researcher is employed by a biopharmaceutical company, and partial financial support for academic fees to enrol in the TU Dublin doctoral research programme was provided by the employer, the researcher’s perspectives, methods and results were not influenced by their employer, nor was the researcher under any commitment to their employer with respect to the direction of research outcomes or findings. The researcher has a personal passion for learning and understanding how to improve learning capabilities in adults, independently of the researcher’s employer.

3.6 Ethics and Privacy

The Research Ethics and Integrity Committee (REIC) application for this research was submitted in March 2022. Approval was received in July 2022. All research activities have been conducted in accordance with TU Dublin's Ethical Guidelines (TU Dublin, n.d.).

Specifically, the researcher

- handled and stored personal information in a strictly confidential manner, in a secure and password-protected location
- used data gained during this research study solely for the purpose of this research study
- did not (and will not) have any power over any of the involved research subjects, each of whom agreed voluntarily to participate

The researcher also undertook formal *research integrity training* sponsored by TU Dublin and received competency-based certificates for the domains of Arts and Humanities, and Social and Behavioural Sciences. These modules train researchers on their professional responsibilities and on how to deal with complex issues that can arise while planning, conducting and reporting research. The next chapter presents the findings from the expert opinions elicited through the *Risk Revolution* podcasts.

CHAPTER 4: EXPERT OPINION THEMATIC ANALYSIS AND LEARNING OPPORTUNITIES

This chapter describes Phase II of the research study, which, through qualitative methods, solicited expert opinions on the status of learning in the biopharmaceutical industry and further explores the emerging PFLEx concept (see highlighted research step in Figure 4.1).

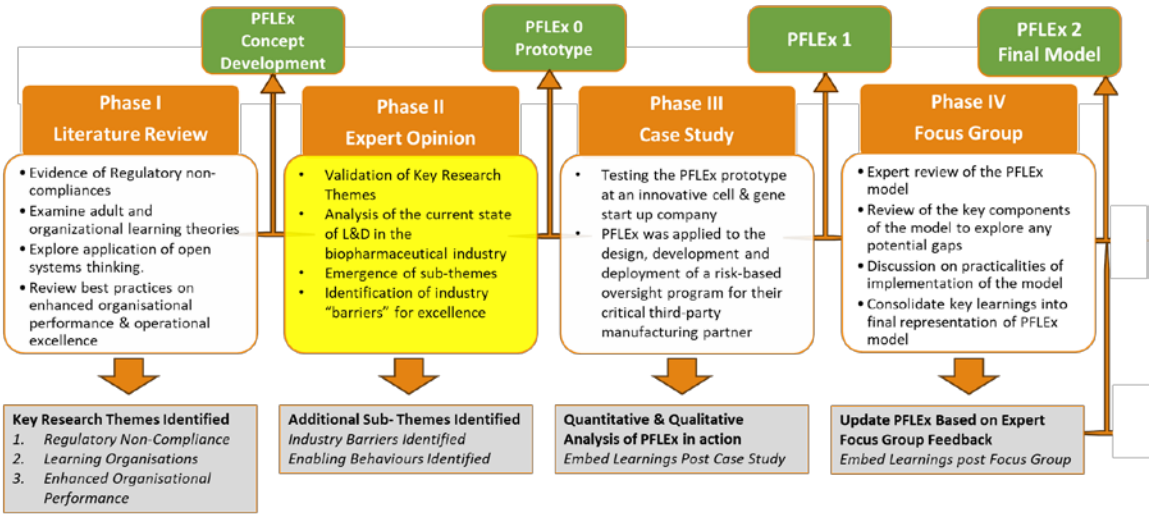


Figure 4.1: Evolution of the design and development of the Patient-focused Learning Excellence PFLEx Model across Research Study Phases I-IV

The expert opinions were gathered through a novel collection process using podcast episodes that were then assessed using a thematic approach to determine the status and challenges faced by the biopharmaceutical industry in embracing organisational learning (Braun & Clarke, 2006).

4.1 Overview of the Expert Opinion Study

4.1.1 The Study Setting and Sample

Because of the necessity to find novel ways to make personal connections with others in the industry network during a global pandemic, an opportunity arose for the researcher to co-host a monthly industry podcast entitled *Risk Revolution*, broadcast through the US-based IVT Network, commencing in September 2020. This was leveraged to elicit expert opinion on a range of topics directly relevant to the industry and the research at hand. Each podcast episode featured one or more experts from the biopharmaceutical sector, sharing a wealth of knowledge and experience about a specified topic, including the failures experienced and key learnings. The main topic for each podcast was selected by the researcher based on the guest's experience and knowledge. The topics for the nine podcasts in the series were as follows:

1. **Adult Learning Theory and its Impact on Training in a cGMP Environment**: Learning theories and models that have relevance to adult learners in the biopharma industry
2. **Quality Risk Management Basics as Part of the QMS**: Basics of risk management principles in the context of ICH Q9
3. **Supply Chain Crisis Planning, Back to Basics – Let's Get Some Facts Straight:** A look at risk management in the broader context, defining the roles of quality professionals, supply chains, supply chain mapping and crisis planning
4. **Developing a Risk Culture, Part 1:** Defining what a risk culture is and illustrating how to build one.

5. **Developing a Risk Culture, Part 2:** Continuing the conversation in cultivating a risk culture
6. **Bias, Heuristics and Risk, Part 1:** Exploring how bias and heuristic traits impact on our ability to identify and assess how we address risk
7. **Bias, Heuristics and Risk, Part 2:** Continuing the conversation in exploring how bias and heuristic traits impact on our ability to identify and assess how we address risk
8. **Facilitator: Friend or Foe:** Discussing the importance of facilitation in the risk management process
9. **Collective Experiences:** Sharing risk management activity experiences as participants and facilitators

4.1.2 Data Collection

The format of the podcasts involved a facilitated philosophical dialogue, which is described by Kvale and Brinkmann (2009) as *knowledge as conversation or knowledge as narrative*, where "the interview is a key site for eliciting narratives that inform us of the human world of meaning". Inquiry conducted through the philosophical dialogues represented "public conversation about the knowledge produced" (Kvale & Brinkmann, 2009). Transcripts were then produced, which were treated as the data source, in preparation for data analysis. A detailed listing of the nine podcast episodes, the experts and the topics under discussion used to collect the research data can be found in Volume 3 of this thesis.

4.1.3 Data Analysis

Transcripts from these monthly podcasts were then analysed using thematic analysis to examine these expert opinions for relevant themes. Thematic analysis is the process of identifying patterns or themes within qualitative data (Braun & Clarke, 2006). Braun and Clarke have provided a six-phase guide which proved to be a very useful framework for conducting this analysis (Maguire, 2017).

- Step 1: Become familiar with the data. The first step in any qualitative analysis is reading, followed by re-reading, the transcripts
- Step 2: Generate initial codes. In this phase, we start to organise our data in a meaningful and systematic way
- Step 3: Search for themes. A theme is a pattern that captures something significant or interesting about the data and/or research question
- Step 4: Review themes. Review, modify and develop the preliminary themes that were identified in Step 3 and determine if they still make sense
- Step 5: Define themes. This is the final refinement of the themes to evaluate if there are interactions between themes or how they relate to each other
- Step 6: Writing up. Summarise in a report, journal article or dissertation

By carefully listening, reading and reviewing the data, the researcher became thoroughly familiar with the content and gained an in-depth understanding of the data. The researcher then examined the transcripts line by line to highlight statements related to

the specific research topic. Codes were then applied to each identified statement. The researcher subsequently leveraged individual codes to help map themes that were related to the research topic. A copy of the analysis is presented in Supplementary Volume 3. Once the themes were identified and mapped in a diagram, the researcher returned to see if any refinements or adjustments were needed.

4.1.4 Characteristics of the Participants

This study included nine industry experts from various companies across the biopharmaceutical industry, as well as consulting firms that were located across the United States and one in Ireland. They represented functional areas such as the supply chain, quality risk management, compliance and auditing, learning and development, and quality systems, each having been in the industry 20+ years. Areas of experience ranged from biologics to small molecules, vaccines, and cell and gene therapy.

4.1.5 Summary of the Podcasts

Table 4.1 presents a summary of the podcast topics, the purpose of the discussions, the key learnings arising, sub-themes which emerged and guest profiles.

Topic	Purpose	Learning	Themes Emerging	Experts
Learning theories and models that have relevance to adult learners in the biopharma industry <Episode Link>	To understand the challenges faced in the industry to meet the needs of adult learners	The industry is affected by - an over-emphasis on basic compliance training - minimal effort in designing training programmes - a lack of experiential learning opportunities - a lack of coaching opportunities	The industry exhibits poor adoption of learning organisation practices to move away from the existing institutionalised, compliance-focused training approach	Over 35 years of GMP-related experience, with an emphasis on developing and delivering training on GMP topics to pharma, biopharma and medical device firms around the world
Basics of risk management principles in the context of ICH Q9 <Episode Link>	To understand why the industry struggles with learning and adopting risk management principles after 15 years since ICH Q9 was introduced into the industry	The industry is - slow to adopt new processes and continuous improvement methodologies - challenged to adopt new processes to improve efficiencies - not supporting change activities with change management principles and communication plans	The industry is slow to adopt change and improve processes	Combined experience of 20+ years practising risk management in the industry through designing and delivering processes and training around the world to companies and health authorities
A look at risk management in a broader context, defining the roles of quality professionals, the supply chain, supply chain mapping and crisis planning <Episode Link>	To understand decision making across the supply chain at an organisation and to understand how knowledge is transferred in this process	The industry is challenged to - adequately manage the knowledge transfer of key information in an organisation - manage complex product life cycle issues - break down silos in communication and decision making across the product life cycle	The industry is challenged to holistically manage the end-to-end product life cycle	Over 20 years of managing large teams in facilities, manufacturing and supply chains. Knowledge emphasis on global supply chains, lean manufacturing, capital asset management and international quality negotiations
Defining what a risk culture is and illustrating how to build one <Episode Link Part 1> <Episode Link Part 2>	To explore what is needed from the learning and development perspective to overcome barriers preventing a proactive risk culture	The industry barriers to enabling a risk culture are - too much of a focus on tools and procedures, and not enough of a focus on the culture, which is needed - accountability not being built into risk programmes to own risk decisions - a lack of education regarding risk management behaviours	The industry has an aversion to embracing risk attitudes and behaviours	Over 25 years of compliance experience in both industry and as an inspector for MHRA. World-renowned expert in risk management, validation and auditing experience. Author of several risk management industry publications and a graduate of a TU Dublin PhD programme

Topic	Purpose	Learning	Themes Emerging	Experts
		- a reactive mindset, failing to reward proactive action planning		
Exploring how bias and heuristic traits impact on our ability to identify and assess how we address risk <Episode Link Part 1> <Episode Link Part 2>	To understand how human bias and heuristics can impact on risk-based decision making and the current landscape in education for this topic	The industry is struggling to - build a desire for organisations to learn about bias - enable an environment encouraging discussions about bias - create learning culture environments - bring awareness to bias	The industry struggles to manage uncertainty through understanding bias and heuristics	Almost 30 years of quality and risk management experience in the pharma industry. Emphasis on building a risk-curious culture in multiple global companies with large product portfolios
Discussing the importance of facilitation in the risk management process <Episode Link>	To discuss the knowledge, skills and abilities that are crucial to the successful facilitation of cross-functional teams and the education provided regarding this	The industry challenges to enabling successful facilitation environments include - developing cultures encouraging curiosity and knowledge seeking - facilitating cultures which encourage being in the know and not asking questions - not embracing vulnerability and environments encouraging psychological safety	The industry is ineffective at cultivating curiosity in team interactions	10+ years of facilitating complex and critical risk management activities for global companies with multiple product portfolios. Well versed and experienced in COVID-19 vaccine manufacturing efforts in response to the pandemic
Sharing risk management activity experiences as participants and facilitators <Episode Link>	To discuss the environments and education cultivated for participants in risk management activities	The industry is grappling with - cultivating cultures of shame and blame - an inability to grow cultures of psychological safety - encouraging information hoarding within organisations - not embracing the behaviours of learning environments.	The industry is unable to provide an environment rich in discussions regarding risk and other issues	10+ years in the pharmaceutical industry, entrenched in quality systems and risk management processes. Built a global risk management programme and has developed and delivered GMP training courses to multiple organisations across the industry

Table 4.1: Summary of podcast

4.2 Emerging Themes

Through in-depth analysis and the extraction of transcript data, a range of industry barriers to learning excellence and the best practice approaches to managing influential behaviours which can counter these barriers were identified. Figure 4.2 summarises these barriers to learning excellence, each of which is discussed in detail in the following sections.

Figure 4.2: Barriers to learning excellence

4.2.1 A Lack of Understanding and Willingness Regarding the Need to Unlearn in Order to Learn

Adam Grant has addressed the underlying issue of how cognitive laziness can pervade and result in an organisation being stuck in a way that is familiar and comfortable. Part of the problem is cognitive laziness. Some psychologists point out that we're mental

misers: we often prefer the ease of hanging on to old views over the difficulty of grappling with new ones. Yet there are also deeper forces behind our resistance to rethinking. Questioning ourselves makes the world more unpredictable. It requires us to admit that the facts may have changed, that what was once right may now be wrong. Reconsidering something, we believe deeply can threaten our identities, making it feel as if we're losing a part of ourselves. (Grant, 2021a)

This ability to unlearn what we think to be true and to rethink our position or understanding of the world around us can be truly challenging for individuals. Overcoming this barrier requires leaders who create the environment for this to happen safely and who demonstrate through their own actions their willingness to relearn. As Grant points out, the capability to listen to new ideas and to be vulnerable when one is not aware of what one does not know may not only make one a stronger leader but may also unlock a culture that embraces the asking of questions and seeking to understand when we do not have all of the answers (Grant, 2021b). These are traits that lead to cultures which innovate and challenge the status quo. The biopharmaceutical industry needs to embrace this ability of unlearning to relearn. This can be achieved by building in systematic processes that enable peer-to-peer reflection, after-action reviews, near-miss exploration and best practice sharing as key elements of building a stronger learning environment. One significant way to debunk old paradigms is to provide specific information using hard facts and good data. It is advisable to prepare actual statistics on outcomes based on the current training/learning methodology and to seek to empower teams to look for new ways to make targeted improvements.

4.2.2 Managing Uncertainty and Change

The work of Pema Chodron (1996) on uncertainty and change is helpful in framing this issue. Chodron states that the world is constantly changing, with everything in a constant state of motion. The idea of staying strongly attached to what has been deemed secure leads people to believe, falsely, that they are in a state of control (Chodron, 1996). The biopharmaceutical industry seeks to achieve a state of control through compliance. Chodron encourages us to learn to stay within the chaos of change, to relax and not panic, but to use this as a source of inspiration. Organisations that continue to maintain control under the guise of compliance are missing opportunities to implement new processes and procedures, and to embrace new ways of working. To overcome its obsession with change aversion, the biopharmaceutical industry must build resilience in leaders, teams and individuals so that change is accepted as a constant and a necessary capability. This must be a behaviour that is included not only in the job description, but also in continuous learning and development within the leadership structure.

4.2.3 Lack of Systems Thinking

Expectations amongst health authorities have helped to focus efforts on business continuity capability and the application of more robust supply chain risk control strategies. This presents the opportunity to apply systems thinking as part of the product management life cycle. Systems thinking is a set of synergistic analytic skills used to improve the capability of identifying and understanding systems, predicting their behaviours, and devising modifications to them in order to produce desired effects. These skills work together as a system. (Rutherford, 2019)

Events rarely occur in linear fashion, and defining the system in terms of both the intrinsic and extrinsic factors can help to identify root causes when failures present themselves, and it better enables the ability to predict potential issues within the system (Rutherford, 2019). Systems thinking should be a required skill for building supply chain organisational mindsets. Risks in meeting patient demand could be greatly reduced if a more holistic, systems thinking approach is an integral part of the biopharma culture. Rewarding mapping exercises of various systems in the organisation to drive continuous improvement activities and action plans is just one way to reinforce this necessary way of thinking.

4.2.4 Lack of a Risk Culture

The industry struggles with promoting a proactive risk culture that encompasses behaviours and attitudes needed to embed and reward employees in order to ensure that issues and opportunities are solved robustly. Industry research has shown that the biopharmaceutical sector struggles with transforming the organisational culture from one focused on compliance toward one focused on excellence (Ballman et al., 2017). Traditionally, much of the emphasis both from the regulators and industry leaders has been on demonstrating the operation of the quality management system and associated business processes that support the commercial operations for medicinal products. The issue of “quality culture” has only been discussed in more recent years, and part of that discussion includes the need to eliminate blame cultures based on fear in order to promote psychological safety to discuss failures and errors.

The podcast dialogues where these concepts were discussed raised the concept of valuing and rewarding *risk curiosity* to change the perception or reframing how risk is viewed. Implementing a proactive risk culture which focuses on prevention rather than the usual "detect and correct" cycle will develop the sustaining behaviours needed across the industry to address this challenge. The ABC (attitude, behaviour, culture) model provides an approach to enhancing performance through people, and not just through systems, by managing attitudes and behaviours with respect to proactive risk prevention (Hillson, 2013). Implementing tools such as the ABC model to develop a risk-curious culture would be a progressive step in moving the biopharmaceutical industry out of the compliance-driven mindset towards a focus on patient-focused learning excellence.

4.2.5 Bias in Thinking

The biopharmaceutical industry does not currently have the culture required to openly discuss how human behaviour can and does impact on decision making. Without a clear understanding of how bias and heuristics may be interfering with the routine application of critical thinking in decision making, the industry will continue to be hindered in terms of truly embracing a learning culture and will continue to make ineffective decisions.

Kahneman points out that it is best to learn to identify opportunities in order to slow our thinking down for complex problems by recognising situations where it may be very harmful if a quick decision is made or if it is a decision where a mistake may be likely (Kahneman, 2013). Potential approaches to managing bias and heuristics within a team involve activities such as enhancing awareness about bias and how this can impact on

decision making, creating an environment where team members can feel sufficiently safe to discuss potential biases about the topic being discussed, and how these influences can be counteracted.

4.2.6 Unwillingness to Embrace Vulnerability, Adopt Change and Improve Processes

Strategies for the implementation of pharmaceutical quality system enablers such as ICH Q9 are still proving to be challenging to the biopharma industry more than 15 years following publication. Despite the widespread availability of a wealth of learning resources, such as conferences, articles, publications and many expert consulting experiences, companies still face a challenge to identify and adequately document their risk-based decisions. If the tools, processes and expertise for supporting and making effective risk-based decisions are widely available, what is observed is not so much a lack of accessibility to knowledge or skills, but rather not wanting to change current practices, even when they are accepted as ineffective. While the evaluated episode was focused very specifically on the QRM topic, the researcher noted that the focus of QRM was really a microcosm of larger challenges across the industry.

When vulnerability is practised, we are open to thinking about creative solutions and listening to many ideas (Brown, 2018). When people are vulnerable and open to asking questions, it shows a desire to understand. To be a good facilitator, one needs to check one's ego and be vulnerable to asking "dumb" questions about the system or process under evaluation. Asking questions that come from a place of seeking to understand encourages the SMEs to explain in detail how or why something is designed to do what it does. It is during these forced explanations by an expert to a layperson that the

difficulties, gaps and risks in the design can be discovered. It is this behaviour which encourages vulnerability that must be embraced.

4.2.7 Lack of Psychological Safety

Amy C. Edmondson is the Novartis Professor of Leadership and Management at the Harvard Business School, a chair established to support the study of human interactions that lead to the creation of successful enterprises which contribute to the betterment of society (Harvard Business School Faculty & Research). Her work is focused on creating environments of psychological safety that lead to innovation, critical thinking, problem solving and learning environments (Edmondson, 2018). When a culture of psychological safety does not exist, employees will withhold their feedback and not provide new ideas for fear of offending management (Edmondson, 2018). This will not result in innovation and may, in fact, cause more mayhem.

In Adam Grant's podcast *Work Life*, Amy Edmondson provided several key benefits to encouraging a culture of psychological safety, which is imperative to explore vulnerability in a learning culture (Grant, 2021b). Accidents are prevented, as teams report mistakes openly and participate in identifying causes and repeat issues. They will also openly report near misses that can help in the future. Innovation thrives, as "out of the box ideas" are openly shared. Diversity allows open thinking and more ideas. When ideas fail, because not all will work out, there must be a culture of acceptance and lessons learned.

4.3 Summary

Carl Jung once said,

> *Everyone carries a shadow, and the less it is embodied in the individual's conscious life, the blacker and denser it is. At all counts, it forms an unconscious snag, thwarting our most well-meant intentions. (Abrams, 1991)*

In contemplating this concept of Jungian "shadows" which can thwart our progress, the idea emerges that these shadows, or barriers, do not just exist in the human psyche or even in small groups or teams, but can exist within organisations and even in industries. It is proposed by the researcher that such barriers present behavioural undertows within the regulated life science sector which prevent us from embracing a healthy learning organisation.

The qualitative data analysis undertaken in this phase of the research provided seven key themes which proved important to consider in further developing the **Patient-focused Learning Excellence Model.**

- Unwillingness to Unlearn to Relearn
- Avoidance of Uncertainty and Change
- Lack of Systems Thinking
- Immaturity in Risk Culture
- Impact of Bias and Heuristics n Decision making
- Not Valuing Vulnerability
- Lack of Psychological Safety

CHAPTER 5: PATIENT-FOCUSED LEARNING EXCELLENCE MODEL DEVELOPMENT

The goal of this research is to develop a practical Patient-focused Learning Excellence (PFLEx) Model driven by enlightened leaders who sponsor and sustain a culture of learning within their organisations. This practical model can be applied within the biopharmaceutical sector to develop structured learning and development (L&D) programmes that encourage learning from mistakes, reducing risk and seeking opportunities to improve organisational performance. This chapter describes the development of the PFLEx Model. This model has been specifically designed to shift the prevailing paradigm away from basic compliance-focused training programmes towards the deployment of L&D programmes that focus on developing capabilities in risk-based decision making, critical thinking and associated proactive behaviours.

The evolution of the design and development of the PFLEx Model has occurred across the four phases of this research study (Research Phases I-IV) and is depicted in Figure 5.1. This chapter outlines the development of the PFLEx 0 prototype (highlighted in the figure below), providing the rationale for the inclusion of each of the key components of the model.

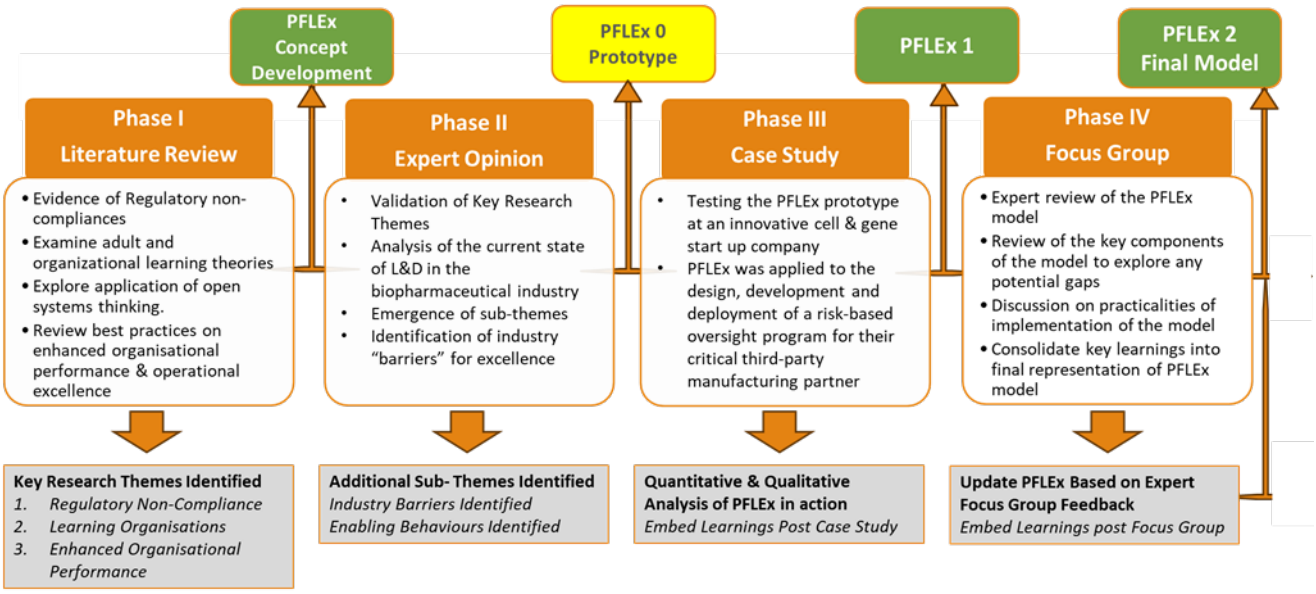


Figure 5.1: Evolution of the design and development of the Patient-focused Learning Excellence PFLEx Model across Research Study Phases I-IV

The list below summarizes the chapters from developing the PFLEx model prototype to the refined PFLEx 2 Model.

- Chapter 6 – outlines how this PFLEx 0 Model was evaluated using a real-world case study
- Chapter 7 – incorporates learnings from the case study into a revised PFLEx 1 Model, which was rigorously reviewed by an industry expert focus group.
- Chapter 8 – presents the refined PFLEx 2 Model resulting from the focus group feedback.

5.1 The Use of a Structured Model as a Platform for Patient-focused Learning Excellence

Garavan (2019) states that in order to succeed within an organisation, members are expected to follow prescribed methods for achieving business goals. However, members

may fall short due to factors such as poorly designed processes, inadequate instructions or insufficient skills. In terms of risk reduction, Boydell reminds us that training is not a universal solution, and it should only be relied upon as a risk control when engineered controls cannot address the identified issue (Boydell, 1976). In cases where training is identified as the enabler to improve organisational performance, experts recommend that a robust, structured approach should be pursued. The use of visual maps, frameworks or models to describe an approach to problem solving is an integral aspect of many academic disciplines and practical fields. The use of structured models can aid in understanding, analysing and solving complex problems, offering a framework for tackling real-world scenarios.

Adopting visual models in problem-solving approaches also enhances communication, fosters collaboration and promotes a structured understanding of complex systems by facilitating the absorption of information (Mayer, 2009). For critical knowledge transfer processes, visual models encourage collaboration among team members and can serve as a reference point for discussion, analysis and decision making. This fosters a shared perspective and helps stakeholders to identify potential issues or benefits, ultimately leading to more effective and well-informed decisions (Gladstein, 1984). In this research study, a structured model was chosen to describe the key aspects that should be considered in designing, developing and deploying a patient-focused learning excellence (PFLEx) programme.

5.2 Overview of the PFLEx 0 Prototype Model

The purpose of the initial PFLEx 0 Prototype Model was to bring together the diverse range of inputs identified in earlier phases of this research study into one model, so that the model could be applied to positively impact organisational performance. These diverse research inputs included the following:

- **Literature review research** which identified evidence of the problem under examination and the extent of regulatory non-compliance and quality defects which can be linked to a lack of organisational learning. Adult and organisational learning theories were used to explore the application of open systems thinking and review best practice on enhanced organisational performance and operational excellence (Chapters 2 and 3).
- **Thematic analysis of the research incorporating expert opinions** identified the range of industry barriers to learning excellence and the best practice approaches to managing influential behaviours which can counter these barriers (Chapter 4).

The Patient-focused Learning Excellence (PFLEx 0) Prototype Model is depicted in Figure 5.2. This initial PFLEx 0 model utilised a typical Improvement House-type model which incorporated the key research themes and subthemes and the inclusion of the barriers to learning which had been identified as limiting factors.

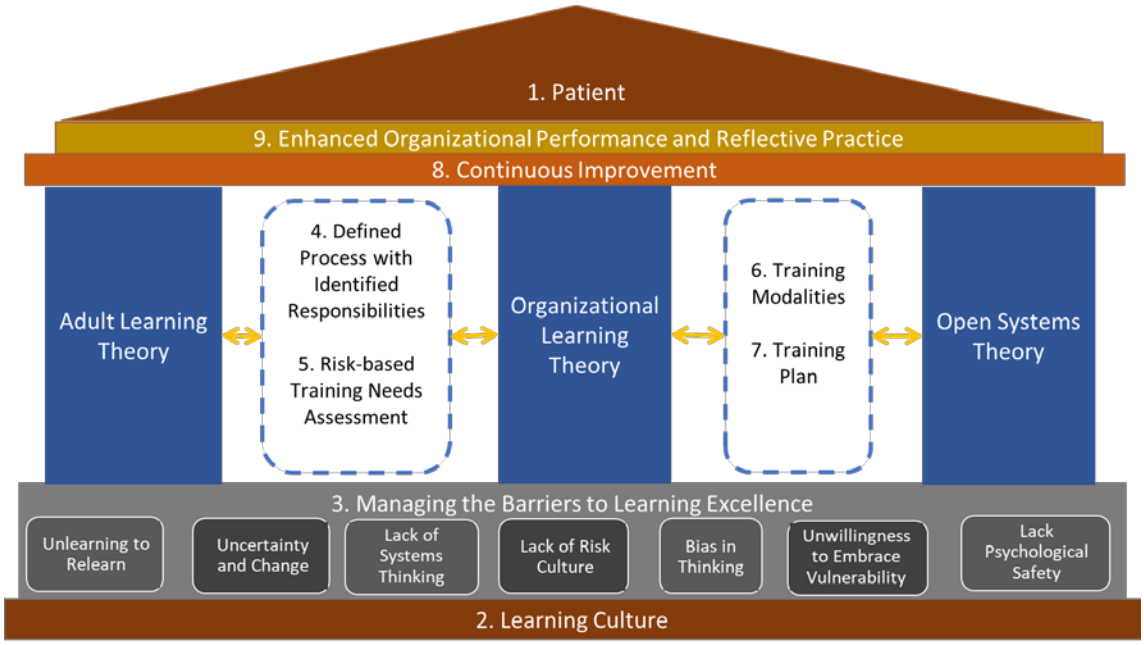


Figure 5.2: PFLEx0 Prototype

The objective is that each L&D Programme derived from the application of the PFLEx Model should be targeted at a specific business process with identified responsibilities (4) to deliver a series of structured outputs. This includes outlining the risk-based learning needs (5), the training content, modality and instructor guidance (6) for coaching the behaviours essential for successful skills and knowledge acquisition. It also involves a detailed training plan (7). Each of these structured outputs are carefully designed to address the business need targeted. Table 5.1 summarises the role and purpose of each of the key elements of the PFLEx 0 Prototype Model.

No.	Element	Purpose
1	**Patient**	The patient is the centre of the business. At the heart of every drug development, manufacturing process and regulatory requirement lies the **goal of improving patients' lives.** The patients' needs must serve as a focal point for each L&D programme designed using the PFLEx Model.
2	**Learning Culture**	The foundation of the PFLEx Model is built on a **culture of learning**, encouraging an organisation to learn from mistakes, ask questions, share ideas and experiment with new approaches.

No.	Element	Purpose
3	**Managing the Barriers to Learning Excellence through Behaviours**	The **barriers to learning excellence** should be identified and managed with enabling behaviours that are woven throughout the design and delivery of the training content, continuous improvement efforts, organisational performance and reflective practices. These enabling learner and leader behaviours are unique features of the PFLEx Model.
4	**Defined Process with Identified Responsibilities**	The implementation essentials for each PFLEx design programme, such as the **defined scope of processes with responsibilities**, **learning needs assessments**, **training modalities** and **training plans,** are strategically placed between the foundation and the roof structure of the diagram and are the common approaches applied to a training programme. The key theoretical principles are uniquely integrated: • **Adult learning principles** – enhance knowledge transfer amongst individuals during training sessions • **Organisational learning principles –** create, capture, retain and transfer knowledge within an organisation • **Open systems theory principles** – effective feedback loops, and their potential to impact leadership decisions on future training investments
5	**Risk-based Training Needs Assessment**	
6	**Training Modalities**	
7	**Training Plan**	
8	**Continuous Improvement**	The effectiveness of the deployed L&D programme must be linked to **continuous improvement** through reflective practices and engagement with the changing business and knowledge landscape.
9	**Enhanced Organisational Performance and Reflective Practice**	Organisational performance measures aimed at demonstrating enhanced business outcomes are designed and built into each programme. **Reflective practices** such as surveys, triggers from the **organisational performance** metrics and Gemba walks are used to continually monitor and improve the L&D programme to deliver on the business needs.

Table 5.1: Summary of the role and purpose of each element in the PFLEx0 prototype

The PFLEx 0 prototype was the first attempt by the researcher to represent a comprehensive approach to building effective L&D programmes that nurture a culture of learning within the biopharmaceutical sector. It should be acknowledged that although the researcher recognised that the PFLEX 0 prototype model required further refinement, it was deemed “fit for purpose” to test the key aspects during the case study discussed in Chapter 6.

5.3 Testing the PFLEx0 Prototype

The PFLEx 0 Prototype model proceeded to the testing and adaptation phase using a case study to evaluate the performance of the model in a real-world context. The case study allowed for a systematic evaluation of the PFLEx 0 Prototype Model within a biopharmaceutical company which gathered user feedback, assessed effectiveness and addressed model improvements.

Details of the case study research methodology are outlined in Chapter 3. Chapter 6 describes the application of the PFLEx 0 Model during a 15-month real-world case study.

CHAPTER 6: CASE STUDY: TESTING THE PFLEX0 PROTOTYPE MODEL

> "To practice a discipline is to be a lifelong learner. You never 'arrive.' The more you learn, the more acutely aware you become of your ignorance"
>
> – Peter Senge (ELM Learning, 2022).

This case study features one biopharmaceutical company's journey (Company A) in enhancing organisational performance through the development of a new business process to improve the performance of its critical Third-party Vendor Risk Management and Oversight (3pVRMO) Programme. In this case study, the researcher piloted the PFLEx 0 Prototype Model to support the development of the new 3pVRMO business process and associated training interventions. The researcher was an integral member of a project team tasked with building this new 3pVRMO business process, as well as designing and deploying the associated training programmes. Company A's goal in enhancing its 3pVRMO business process was to improve resilience in its critical supply chain and reduce risks to the patients awaiting their therapies. From a research study perspective, this chapter summarises Phase III of the research (see highlighted section below) and supports the ongoing evolution of the Patient-focused Learning Excellence (PFLEx) Model. See Figure 6.1 for the purpose and outcomes of this phase of the research.

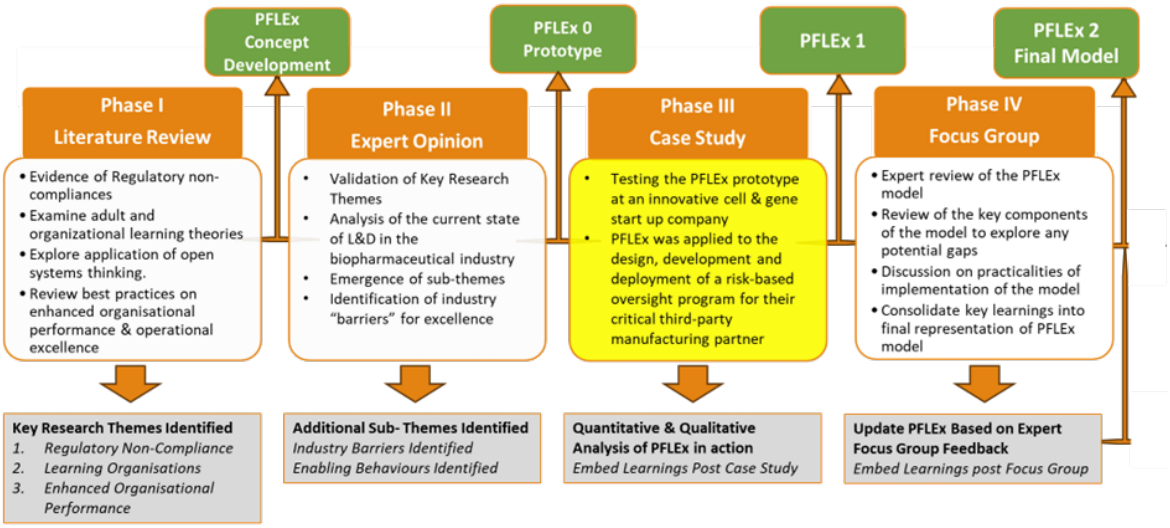


Figure 6.1: Evolution of the design and development of the Patient-focused Learning Excellence PFLEx Model across Research Study Phases I-IV

6.1 Case Study Research Purpose

The primary research purpose of this case study was to demonstrate the application of the PFLEx 0 Prototype Model in a practical, real-world context to test the model's approach, collect feedback and identify improvements. The researcher spent 15 months guiding and monitoring the implementation of the PFLEx Model within Company A, targeting the development, implementation and effectiveness monitoring of a new 3pVRMO business process and the associated training. Full details of the Company A case study for the design of the new 3pVRMO business process and the associated training programme can be found in Appendix 1.

6.2 Regulatory Requirements Governing Third-party Contract Organisation Oversight

The use of third-party vendors to produce IMPs and commercial products is subject to very specific health authority regulations. The global regulations regarding the oversight

of vendors are summed up in Table 6.1. Compliance with required regulatory health authority expectations was deemed critical to the success of the new 3pVRMO business process for Company A, and these regulations were central to the design of the new business process.

Regulatory Reference	Details
Eudralex Volume 4, Chapter 7 (Outsourced Activities)	7.5 Prior to outsourcing activities, the Contract Giver is responsible for assessing the legality, suitability and the competence of the Contract Acceptor to carry out successfully the outsourced activities.
	7.5 The Contract Giver is also responsible for ensuring by means of the Contract that the principles and guidelines of GMP as interpreted in this Guide are followed
	7.7 The Contract Giver should monitor and review the performance of the Contract Acceptor and the identification and implementation of any needed improvement
US FDA 21CFR 200.10 (Contract Facilities)	The Food and Drug Administration is aware that many manufacturers of pharmaceutical products utilise extramural independent contract facilities, such as testing laboratories, contract packers or labellers, and custom grinders, and regards extramural facilities as an extension of the manufacturer's own facility.
	The owner/sponsor's quality unit is legally responsible for approving or rejecting drug products manufactured at a contract facility.

Table 6.1: Vendor Oversight Regulatory References

6.3 Testing the PFLEx 0 Prototype Model – Design, Development and Deployment of a New Vendor Risk Management and Oversight Training Programme

The remainder of this chapter is divided into subsections, each summarising the activities and learnings gained as each step (steps 1-9) of the PFLEx 0 Prototype Model was implemented. For details of the PFLEX 0 Model outputs specific to Company A from each step, please review the details provided in Appendix 1.

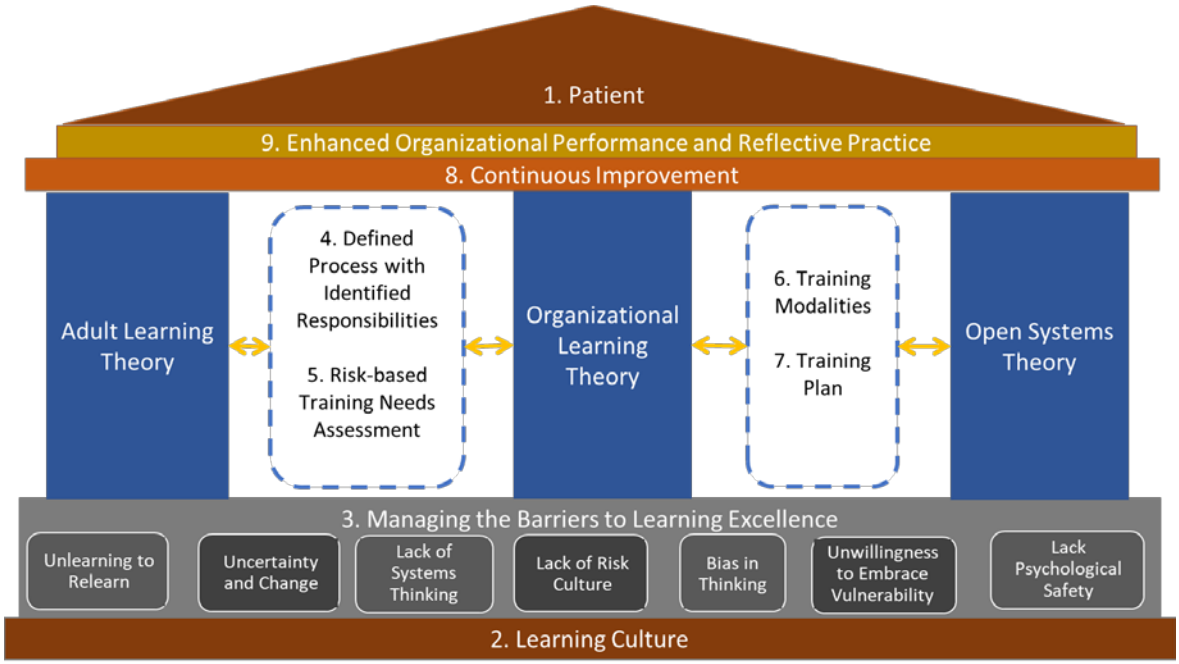


Figure 6.2: PFLEx0 Prototype

6.3.1 Application of PFLEx 0, Step 1 – Putting the Patient First

Step 1 of the PFLEx 0 Model outlines that the patients' needs must be a clear priority for all involved in the development, manufacture and distribution of a drug product. During the case study, it was found that Company A routinely facilitated engagement and interaction with its patient community. Patients were invited to speak to the employees during company communication opportunities and were even engaged with the company board during decision making regarding patient access to their therapies.

Company A was transparent about the therapeutic risks and benefits and was often closely involved with the patient's families to provide education about the disease, as well as the therapy. Ensuring that the patient had access to their drug was emphasised as paramount during internal company decision-making discussions, and this drove

many decisions during the COVID-19 pandemic, when supply chain stresses were challenging distribution models. The researcher found that putting the patient first was an essential aspect of Company A's culture, and this strongly validated the value of the inclusion of the patient in PFLEx 0 Model Step 1.

6.3.2 Application of PFLEx0, Step 2 – Learning Culture Assessment

In Step 2, the project team assessed the current learning culture within Company A to establish its current state. Upon completion of the learning culture assessment (see Table 6.2), the PFLEx 0 Model was used to guide the development of the new *3pVRMO* business process, and the cross-functional project team integrated actions throughout the design to address the learning culture needs.

Desired Learning Culture Attributes	Company A Learning Culture Assessment of Current State
Systematic use of structured problem-solving (SPS) tools and approaches	• Many problem-solving tools were available, including root cause analysis, risk management and operational excellence tools. • There were certified practitioners to support and facilitate formal problem-solving exercises. • However, there was room for improvement in putting together an SPS action plan with identified support resources to execute problem-solving exercises.
Experimentation with innovation and new approaches	• New approaches, technologies and tools/techniques were encouraged by the leadership of this organisation. • The challenge for Company A was to ensure that innovation was coupled with simplicity rather than a tendency to over-complicate new processes.
Learning from its own experience and history	• Knowledge management was found to be very challenging for Company A. While it had many senior employees with a rich history in the industry, they were challenged with regard to sharing their knowledge in a way that increased the skills and abilities of the staff. • There were also challenges regarding access to knowledge repositories, and important decisions and information often resided outside of the PQS, which made it difficult to ensure that it was retrievable and presentable. This made learning from past experiences and mistakes difficult.

Desired Learning Culture Attributes	Company A Learning Culture Assessment of Current State
Learning from the experiences and best practices of others	• Company A was very transparent, and employees shared experiences in organic discussions. • It was found that a more robust infrastructure of communities of practice (knowledge-sharing CoPs) was needed for the sharing of best practice. • Lessons learned were documented to support a project or team, but the actions were often not followed through to completion and were lost to the competing priorities of the company.
Transferring knowledge quickly and efficiently throughout the organisation	• Knowledge transfer was often delayed and not efficiently transferred throughout Company A. • Key current or historical information was difficult to retrieve in the electronic filing systems.

Table 6.2: Findings from Company A's learning culture assessment

6.3.3 Application of PFLEx0, Step 3 – Managing the Barriers to Learning Excellence

Embedding influential behavioural elements which counterbalance the institutional barriers to learning excellence is a unique aspect of the PFLEx Model design process. To examine this aspect of the model in detail, the researcher maintained a journal throughout the case study (Volume 3), observing and recording the behaviours of the different cross-functional team members during the project life cycle. These findings have been synthesised and summarised as a key output of the case study, and they identify the *enabling behaviours* essential for companies wishing to learn from their mistakes. These enabling behaviours can be found in detail in Section 6.3.10, and they inform the ongoing evolution of this unique aspect of the PFLEx Model.

6.3.4 Application of PFLEx0, Step 4 – Clearly Define the Scope of the New Business Process

The PFLEX Model emphasises the importance of the clarity of scope for both the targeted new business process development and the associated learning and development programmes, including the identification of clear roles and responsibilities for the delivery of the targeted business need. For this phase of the case study, the project team followed a five-step structured project methodology to engage stakeholders and to define the scope of the new 3pVRMO business process. This is both a comprehensive and a critical step to ensure that the new process design and associated training programme are purposefully designed to fully understand and deliver on the targeted business need. The five-step scope definition process is outlined in Figure 6.3, and the details of the scope definition exercise for the new 3pVRMO business process can be found in the completed case study in Appendix 1.

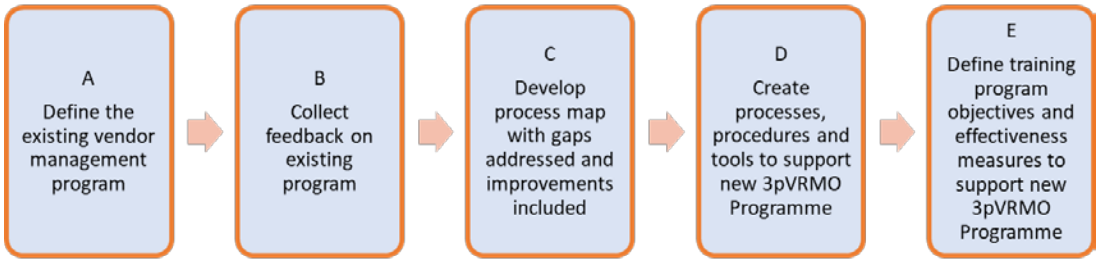


Figure 6.3: Defining the Scope of the New Process and Associated Roles/Responsibilities

6.3.5 Application of PFLEx0, Step 5 – Risk-based Training Needs Assessment

At the next step, a risk-based training needs assessment was conducted which involved evaluating three critical factors:

1. **The impact of a specific task or activity on overall GxP operations.** Focusing on identifying those activities that, if not performed optimally, may pose a significant risk to the organisation.
2. **The complexity or difficulty in performing a given task**. Activities with a higher degree of complexity may require tailored training interventions to mitigate risks associated with errors or inefficiencies.
3. **The frequency with which an activity is undertaken**. Frequent activities central to core operations may require routine oversight to ensure sustained competence and risk mitigation. Frequently performed operations provide an environment for mastery of the skill. Infrequent operations may require additional "refresher" interventions prior to execution.

The team targeted high-risk activities with more intensive training modalities such as experiential on-the-job training (OJT), while medium- to lower-risk activities were targeted with training modalities such as supportive job aids or instructor-led training sessions. The detailed risk-based training needs assessment for Company A is provided in Appendix 1. Based on the outputs from the risk-based training needs assessment exercise, the team recommended the development of **five specific training courses** to address the **five** high-risk activities identified. The training course titles, modalities, objectives and details of who should attend are all summarised in the section titled

"Design of Five Critical Training Programmes to Address the High-risk Training" in Appendix 1.

6.3.6 Application of PFLEx0, Step 6 – Designing Course Content Using the ALECT Approach

The next step in the application of the PFLEx 0 Model was to design detailed course content for the five critical training programmes using the Adult Learner Effective cGMP Training (ALECT) tool, designed and published by the researcher earlier in the research study (Richter & Calnan, 2020). The ALECT tool provides a structured approach to ensure adult learning concepts and experiential learning methodologies are considered in designing the format, content and delivery of instructional course material. During the Company A case study, the ALECT tool was used to design all course content for each of the five critical training courses. The case study details shared in Appendix 1 demonstrate how the researcher used the ALECT tool to develop one of the critical training courses in the new 3pVRMO business process. The example shown is for the **Vendor Selection On-the-Job Training (OJT) Course**. Each Company A trainee would have the opportunity to

- commence their learning with an initial virtual instructor-led training (vILT) overview that allowed multiple learners to attend and learn from each other, based on questions asked and experiences shared
- participate in individual role-based OJT sessions that provided 1:1 "how to" intensive time with an instructor to enable the learner to become fluent in the use of the new 3pVRMO business process and tools

- access multiple reflective coaching sessions tailored for the individual learner as real-world use of the new 3pVRMO business process and tools presented challenges, or to address complexities that were not covered in the initial training sessions

6.3.7 Application of PFLEx0, Step 7 – Developing a Training Plan

Once the training objectives, content, methodology, evaluation approach and effectiveness measures were defined, a training plan was developed for the 3pVRMO business process to ensure a consistent approach to deployment. The training plan included details of the following elements:

- Detailed **learning objectives** developed to ensure the plan provides clear direction on training modality, guiding the design, development and delivery of the content. These objectives also defined what learners could leverage for evaluation and assessment, allowing trainers to measure progress and success.
- A link to the original **risk-based training needs assessment** to ensure needs were appropriately addressed in the plan.
- The **training curriculum** that outlined role assignments in the programme, and any additional non-training educational components such as templates or tools that support the learning experience.
- **Effectiveness measures** to determine the standards by which the learners' performance or knowledge would be measured. These included metrics such as accuracy, quality or the proficiency level of skills and abilities.

Training activities were then scheduled for the learners as per the approved training plan, and they were evaluated in regard to effectiveness and continuous improvement opportunities on an ongoing basis. Given the number of learners in this Company A case study and the range of training to be delivered across the functional teams, this phase of the case study extended to almost one year in duration. This was a comprehensive deployment activity, and several key lessons were learned during this period in the case study. These findings are summarised in Section 6.3.10.

6.3.8 Application of PFLEx 0, Step 8 – Continuous Improvement

The purpose of this section is to summarise the post-deployment case study survey data, learner and instructor feedback, and the lessons learned from learners and instructors for the new 3pVRMO business process and training programme. This qualitative post-deployment data provided insights into the effectiveness the new 3pVRMO business process and training programme, and it identified areas for continuous improvement. The detailed data analysis and summary from the survey are documented in Supplemental Volume 3. Overall, the feedback demonstrated that Company A now viewed its revised third-party vendor risk management business processes as a range of practical, easy-to-use tools and approaches, effective for reducing risk and improving organisational performance and decision making.

Coaching, leadership support and ongoing training were identified as essential in ensuring the effective use of the new business process. The high-level themes that were identified in the post-deployment survey were as follows:

- The importance of having a clear and consistent structured processes to execute the third-party vendor risk management and oversight process.
- The need for clear instruction and definition regarding the identity of the "critical third-party vendors".
- The importance of leadership coaching with teams and individuals regarding continued effective use of the new 3pVRMO business process.
- The need for the ongoing evolution and continual improvement of third-party vendor risk management and the oversight process based on a proactive review of the effectiveness measures incorporated into the new process.
- Areas for ongoing improvement include planning for periodic training/refresher courses.

The data also suggest that the following elements should be sustained to continue to support what is working well.

- The hands-on training/OJT was reported to be particularly helpful because information is provided as it is needed rather than being front-loaded during staff orientation training or new-hire onboarding.
- Additionally, the 1:1 and small group interactions helped to establish good relationships between the teams.
- The new *Vendor Selection Risk Assessment Template* provided an objective evaluation and ranking of the risk associated with each respective site during vendor site selection.

- The *risk management plan* provides a platform to raise shared risks with the vendor and jointly plan mitigation measures.
- The *operational risk assessment* helps the vendor management team to keep track of risks and also to determine whether the risk control actions taken to mitigate risks were successful.

Based on the data provided, the cross-functional project team developed the following list of recommended actions to further improve the 3pVRMO business process:

- Provide leadership coaching to third-party vendor business owners and managers to help them interact with their own teams and individuals regarding the use of the risk management plan.
- Develop a standard work instruction helpful for the internal Company A vendor business leads to ensure that the requirements for selecting and adding new vendors are fully met prior to entering into a contractual arrangement.
- Further streamline the 3pVRMO business process so that all existing vendors are in compliance with the revised SOPs.
- Coordinate training across Company A so that everyone is on the same page regarding third-party vendor risk management and oversight.
- Facilitate periodic training and refresher courses to ensure infrequent users of the 3pVRMO business process have opportunities to retain the knowledge.

- Establish an ongoing 3pVRMO community of practice to provide a forum for team members to openly discuss challenges they are experiencing and refresh on basic concepts.

- Develop a self-assessment tool to provide an opportunity for the learner to assess their skills prior to taking the training. This gives the learner an understanding of their existing abilities and allows the instructors to tailor the learner's experiential learning to target areas that need strengthening. This approach creates a more personalised and practical learning experience.

The case study survey provided an excellent opportunity to collect continuous improvement feedback, as well as anecdotal feedback provided by learners during training sessions or 1:1 coaching sessions. The project team met several months after initial deployment of the new 3pVRMO and put together a plan to implement these improvements.

6.3.9 Application of PFLEx0, Step 9 – Enhanced Organisational Performance and Reflective Practice

A key objective of the PFLEX 0 Model is to ensure that enhanced organisational performance is targeted, and proactively monitored, to confirm delivery of real business value in exchange for the purposeful business process and instructional design efforts expended. This is achieved using a combination of carefully designed effectiveness metrics and the application of routine reflective practices. For Company A, the new 3pVRMO business process metrics firstly tracked where a vendor selection risk

assessment, operational risk assessment and risk management plan existed for a CMO. This helped to ensure that third-party vendor risk management was a key priority for the organisation; it also enabled improved visibility of any gaps and tracked progress to ensure it was being made in terms of managing the identified risks. One additional key metric was added to provide Company A with an overall vendor risk profile ranking for each vendor, which involved colour-coded risk rankings by vendor, for review during quarterly vendor performance reviews. This metric would help Company A to better understand the overall risk landscape being managed by it as contract giver during strategic business decisions.

6.3.10 Key Learnings from the Company A Case Study: Addressing Barriers to Adopting Learning Excellence by Embedding Enabling Behaviours

This research study began by identifying the institutional barriers that exist within the biopharmaceutical industry which hinder organisations from learning from their mistakes. A unique aspect of the PFLEx Model is the identification and embedding of influential enabling behaviours to counter the effects of these barriers in the learning process. Throughout the Company A case study, the researcher collected and documented observations in journal entries during team meetings and presentations to stakeholder communities and the core team. The data were used to compare with the thematic analysis from Chapter 4 to collect evidence of the existence of the barriers to learning excellence observed with regard to the team dynamics. Team behaviours were confirmed by actual observations from the researcher's journal entries across several months of observing the team in action. During this time, two additional barriers to

learning excellence were also identified and assessed for inclusion in the revised PFLEx Model.

Table 6.3 provides a summary of the barriers to learning excellence, along with the researcher's observations during the Company A case study, along with the key behavioural learning gained from the case study. The journal entries can be viewed in Volume 3. These case study observations and key behavioural learnings resulted in the identification of the enabling behaviours necessary to counter the traditional organisational barriers to learning excellence. These enabling behaviours have been integrated into the next revision of the PFLEx model (PFLEx 1).

Barriers to Learning Excellence	Researcher's Behavioural Observations during Company A Case Study	Key Behavioural Learning Gained during Company A Case Study
Unlearning to Relearn	- The premise of the project was to improve on an existing programme that was ineffective in its design and relied too heavily on "read-and-understand" of procedures. - The team and sponsor stated that they were open to new ideas shared by the team lead. - The lead brought ideas forth; the team found pilot users and collected feedback for modifications.	- The team were enthusiastic to improve their ability to address risks in the third-party network. - They were keen to learn new skills and were very engaged in the design of the new process. - They demonstrated a strong growth mindset throughout the project.
Uncertainty and Change	- The team experienced some challenges in embracing the necessary changes themselves. - Some key stakeholders were resistant to change. - The lack of a structured process to manage change led to uncertainty for those impacted by the change.	- There was a lack of skills and leadership in change management, which led to behaviours that caused delays. - Learning to embrace change is a necessary prerequisite for all personnel in an

Barriers to Learning Excellence	Researcher's Behavioural Observations during Company A Case Study	Key Behavioural Learning Gained during Company A Case Study
	- The team lost time during the project as they dealt with their own feelings of uncertainty about change. - The uncertainty of how this training programme would be received by the end users and trainees was an uncomfortable point for many of the team participants.	environment where continual improvement is now a regulatory expectation. - Despite concerns around a lack of certainty, the team did persevere and continued with their efforts, as they believed the programme would deliver the business benefits needed ("understanding the why").
Lack of Systems Thinking	- The cross-functional design of the team allowed for constant feedback from stakeholders and users all along the journey to ensure the tools and training were not developed within silos. - It was observed that the team were diligent in considering the various platforms and services provided by vendors, including how these services linked into the supply chain for various products. - When evaluating all the moving parts with a systematic mindset, the team had to consider how the tools would be leveraged across the various vendors, from the higher-complexity perspective of a drug manufacturer.	- The team were coached on adopting a systems thinking approach while considering the end-to-end design of the programme. - They struggled at times with maintaining a high-level perspective to ensure the new process addressed all of the end-to-end process connections required.
Lack of Risk Culture	- One of the key behaviours the initiative highlighted was the concept of being *risk-curious* by exploring risk discussions and taking calculated risks when appropriate and when communicated to/by leadership. - The researcher observed the case study team being risk-curious during the development of the new 3pVMRO programme and training programme development.	- It was noted by the team how critical a healthy risk culture, coupled with risk-curious behaviours (speaking up, asking why, etc.), is to successfully develop an effective vendor oversight training programme.

Barriers to Learning Excellence	Researcher's Behavioural Observations during Company A Case Study	Key Behavioural Learning Gained during Company A Case Study
	- The researcher viewed a shift in perception by the team to one that noted the benefit of taking risks to innovate and improve the existing vendor risk management programme.	
Bias in Thinking	- The team found it difficult to discuss risk and uncertainty at times, which was evident in the early pilots of the new tools and the lack of experience in assessing the likelihood of occurrence of a risk. - The team was often uncomfortable in determining the level of detail needed to reduce uncertainty in order to adequately assess the risk for a vendor.	- The difficulty in understanding and quantifying risk resulted in delays in the project at times. - There was sufficient evidence of status quo bias across the organisation that had to be overcome.
Unwillingness to Embrace Vulnerability	- This cross-functional team was very open in discussing new ideas, and many members of the team acknowledged that they were not risk experts but were open to trying new tools and approaches. - This showed courage and strength from the team members and a willingness to learn. - The leader of the team was not familiar with the third-party contract organisation oversight needs in the rare disease space. Using her listening skills and asking questions of the team members demonstrated vulnerability in her leadership, allowing for an innovative, collaborative approach to be developed.	- This team was open and curious during the design and development process. It was noted that this was an important behaviour to have in place when introducing a new approach or process. - Vulnerability was valued and modelled by the team lead. - Team members were encouraged to share details of their lack of experience or knowledge in a safe environment.
Lack of Psychological Safety	- There were team interactions that reflected differing opinions of the 3pVMRO process changes and, at times, dissenting voices. - It was observed that team members were encouraged to express a dissenting opinion as an opportunity to strengthen the programme.	- The behaviour of this team was open and transparent during risk and issue discussions. - Different perspectives were welcomed and encouraged.

Barriers to Learning Excellence	Researcher's Behavioural Observations during Company A Case Study	Key Behavioural Learning Gained during Company A Case Study
	- As tools were piloted, the teams openly shared with the vendors risks and issues that were being experienced.	- Although there were rich risk and issue conversations at the company, continuing to sustain that as part of the culture remains a work in progress.
Inability to Provide Strong Sponsorship **(New Barrier Identified during Case Study)**	The team observed many instances of a sponsor myopically focused on project execution timing and accountability to the schedule (*getting it done*) rather than on delivering the business and patient outcomes targeted (*getting it right*) - The sponsor issued constant reminders during report-out presentations that the timing of the project was getting close to being overdue. - Sponsor behaviours *not* observed included acting as an advocate or coach and using their influence to direct a positive outcome.	- The team provided feedback to the researcher indicating that this type of sponsor behaviour was a barrier to truly achieving the goal of integrating organisational learning components to improve organisational performance in the supply network.
Difficulty in Practising Patience and Misalignment of Objectives **(New Barrier Identified during Case Study)**	- As the new 3pVRMO process was under development, the project sponsor began to exhibit impatience. - It was evident to the researcher that the endgame of the project was viewed by the sponsor as the completion of the tools, templates and SOP, *and not* the deployment of a skills-based qualification training programme. - This misalignment regarding the end deliverable from the team caused disagreement on the final due dates for project closure.	- The team leader drew the sponsor's attention back to the scope and value of the work as it relates to qualifying personnel to perform the required tasks outlined in the new 3pVRMO process. - This honest dialogue with the sponsor led to a complete change of mindset and approach. - The sponsor was impressed with the new process and the proposed training programme. - The team provided feedback suggesting

Barriers to Learning Excellence	Researcher's Behavioural Observations during Company A Case Study	Key Behavioural Learning Gained during Company A Case Study
		that sponsor impatience could result in inappropriate training vital to ensuring the new risk management process was beneficial to the user and the business.

Table 6.3: Company A case study behavioural observations and learnings gained

6.3.11 Summary of the PFLEx0 Prototype Model Issues and Remediations

The outcomes of Company A case study resulted in identifying limitations in the PFLEx model that should be addressed to allow the model to fully realise the benefits of improving organisational performance and cultivating an environment where an organisation can learn from its mistakes and reduce the risk to patients. The limitations identified and modifications to the model are summarised in Table 6.4.

Limitations Identified	Modification to Model
The model lacked a systematic deployment structure for experiential learning, continuous improvement practices and reflective elements working together.	An experiential learning cycle was added to the learning deployment model, encompassing *learning by doing*, reflecting, coaching and developing active experimentation. A *knowing, doing, being* continuous learning cycle was established.
The necessity for a transformative shift from learning barrier-orientated behaviours to incorporating the enabling of "influential" behaviours.	The learning culture barriers were changed in the PFLEx Model to facilitate enabling behaviours.
The model lacked a framework to guide leader sponsorship initiatives.	The establishment of a robust foundation in leadership sponsorship was added to the PFLEx Model.
The theoretical principles of adult learning, organisational learning and open systems theory were depicted as pillars of the instructional design process only.	Adult learning principles, organisational learning and open systems theory now show as underpinning framework for the complete model.

Limitations Identified	Modification to Model
The PFLEx Prototype combined enhanced organisational performance and reflective practice but did not clearly identify the organisational performance tools to proactively manage and optimise effectiveness outcomes.	Incorporated detailed tools into the model that enabled proactive performance management of effective outcomes.

Table 6.4: Limitations identified in the PFLEx0 Prototype Model and related modifications

The main improvements recommended from PFLEx 0 to PFLEX 1 include the following:

- The establishment of an enhanced foundation structure for leader sponsorship.
- The integration of adult learning principles, organisational learning and open systems theory underpinning the model.
- The incorporation of detailed performance management strategies.
- Leveraging continuous improvement tools.
- Utilising structured deployment via experiential learning and reflective practice to further reinforce this dynamic model.
- The PFLEx Model positions learning as pivotal for addressing mistakes and proactively managing patient risks. The revised PFLEx Model achieves this through the inclusion of an *Experiential Learning Cycle* designed to encourage a shift in how organisations think about learning.

6.4 Chapter Summary

This Company A case study focused on the journey of one biopharmaceutical company as it endeavoured to improve its critical third-party vendor risk management and oversight capability by implementing a targeted new business process and training

intervention. The PFLEx 0 Prototype Model was applied to the design, development and deployment of the new 3pVRMO process, and it represents Phase III of the research methodology. The modifications to improve the PFLEx Model are discussed in Chapter 7.

CHAPTER 7: THE REVISED PATIENT LEARNING EXCELLENCE MODEL – PFLEX1

The Company A case study provided an excellent real-world opportunity to identify the areas to strengthen the PFLEx Model. This chapter summarises the reflections from Phase III of the research and presents an improved PFLEx1 Model (see highlighted research step in Figure 7.1, below).

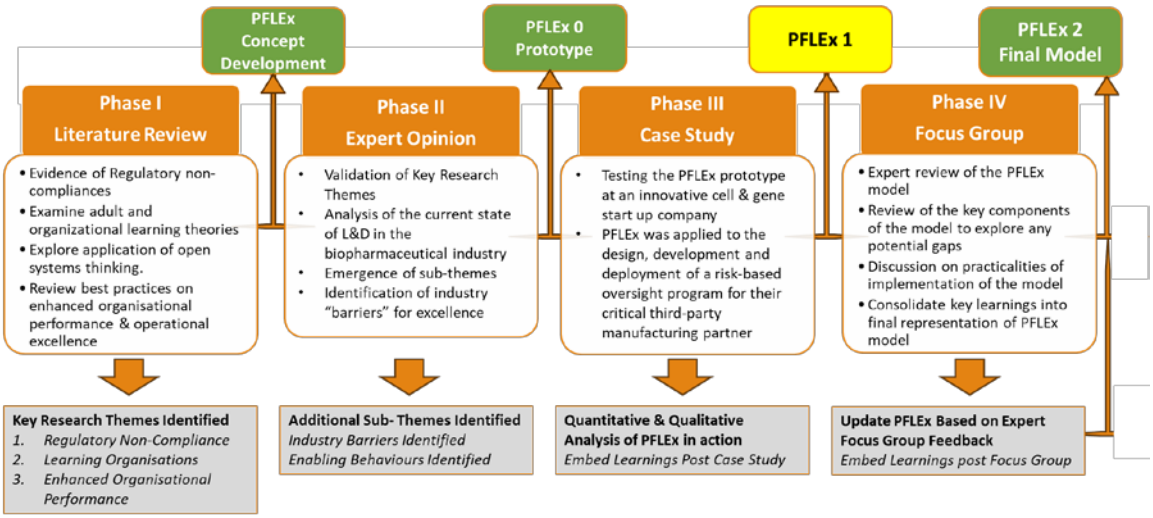


Figure 7.1: Evolution of the Design and Development of the Patient-Focused Learning Excellence PFLEx Model Across Research Study Phases I-IV

7.1 Introduction to the Revised PFLEx1 Model

The revised PFLEx 1 Model, presented in Figure 7.1, offers a dynamic and adaptive approach to improve organisational learning, poised to deliver both short-term benefits and longer-term sustainable improvements for organisations.

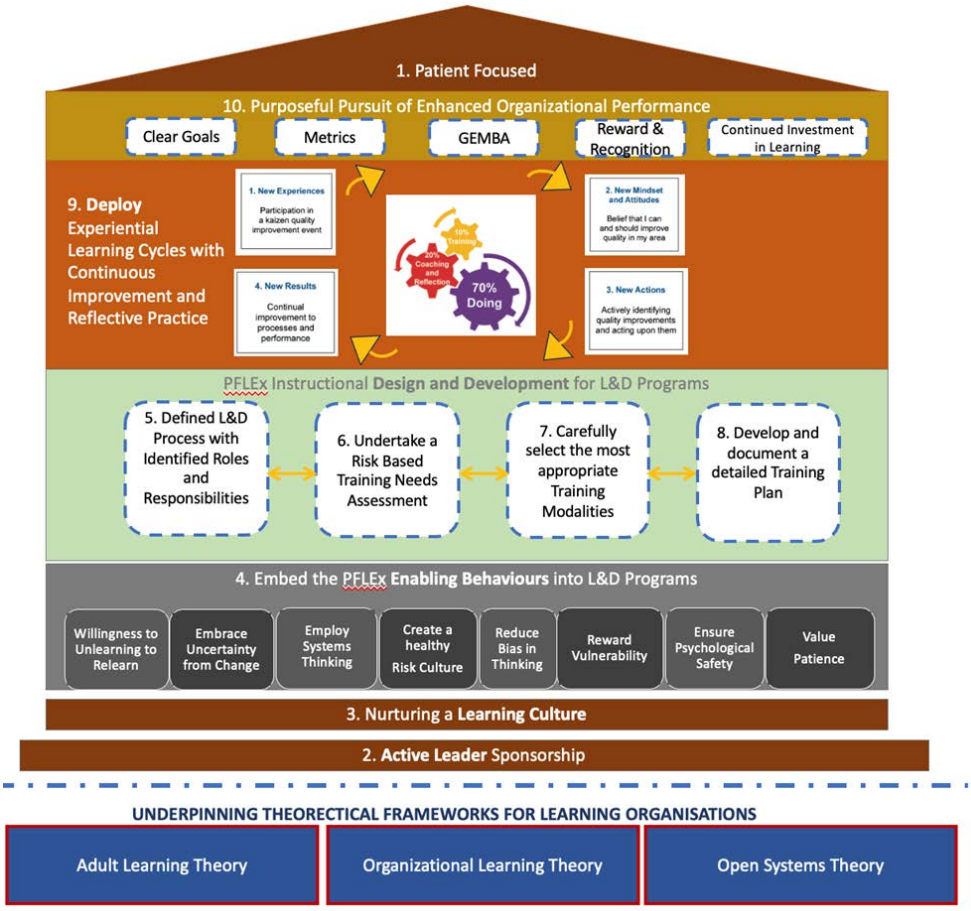


Figure 7.2: Patient-focused Learning Excellence (PFLEx1) Model

The revised PFLEx 1 Model

- continues to focus firstly on the patient (1)
- embeds foundational theoretical frameworks into all L&D activities to build organisations that can learn from their mistakes
- emphasises the importance of active leader sponsorship for nurturing a culture of learning (2,3)
- outlines the *enabling behaviours* which support learning excellence (4)

- provides a purposeful design and development phase for business processes and their associated L&D programmes (5, 6, 7, 8)
- provides a structured L&D deployment phase that includes *experiential learning cycles* with continuous improvement and reflective practices (9)
- recommends proactive performance management tools with clear goals and effectiveness metrics, in addition to the use of GEMBA and the inclusion of reward and recognition programmes to reinforce the enabling behaviours, while it also supports decisions related to ongoing investment in learning (10)

The application of the revised PFLEx 1 Model is intended to set the stage for sustained operational excellence, enabling organisations to navigate challenges, embrace continuous learning and improvement, and ultimately deliver enhanced patient outcomes.

7.3 The Potential Impact of a Revised PFLEx Model on Organisational Performance by Enabling Companies to Learn from Their Mistakes

This section illustrates how the revised aspects of the PFLEx 1 Model enable companies to use mistakes as learning opportunities and foster a culture of continuous improvement within their workforce.

7.3.1 Repositioning the Principles of Adult Learning, Organisational Learning Theory and Open Systems Theory in an Enhanced Foundational Structure (Enhancement of Foundation)

Integrating the principles of adult learning theory, organisational learning theory and open systems theory into the foundation of the PFLEx 1 Model ensures that these principles influence activities across the entire model, and not just the instructional design and development phase, as was the case in PFLEx 0. It is worth reiterating that these theoretical frameworks are foundational to the PFLEx Model because

- the inclusion of *adult learning principles* allows the L&D Leaders to tailor learning initiatives to the workforce's unique needs, enhancing employee engagement and knowledge usage
- the inclusion of *organisational learning principles* facilitates systematic knowledge transfer, knowledge capture and integration of lessons learned from mistakes into practice
- the inclusion of *open systems principles* provides a framework for understanding organisational interconnectedness, encouraging a holistic problem-solving approach that addresses mistakes not in isolation but by examining systemic factors, fostering a more effective learning process across the organisation

These foundational learning principles enhance communication between individuals and teams within the organisation, promoting open discussions about insights from mistakes, fostering continuous improvement and reducing risks to patient safety.

Additionally, they contribute to the long-term sustainability of an organisation's learning initiatives.

7.3.2 Establishment of a Robust Foundation in Leader Sponsorship (Enhancement of Step 2)

The establishment of robust leader sponsorship provides clear direction and purpose for learning initiatives (Whitten, 2002). Leaders can play a pivotal role in ensuring that learning efforts align with strategic goals and patient-focused outcomes. When leaders actively support and endorse patient-focused learning, it fosters a strategic approach to continuous improvement and instils a mindset that values learning and growth within the organisation.

7.3.3 Embedding Enabling Behaviours (Enhancement of Step 4)

Embedding the enabling behaviours for learning excellence (Step 4) into all the activities across the PFLEx Model is a novel feature of the model, focusing L&D programmes not just on learning objectives and outcomes, but also on the behaviours that will enable and sustain learning. Introducing the enabling behaviours represents a paradigm shift that can transform L&D programmes from traditional compliance-focused training exercises towards a culture of patient-focused learning excellence. The enabling behaviours identified from the Company A case study are shown in Figure 7.3.

Figure 7.3 Enabling behaviours supporting a patient-focused learning excellence culture

Pivoting from examining the "barriers to learning" to a focus on enabling behaviours is a crucial aspect of the revised PFLEx model. The enabling behaviours selected encourage open communication and knowledge sharing; individuals feel more comfortable discussing mistakes and lessons learned, facilitating a transparent exchange of information that benefits the entire organisation and contributes to building resilience in the face of challenges. Embedding these behaviours into the everyday workflows can turn each task into a learning opportunity and remove the reliance on formal training programmes as the main currency of learning.

How these enabling behaviours can help organisations to learn from their mistakes and improve operational performance are described in Table 7.1, below.

Enabling Behaviour	How Does this Behaviour Enable Organisations to Learn from Their Mistakes and Improve Overall Operational Performance?
Willingness to unlearn to relearn	This ability to unlearn what we consider accurate and rethink our position or understanding of the world can be challenging for individuals. Overcoming this barrier requires learning leaders who create the environment for this to happen and who demonstrate their willingness to relearn through their own actions. The capability to listen to new ideas and to be vulnerable by asking questions and seeking to understand is central to cultures that innovate and challenge the status quo (Grant, 2021a).
Embrace uncertainty from change	Staying firmly attached to what has been deemed secure leads people to falsely believe they are in a state of control (Chodron, 1996). Chodron encourages us to learn to stay within the chaos of change and to use this as a source of inspiration. Biopharmaceutical organisations that maintain control under the guise of compliance are missing opportunities to implement new processes and procedures and embrace new ways of working.
Employ systems thinking	Events rarely occur linearly, so defining the system in terms of intrinsic and extrinsic factors can help to identify root causes when failures present, and can also help to better predict potential issues within the system (Rutherford, 2019). Systems thinking should be a required skill to reduce risks in meeting patient demand and building resilience in supply chains.
Create a healthy risk culture	Transforming organisational culture is difficult (Ballman et al., 2017). The issue of "quality culture" has been much discussed only in recent years, including the need to eliminate blame cultures based on fear and to promote psychological safety to reveal failures and errors. It is essential to value and reward risk curiosity to change the perception and reframe how risk is viewed. Implementing a proactive risk culture that focuses on prevention rather than a "detect and correct" cycle will help to develop the sustaining behaviours needed.
Reduce bias in thinking	For complex problems, it is useful to identify opportunities to slow our thinking down and avoid making "quick" decisions where a mistake may be likely (Kahneman, 2013). Enhancing awareness about bias can improve decision making, creating an environment where team members feel sufficiently safe to discuss potential biases and seek strategies to counteract these influences.
Reward vulnerability	When vulnerability is accepted, we are open to thinking about creative solutions and listening to many ideas that directly correlate (Brown, 2018). When people are vulnerable, it shows a desire to understand. Asking questions that come from a place of seeking to understand encourages teams to explain in detail how or why something is designed to do what it does. During these explanations, the difficulties, gaps and risks in the design can be discovered. Brown describes vulnerability as the willingness

Enabling Behaviour	How Does this Behaviour Enable Organisations to Learn from Their Mistakes and Improve Overall Operational Performance?
	to show up and be seen without a guarantee of outcome and as the birthplace of innovation, creativity and change (Brown, 2018).
Ensure psychological safety	When a culture of psychological safety does not exist, employees will withhold their feedback and not provide new ideas for fear of offending management. Embracing psychological safety leads to innovation, critical thinking, problem solving and learning environments (Edmondson, 2018). People must be allowed to share ideas in their early thinking stage, to ask unexpected questions and to brainstorm ideas. This ability creates a culture in which minor mistakes do not result in punitive action and where actual mistakes are treated as learning opportunities.
Provide strong sponsorship	Powerful sponsorship can be defined as involving attributes such as clearly understanding the problem to be solved, building the right team with the right SMEs, holding a team accountable for results and advocating, coaching and influencing where necessary (Whitten, 2002). A model where managers give support and guidance rather than instructions results in employees learning how to adapt to changing environments to free up innovative ideas and new energy (Ibarra & Scoular, 2019). A sponsorship style that embraces coaching results in encouraging the most creative and novel ideas for problem solving.
Value patience	Patience in leadership has been shown to drive the success of both (a) futurist behaviour leaders (task-oriented leaders) and (b) facilitator behaviour leaders (relationship-oriented). When patience was measured between these two types of leaders, success was amplified. Patience allowed the *futurist* to take the time to explain the vision and onboard supporters, and it allowed the *facilitator* to encourage collaboration when team members face challenges (Sluss, 2020).

Table 7.1: How enabling behaviours can help organisations to learn from their mistakes and improve operational performance

7.3.4 The Addition of the Experiential Learning Cycle to the Model (Enhancement of Step 9)

Integrating an experiential learning cycle into the PFLEx 1 Model (Step 9) builds in opportunities for learners to experience, reflect, think, develop theories and practise active experimentation. These design and deployment features were shown to have a profound impact on organisational performance during the Company A case study. The use of an experiential learning cycle encourages a continuous improvement mindset where positive and negative experiences are viewed as opportunities for reflection,

learning and refinement. The cycle becomes an iterative process that contributes to ongoing enhancements in organisational performance. The cycle is based on a 70:20:10 learning principle (Training Industry, 2023), where 10% of knowledge transfer is achieved through formal training, 70% of skills and ability development is achieved through the learner actually "doing" the task and the final 20% of understanding and mastery of that task is achieved through reflection and coaching. See Figure 7.4 for an excerpt from the PFLEx 1 Model showing how a learner can develop a new mindset and attitude by participation in a new experience, undertaking new actions and reflecting with peers and coaches on the results achieved.

Figure 7.4: Experiential learning cycle (Step 9 of PFLEx 1 Model)

The active experimentation (doing) phase of the experiential cycle provides a structured approach to learning from mistakes. The reflective aspect of the experiential learning cycle promotes adaptability, which results in organisations becoming adept at adjusting strategies and practices based on insights gained from recent and past experiences. Instead of viewing errors as failures, teams view them as valuable sources of learning.

This perspective shift encourages a proactive response to challenges, minimising the likelihood of repeatedly experiencing the same mistakes. This aspect of the PFLEx Model also offers the opportunity to integrate learnings from health authority inspections, internal and customer audits, industry publications and best practice guidance into the learning experience, influencing how knowledge is managed within a company.

The experiential learning cycle encourages collaborative team learning. Teams engage in collective reflection and experimentation, fostering a sense of shared responsibility for organisational performance. This collaborative approach strengthens team dynamics and communication, contributing to more resilient organisations. Teams also become adept at problem-solving by honing skills in relation to identifying issues, developing hypotheses, testing solutions and implementing changes. Integrating an experiential learning cycle in the PFLEx1 Model cultivates a culture that is adaptive, patient-centric and focused on continuous improvement, promoting an environment where individuals are eager to seek, share and apply knowledge.

7.3.5 Integrated Proactive Performance Management Tools (Enhancement of Step 10)

A significant benefit of incorporating a range of detailed instructional design and development tools into the PFLEx model (Steps 5-8) is that it provides a systematic process for identifying the business need and matching the L&D interventions to meet that need. This enables teams to track the effectiveness of these interventions though the use of purposefully designed performance management tools (Step 10), which are utilised to capture relevant real-time and historical data to identify trends and patterns and to confirm that the targeted business benefits have been achieved. The integrated

performance management tools include a range of leading metrics, proactive use of GEMBA practices and reward and recognition practices to reinforce enabling behaviours. These performance management practices ensure that organisations are consistently aware of their performance status for prompt adjustment. This proactive approach allows for more efficient resource allocation, directing resources to areas that directly impact on patient safety and organisational effectiveness. Additionally, the tools contribute to strategic planning by providing a comprehensive view of organisational performance, aiding the processors of goal setting and resource allocation for long-term improvements.

Beyond operational benefits, integrating proactive performance management tools fosters a mindset of accountability and a cultural shift towards proactivity within the organisation. Teams adapt to identifying and addressing potential issues, creating a culture of continuous improvement and vigilance. Moreover, these tools contribute to a structured learning process, allowing organisations to analyse root causes of performance deviations and implement targeted improvements.

7.6 Testing the PFLEx1 Model with a Focus Group

In the ongoing refinement of the model, an industry expert focus group was assembled to gather feedback on the newly evolved PFLEx1. This step was essential to collect diverse perspectives and real-world experiences beyond the case study. The focus group provided a forum for industry stakeholders to assess the model's effectiveness, capture observations and collaboratively identify potential improvement areas. The focus group

activity aimed to validate the practical applicability of PFLEx1 within the organisational context and served as a crucial platform for refining the model and ensuring its alignment with the evolving needs of practitioners. The focus group design, feedback and incorporation of the insights gained for incorporation into the final model are discussed in Chapter 8.

CHAPTER 8: TRANSFORMATION TO THE FINAL PFLEX2 MODEL

This chapter describes the feedback from the industry expert focus group and the refinement of the PFLEx1 model to the final PFLEx2 model. This chapter summarises insights gained from the Phase IV research activities, the expert Focus Group. See highlighted step in Figure 8.1 below.

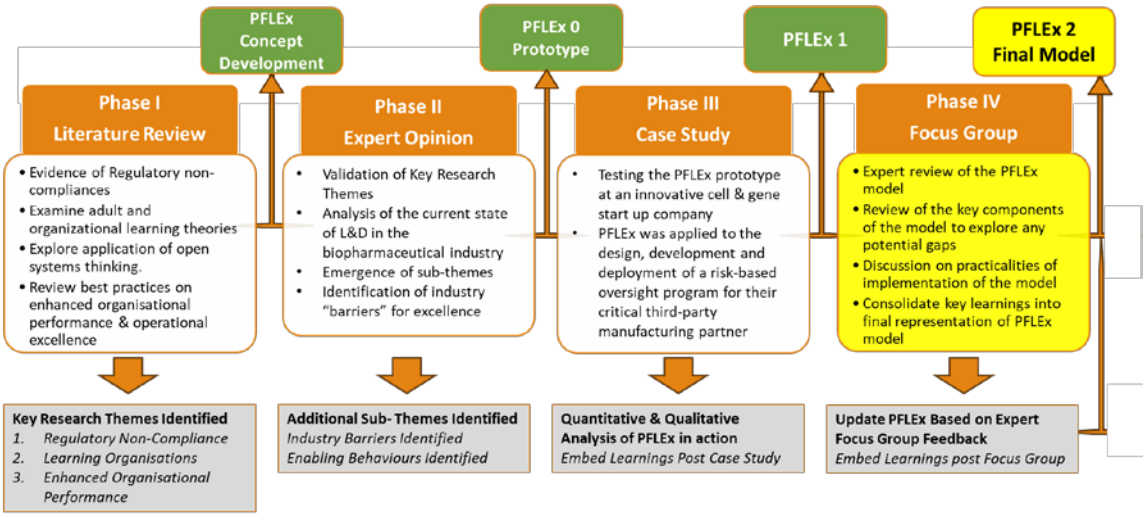


Figure 8.1: Evolution of the design and development of the Patient-focused Learning Excellence PFLEx Model across Research Study Phases I-IV

8.1 Focus Group Purpose

The purpose of the focus group was to obtain a critical evaluation of the PFLEx1 Model by a group of industry experts concerning the operationalisation of the model within biopharmaceutical organisations. The feedback provided by this group was integrated into a final model (PFLEx2).

8.2 Methodology and Structure of the Focus Group

The research methodology selected for this phase of the study utilised a focus group, which is a well-established qualitative research method leveraged in the social and behavioural sciences (Nyumba et al., 2018). Focus groups involve purposive sampling of a small group of participants known for their expertise and willingness to engage in open discussions on a specific topic, guided by a skilled moderator (Bloor et al., 2001). The purpose of a focus group is to extract in-depth insights from participants, exploring their personal experiences, beliefs, perceptions and attitudes, thus offering a rich understanding of the research subject (Myers & Macnachten, 1999). Utilising open-ended questions, this method encourages diverse responses, facilitates an examination of decision-making processes and takes into account situational factors (Gundumogula, 2020). This research methodology was chosen as it offers a comprehensive exploration of human behaviour, attitudes and decision-making processes, which was important in obtaining the feedback for the implementation of a learning-focused model across the organisation.

Participants were selected using purposive sampling, based on their knowledge of the topic, willingness to share their views and their ability to communicate thoughtfully (Bloor et al., 2001). This approach was aimed at selecting a group with a depth of understanding about the learning environment in the pharmaceutical industry.

Expertise	Job Title	Academic Background
QRM/KM/PQS	Head of PRST	Professor
QRM/KM/Quality Culture	CEO/Consultant	PhD
QRM/KM/PQS	Principal Consultant	PhD Student
KM/PQS	Head of KM Center of Excellence	PhD

Expertise	Job Title	Academic Background
QRM/KM	CEO/Consultant	Senior Research Fellow
Learning and Development	Learning Leader	Master's Degree in Human Resources
PQS/Quality Culture	SVP, Pharm Dev and Manufacturing	PhD
QRM/KM/PQS	Executive Director, Product Management & Dev Operations	PhD

Table 8.1: Focus group participants

The members of the focus group were provided with a pre-read document presenting the PFLEx1 Model and the discussion questions in advance of the session, to ensure rich dialogue within the time provided. During an opening presentation, the focus group facilitator provided an overview of the PFLEx1 Model, with the following questions for the participants to discuss:

- Can the patient-focused Learning Excellence (PFLEx1) Model be effectively integrated into the existing learning infrastructure within a biopharmaceutical company?
- What needs to be improved, and what needs to be sustained within the model? Why? Provide suggestions for improvements.
- How can the model be improved to enable organisations to achieve sustained commitment from leadership in supporting patient-focused learning excellence programmes?

The presentation slides used to facilitate the focus group activity can be found in Volume 2.

8.3 Data Analysis and Summary of Outcomes

The discussion points provided by the focus group participants were collected into notes that were then sorted into themes by the researcher using Braun and Clarke's thematic analysis framework discussed in Chapter 3. The detailed notes and coding can be found in Volume 3. The following themes for improvement to the model were collected as an output of the focus group activity.

Improvement Theme	Supporting Discussion Points
The PFLEx1 Model needs to be inclusive and holistic across the learning landscape of a company	- Cannot be limited to implementation in the Quality organisation - Needs to incorporate EH&S, strategy, HR, learning and development courses, etc. - Who will own the model? - Consider all companies across the pharma industry, including generics, to be a part of this model
Flexibility should be incorporated into the PFLEx1 Model to enable organisations of various maturities to adopt it	- Remove the numbers and rigidity in the structure of the model and convert it into a flow diagram - Need to consider how aging facilities and organisations can adapt to this model - Consider start-up environments and how they can use this model - Consider the scalability of the model - Regulatory intelligence, audit findings and change management activities; events from the PQS need to feed into this process to sustain knowledge management
The patient should be an input for the process. The output of the process should improve the company's organisational performance, ultimately benefitting the patient	- A patient focus needs to be driving the process, and risks to the patient need to be key inputs - The organisational performance improvement needs to benefit not just the patient's therapeutic experience, but the overall patient experience (human experience) - Must tie the purpose of this model and to those interacting in the model, to serving the patient (human) experience
The model must be actionable	- Define actions for what it means to focus on the patient and to be patient-centric

Improvement Theme	Supporting Discussion Points
	- Tie this model to an assessment so that companies can see some of these key inputs are already in place and others may need to be implemented - Consider the motivation of employees in adopting the changes proposed in this model

Table 8.2: Improvement themes collected from the focus group

The focus group agreed during the session that the PFLEx1 Model was comprehensive and did not have any significant gaps or missing components. The model was viewed as beneficial and capable of operationalisation following the integration of the expert feedback provided. The revised PFLEx2 Model is summarised in the next section.

8.4 Introduction of PFLEx2 Model and Overview of Revisions

The focus group highlighted several commendable aspects of the model that could enhance organisational learning and underscore the importance of learning from mistakes. Simultaneously, the group identified areas requiring improvement, with proposed modifications aimed at optimising the model for ease of implementation. Notably, the focus group suggested a reframing of the visual image depicting the model to position the *patient experience* as the input to the model, with the *performance outcomes* positioned as the output of the model. The experts suggested that the model should facilitate a flexible application approach, to allow for companies which are less mature in their development as well as those more mature organisations. Lastly, the experts noted that the model must be actionable.

Various themes surfaced throughout the focus group session, offering valuable insights into potential enhancements for the PFLEx1 Model. Subsequently, the researcher

considered each idea for improvement and modified the existing model, incorporating the innovations derived from the focus group discussions. The revised PFLEx 2 Model is presented in Figure 8.2.

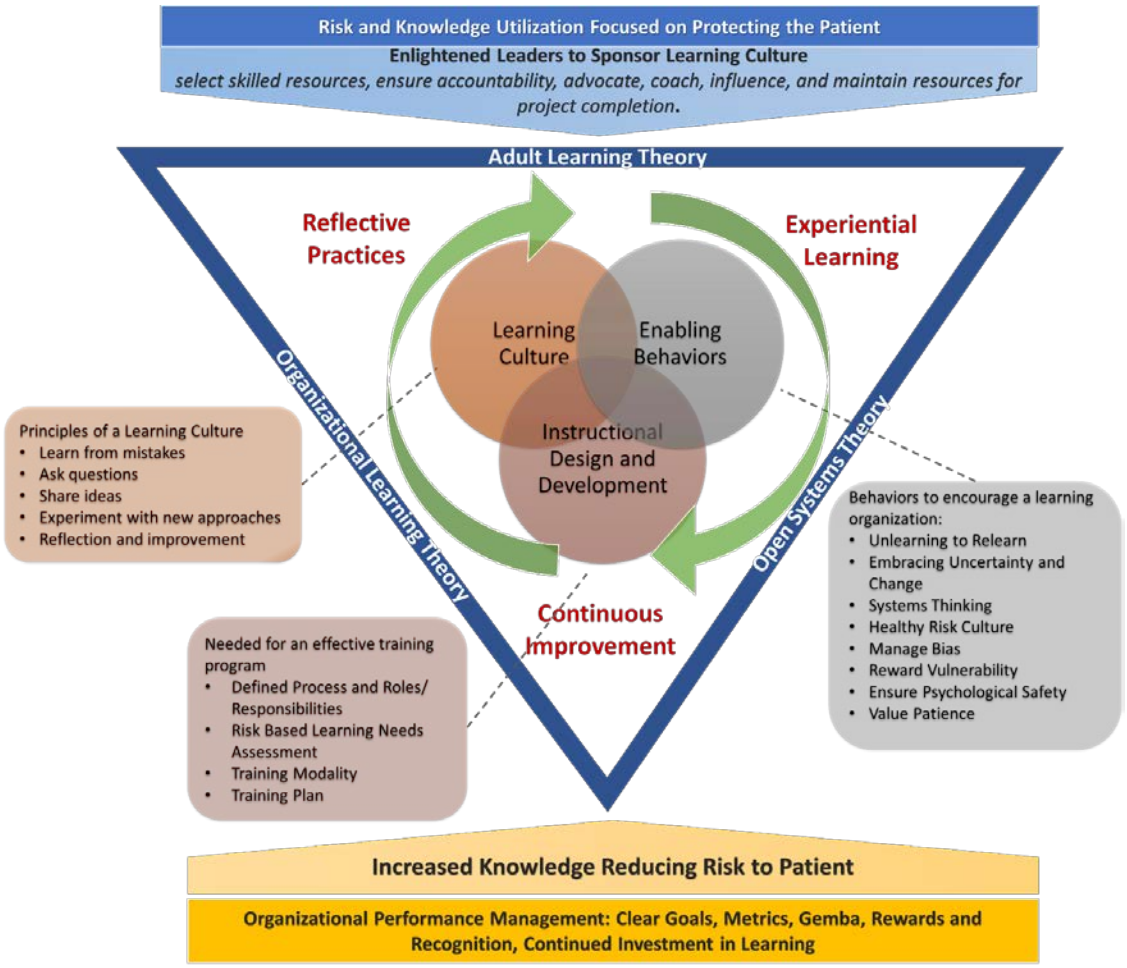


Figure 8.2: Revised Patient-focused Learning Excellence FLEx2 Model

The rationales for the PFLEx 2 Model enhancements are summarised in Table 8.3.

Improvement Idea	Integration into PFLEx2
The PFLEx1 Model needs to be inclusive and holistic across the	Ensure a holistic organisational learning approach by avoiding an exclusive focus on specific departments or roles. The model should be accompanied by enhanced stakeholder involvement in

Improvement Idea	Integration into PFLEx2
learning landscape of a company	implementation to ensure functional areas' needs are met. Customisation options can be implemented for different departments or teams, so that the model will remain flexible and adaptable to the diverse requirements of various organisational units. The continuous improvement cycle and reflective practices are built to ensure constant revisiting of the culture, behaviours and instructional design and development. Hence, as the company landscape changes, these will be revisited to ensure they continue to meet the business's needs.
Flexibility should be incorporated into the PFLEx1 Model to enable organisations at various maturities to adopt it.	Enable flexibility for organisations at different maturities by constructing an adaptive framework that scales across various developmental stages of a programme, allowing organisations to selectively adopt model elements based on their specific needs and maturity levels. Future work on the model should include comprehensive guidance tailored to different organisational maturities for effective model implementation. Develop scalable learning paths and continuous improvement mechanisms to accommodate organisations' diverse capabilities and goals. In addition, more case studies showcasing successful PFLEx1 implementations in organisations at various maturities could serve as practical implementation examples.
The patient should be an input in the process. The output of the process should improve the company's organisational performance, ultimately benefitting the patient.	Incorporate a patient-centric approach to ensure the patients' needs are fundamentally linked to the organisational learning and improvement processes. The model must be aligned with outcome-focused metrics in an organisation that measure both internal efficiency gains and tangible benefits to patient well-being. The organisation must implement methods for measuring the effectiveness and direct impact of the targeted organisational changes on patient outcomes, fostering a culture where improvements in organisational performance ultimately benefit the patients.
The model must be actionable.	The new PFLEx2 Model should have an action plan and assessment for implementation. It should encourage organisations to engage in pilot programmes, establish measurable milestones and offer ongoing support mechanisms for expert consultations and shared best practices. Organisations can integrate their own accompanying toolkits and resources to design training programmes that educate organisational leaders and staff on practical implementation of the model. The model must seamlessly integrate with existing processes to establish feedback loops for organisations to provide input on its effectiveness and suggest improvements. The model offers a practical and dynamic guide through these improvements, empowering organisations to effectively implement patient-focused learning and enhance overall organisational performance.

Table 8.3: Improvement ideas from PFLEx1 and the transition to PFLEx2

8.4.1 Reframing the Visual Model From an "Improvement House" Design to a "3-dimensional Learning" Flow Diagram

The improved PFLEx2 Model incorporates a structured patient-centric approach on the input side of the model, positioning risk and knowledge of the patient as central to the organisational learning and improvement processes. On the output side of the model, outcome-focused metrics measure the effectiveness of the targeted L&D improvement at delivering improved organisational performance. The model fosters a learning culture through selected enabling behaviours, which are purposefully embedded into the instructional design and development processes using an experiential learning cycle approach. This 70:20:10 cycle facilitates three dimensions of learning ("Knowing, Doing and Being"), enabling learners to gain new knowledge, skills and abilities through practical "learn-by-doing" deployment methods, with reflective practices built in to feedback ideas for continuous improvement. This enables the PFLEX Model to act as a dynamic guide, empowering organisations to improve organisational performance.

8.5 Implementing the PFLEx Model: A User Guide for Learning from Mistakes to Improve Organisational Performance

After synthesising the findings of Chapters 2, 3 and 4, re-evaluating the Chapter 6 case study, feedback from the focus group and integrating enhancements resulting in the PFLEx2 Model, an *Implementation Guide* with action plans for each process delineated

in the model was developed as an initial “how to” user guide. This user guide is provided in Appendix 2.

8.6 Summary

The PFLEx2 Model offers a transformative approach beyond the compliance-focused training programmes traditionally found in the biopharmaceutical industry. By integrating the theoretical frameworks, enabling behaviours and proactive performance management tools, the model not only addresses the shortcomings of existing training programmes in the industry, but also emphasises the importance of building capabilities crucial for detecting and addressing vulnerabilities. This strategic focus, coupled with a commitment to the continuous improvement culture embedded in the model, supports the development of more mature pharmaceutical quality systems. Such mature systems can significantly reduce the risk of drug shortages, supporting the broader goal of assuring patient safety and promoting operational excellence within the biopharmaceutical industry.

The PFLEx2 Model, with its patient-focused learning framework, emerges as a comprehensive yet practical framework to navigate challenges, minimise risks and foster a resilient and adaptive biopharmaceutical ecosystem that can learn from its mistakes, contributing to a reduction in recalls and quality defects. The researcher acknowledges that the model is academically rigorous, particularly through the embedding of the theoretical frameworks. In Chapter 10, the researcher suggests future work to simplify the model for practical application, in order to make it accessible to companies with

varying levels of understanding and maturity, ensuring they can transition from compliance-focused training programmes to learning excellence programmes. The goal is to positively enhance their overall experience with the model without being intimidated by academic language.

CHAPTER 9: OUTPUTS AND IMPACT OF THE RESEARCH

The purpose of this chapter is to summarise the outcomes and impact of this research study. As a reminder, the problem statements leading to this research were grounded in some key industry data:

- The US FDA analysed 163 drugs that were in short supply in the five-year period between 2013 and 2017; 62% were associated with repeated manufacturing or product quality problems.
- US FDA Drug Manufacturer Inspection Observations from 2013-2020 indicated a similar trend of repeated failure events presented in the year-on-year data.

The data indicated that despite the many scientific, technological and economic advances over the past several years in a well-funded, high-revenue industry operated by highly qualified personnel, the opportunity to build the organisational capability to learn from mistakes and continuously improve performance outcomes has not been fully realised. This is the conclusion drawn by the *US FDA 2019 Drug Shortages Report*, which noted that an organisation that builds a foundation of basic cGMP requirements coupled with a lack of continual improvement will result in drug shortages (US FDA, 2019). However, those organisations that strive to build capability to detect and address vulnerabilities, coupled with a continuous improvement culture, facilitate a mature quality system that significantly reduces the risk of drug shortages (US FDA, 2019). This is a point highlighted by Fugate:

> *Right now, it is saying that we are doing the same things wrong, year after year. We can improve, and we must. It just takes time to mentor and develop the workforce to resolve the root causes of these observations. (Fugate, 2018)*

The biopharmaceutical industry is not learning from its mistakes, and this lack of responsiveness to learning presents risks to patients and has negative consequences for organisational performance. The researcher was introduced to the problem of drug shortages as a "wicked problem", defined as "a problem highly resistant to solutions" (Rittel & Webber, 1973). Ramnarine has found that wicked problems are highly complex, stubborn problems that cannot be well-defined, do not have easily defined solutions and cannot be solved by any one group of people (Ramnarine, 2021).

This researcher chose to pursue one aspect of this "wicked problem" of drug shortages, by evaluating the application of a learning model for improving organisational performance. The researcher acknowledges that there are many other possible solutions and stakeholders that together can deliver improvements to impact this challenge faced by the industry. In summary, this research explored the theoretical frameworks of *adult learning theory*, *organisational learning theory* and *open systems theory* to develop a **Patient-focused Learning Excellence Model** using a mixed methods research methodology which included the following:

- a detailed literature review to draw upon the existing body of knowledge
- elicitation of a range of expert opinions to better understand the problem under review

- an evaluation of current US biopharmaceutical regulatory surveillance and supply chain performance data to determine the connection between identified potential patient risks and the associated lack of organisational capability
- an industry-based case study within the biopharmaceutical industry
- a focus group that provided feedback to the learning model in relation to its practicality and effectiveness

The researcher focused on building a model that could move the biopharmaceutical industry from providing training and education for personnel based on fulfilling regulatory compliance requirements towards a patient-focused learning excellence programme focused on learning from mistakes to reduce risk and improve overall operational performance. This transformation from “two-dimensional” basic training programmes which are often primarily focused on documenting successful completions of “read-and-understand” procedures, towards “three-dimensional” learning excellence programmes, which are carefully designed with inputs concentrated on patient needs, enabling behaviours and experiential learning cycles, led the researcher an ambition of facilitating the transformation from 2D training to a 3D patient-focused learning excellence model within the biopharmaceutical industry.

The illustration below outlines the progression of this research, showcasing the evolution of PFLEx Model designs as the study transitioned from exploring learning theories to conducting expert opinion research, case studies and focus group research.

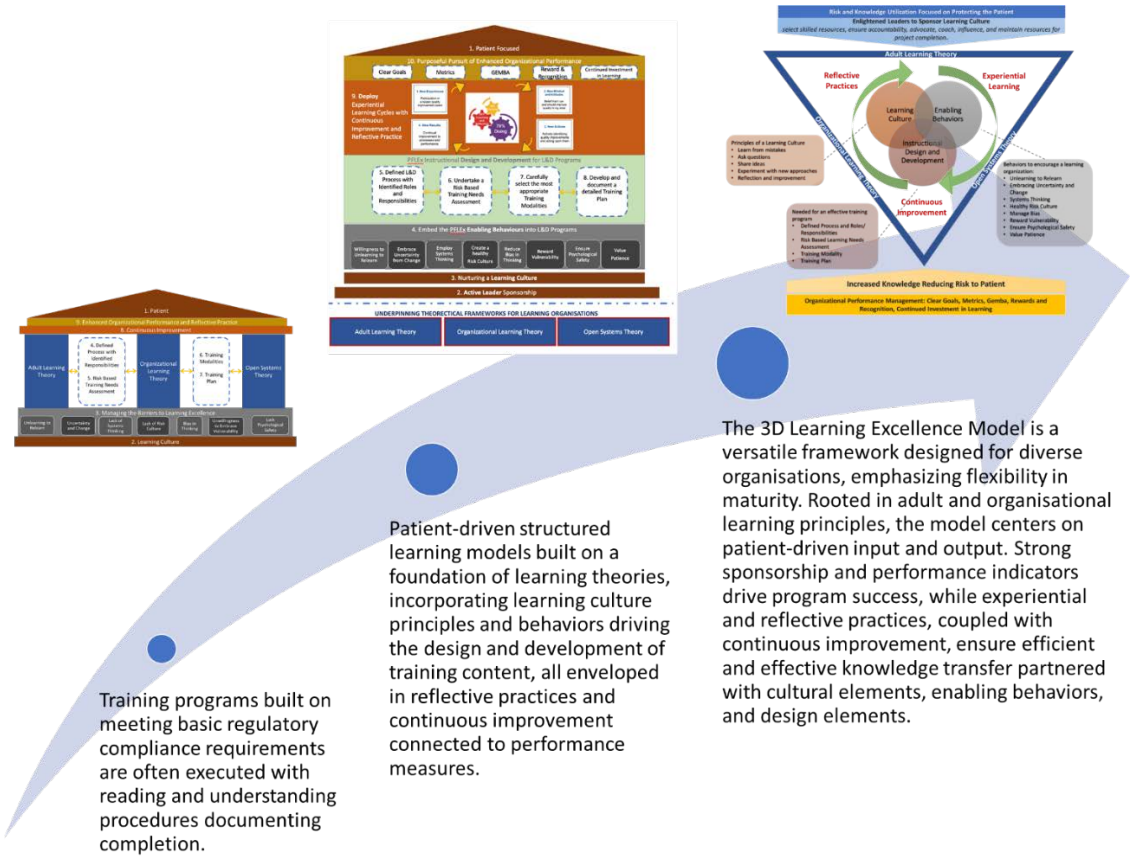


Figure 9.1: Transforming from a 2D training programme to a 3D Patient-focused Learning Excellence Model

9.1. Research Outputs

As a result of this research journey, four key research outputs were developed:

1. Defining what a *Learning Culture* for the Biopharmaceutical Industry entails
2. Determining the *enabling behaviours* necessary for an organisation that wants to learn from mistakes and improve organisational performance
3. The Adult Learner Effective cGMP Training Tool (ALECT) for the purposeful instructional design and development of L&D programmes
4. The Patient-focused Learning Excellence Model (PFLEx)

9.1.1 Output #1: Defining a Learning Culture for the Biopharmaceutical Industry

The researcher used the research collected during the literature review to assess the works of Schein, Schon, Edmondson, Garvin and others to identify the essential characteristics of a *learning culture*. It became clear that learning organisations are skilled at five main activities:

1. systematic problem solving
2. experimentation with new approaches
3. learning from their own experience and history
4. learning from the experiences and best practice of others
5. transferring knowledge quickly and efficiently throughout the organisation

These five skills are in alignment with the FDA comment in the Drug Shortages Report that organisations which strive to build the capability to detect and address vulnerabilities, coupled with a continuous improvement culture, facilitate a mature quality system that significantly reduces the risk of drug shortages (US FDA, 2019). Tying these five skills to the triangulation of the research theoretical framework, defined in Chapter 3, provided the outline for the PFLEx0 Model evaluated the case study research conducted in Chapter 6. Defining the key skills necessary for a *learning culture* to flourish allowed the researcher to link the behaviours needed to improve organisational performance during the 15-month case study. The output of the case study research identified the behaviours that can enable the biopharmaceutical organisation to fully adopt learning organisation concepts.

9.1.2 Output #2: Determining the Enabling Behaviours of a Learning Organisation

Themes identified during the Phase II qualitative analysis and Phase III case study research identified potential barriers to learning within organisations. These barriers counteract continuous improvement and result in organisations that do not learn from their mistakes, with repeated failures that contribute to quality defects, product recalls and even drug shortages. The case study research underscored the real challenge of attempting to implement the key learning principles from *adult* learning theory, organisational learning theory and open systems theory without understanding the malign influence of these and addressing the identified barriers. Recognising these barriers allowed the researcher to identify the enabling behaviours necessary to nurture a culture of learning. This consists of willingness to unlearn and relearn, embracing

uncertainty, employing systems thinking, fostering a healthy risk culture, reducing bias, rewarding vulnerability, ensuring psychological safety and valuing patience. Each of these serve as countermeasures to the identified barriers, facilitating the growth of a learning organisation.

9.1.3 Output #3: The Adult Learner Effective cGMP Training (ALECT) Tool

The ALECT instructional design and development tool offers a structured process for instructor and course designers to incorporate the guiding principles from the theoretical frameworks with an experiential learning cycle deployment approach when creating learning events. Emphasis is placed on capturing the creative thinking needed when designing impactful learning. The ALECT tool can also be integrated with the risk-based training needs assessment. The ALECT tool identifies learning needs, intervention training and gaps for the purpose of aligning the curriculum with guiding learning principles. ALECT measures effectiveness through productivity, efficiency, employee satisfaction and knowledge retention indicators. The experiential learning cycle fosters reflective practices tied to continuous improvement. ALECT also provides feedback on the effectiveness of learning initiatives, assessing their impact on knowledge transfer, skill development and application. This tool identifies the organisation's strengths and areas for improvement, guiding future changes.

9.1.4 Output #4: 3D Patient-focused Learning Excellence Model

The following elements were considered in the development of the Patient-focused Learning Excellence (PFLEx) Model:

- Expert opinion research identified industry barriers to embracing a culture of learning in Chapter 4; this finding was enhanced with data incorporated from the case study research in Chapter 6.

- Case study research outputs that developed and deployed a new business process and an associated training intervention, as detailed in Chapter 6.

- Focus group research that provided critical feedback for the implementation of the model and direct improvements needed to operationalise the model within organisations.

This led to the evolution of the final PFLEx Model depicted in Figure 9.2.

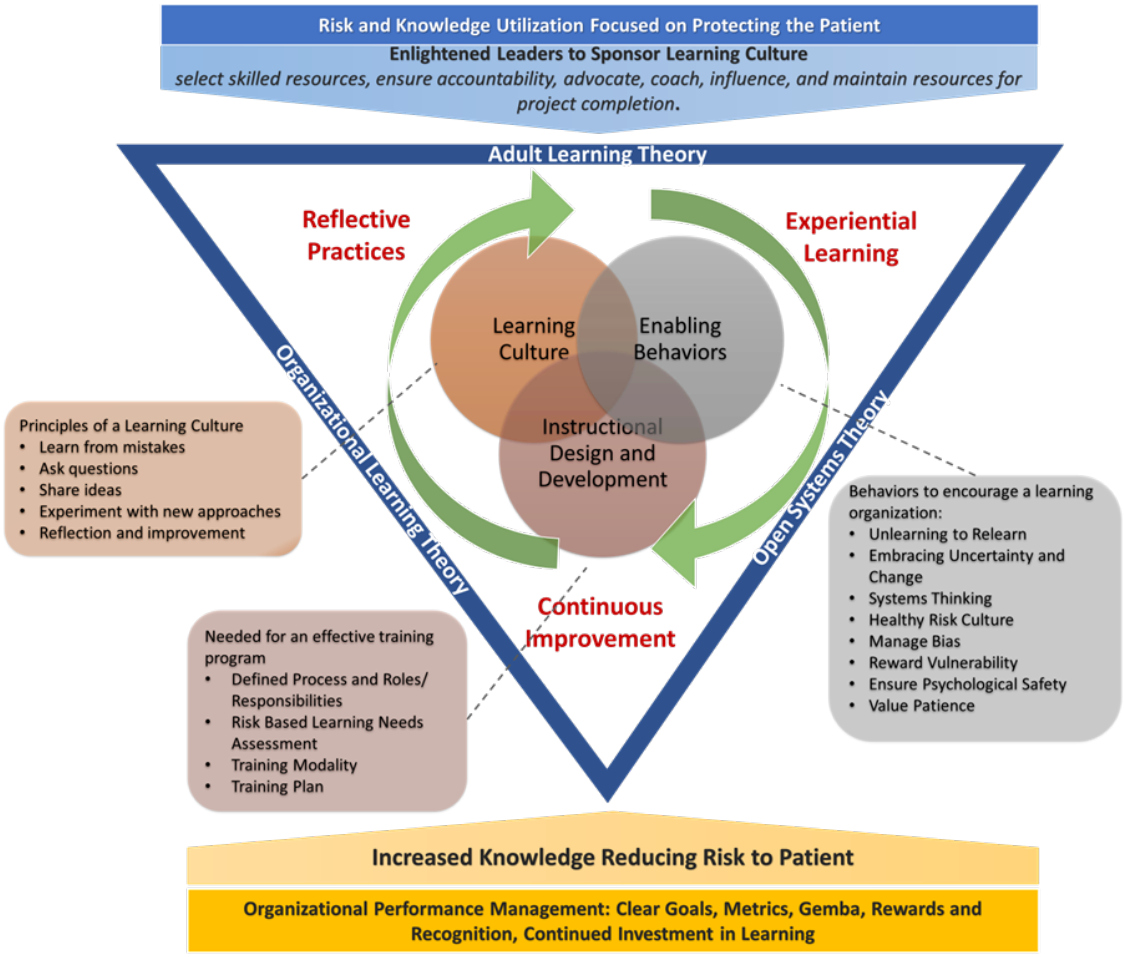


Figure 9.2: 3D Patient-focused Learning Excellence Model (main research output)

As detailed in Chapter 8, this Patient-focused Learning Excellence Model reduces the risk to the patient by enabling a culture that learns from mistakes and improves organisational performance, helping to reduce recurring failures that lead to quality defects, product recalls and drug shortages. This model strategically manages risks and employs comprehensive knowledge to prioritise patient safety.

Enlightened leaders play a pivotal role in sponsoring a culture of learning. Through specific skills and behaviours, these leaders can prioritise learning, communicate its importance and foster a safe environment for questioning, experimentation and continuous improvement. Enlightened leaders promote a mindset of learning from both successes and failures, ensuring a culture of continuous learning and improvement. In summary, the model is a transformative approach that fosters a continuous improvement culture and contributes to a resilient and adaptive biopharmaceutical ecosystem.

9.2 Summary of Research Impact

The research discussed in this thesis goes beyond academia, positively impacting on industry practices, policymaking, and healthcare. By examining critical issues in the biopharmaceutical industry, such as drug shortages and quality defects, this study offers insights which are valuable to patients, regulatory agencies, biopharmaceutical companies and their employees. The research aims to improve patient safety, organisational performance and learning strategies within the industry through its findings. This section highlights how the research outcomes, if implemented, can positively re-shape biopharmaceutical practices and employee engagement, enhance patient care and improve relationships with health authorities. Table 9.1 maps the research outputs to the beneficiaries of the outputs and the anticipated positive impacts of their implementation.

Research Output	Anticipated Positive Impact of Research Output			
	Patient	**Biopharmaceutical Company**	**Biopharmaceutical Employee**	**Regulatory Health Authority**
Defining what a learning culture for the biopharmaceutical industry entails	• Reduction in drug shortages and quality defects, providing a reliable drug supply as organisations learn from mistakes and implement improvements. • Transferring knowledge quickly and efficiently throughout the organisation allows organisations to implement solutions more rapidly, leading to improved patient outcomes.	• Addresses complex challenges more efficiently through systematic problem solving, leading to improved processes and outcomes. • Experimentation with new approaches allows for the exploration of innovative solutions and adaptation to changing market dynamics. • Learning from internal experiences and external best practices enables the company to effectively leverage its history and industry knowledge, leading to continuous improvement and competitive advantage. • The ability to transfer knowledge quickly and efficiently throughout the organisation ensures that insights and learning are disseminated across teams, facilitating collaboration and alignment toward common goals.	• Empowers employees to thrive in a dynamic and fast-paced industry by providing tools, resources and opportunities to learn, innovate, continuously improve and develop. • Enhances employees' professional capabilities. • Drives organisational growth and encourages employees to succeed by making meaningful contributions to the advancement of patient outcomes.	Views the company as • committed to quality and innovation • a partner due to its receptiveness to collaboration and knowledge-sharing initiatives • adaptive and resilient, crucial for navigating dynamic healthcare landscapes effectively • strong at attracting and retaining talent, showing stability within the company's organisation • a model of best practice, inspiring other companies to adopt similar approaches in the industry

Research Output	Anticipated Positive Impact of Research Output			
	Patient	**Biopharmaceutical Company**	**Biopharmaceutical Employee**	**Regulatory Health Authority**
Determining the enabling behaviours of a learning organisation	• Creates a pharmaceutical industry focused on continuous learning and innovation to improve patient-centric care. • Patients receive safer, more effective medications with their best interests in mind, ultimately leading to improved treatment outcomes and enhanced quality of life.	• Improves decision making, employee morale, productivity and patient outcomes regarding access to high-quality treatments. • Positions the company as a leader in the industry, capable of responding effectively to evolving challenges and opportunities in the dynamic pharma landscape.	• Encourages employees to abandon outdated practices and embrace new knowledge and skills. • Cultivates resilience and flexibility in employees, empowering them to confidently navigate change. • Viewing problems and opportunities from a systemic perspective, employees can identify interconnected factors and anticipate potential impacts. • Encourages employees to take calculated risks and learn from successes and failures. • By reducing bias, employees can make more informed and equitable choices, fostering a culture of fairness, respect and diversity within the workplace.	Views the company as • cultivating a culture of learning, innovation and excellence, which resonates positively with health authorities striving to improve patient safety. This alignment enhances the potential for collaboration and partnership between the company and the health authority, benefiting patients' advocacy and the broader healthcare community.

Research Output	Anticipated Positive Impact of Research Output			
	Patient	**Biopharmaceutical Company**	**Biopharmaceutical Employee**	**Regulatory Health Authority**
			• Creates an environment where employees feel safe to admit mistakes, ask for help and openly share ideas. • By ensuring psychological safety, employees can express themselves authentically, leading to higher levels of engagement, creativity and collaboration. • By valuing patience, employees can maintain focus, resilience and commitment to achieving meaningful goals and objectives over time.	

Research Output	Anticipated Positive Impact of Research Output			
	Patient	**Biopharmaceutical Company**	**Biopharmaceutical Employee**	**Regulatory Health Authority**
The Adult Learner Effective cGMP Training Tool (ALECT) for the purposeful instructional design and development of L&D programmes	• The enhanced effectiveness of training programmes within the biopharmaceutical industry ensures that personnel responsible for manufacturing medications receive comprehensive and accessible training on current good manufacturing practices (cGMP), reducing errors.	• Optimises training effectiveness. • Ensures compliance. • Reduces costs. • Fosters continuous improvement. • Enhances employee engagement. • Positions the company for long-term success in a competitive and dynamic business environment.	• Ensures that training programmes are engaging, relevant and practical, leading to a more enriching learning experience for employees. • Helps employees understand industry-specific requirements, resulting in employees feeling confident in their knowledge and skills, leading to improved job performance and productivity. • Promotes a culture of quality and compliance within the organisation by providing employees with the necessary knowledge and tools to adhere to guidance. • Saves time and resources for employees and the organisation by providing a structured framework for instructional design, ongoing evaluation and refinement of training	Views a company as • ensuring the training programme aligns with regulatory requirements • enhancing the effectiveness and engagement of training programmes, resulting in a more optimised learning experience for employees • demonstrating consistency and standardisation across training programmes, ensuring that all employees receive the same intensity of instruction and knowledge. This consistency is essential for maintaining uniformity in practices and processes.

Research Output	Anticipated Positive Impact of Research Output			
	Patient	**Biopharmaceutical Company**	**Biopharmaceutical Employee**	**Regulatory Health Authority**
			programmes based on feedback and performance data, enabling employees to improve their knowledge and skills continuously.	
The Patient-focused Learning Excellence Model (PFLEx)	• By embracing the PFLEx2 Model, companies prioritise patient needs and preferences throughout drug development. Involving patients in activities such as clinical trials, soliciting feedback on packaging and instructions, and tailoring treatments to individual patient needs ultimately lead to more personalised and effective care.	• Enhances organisational learning. • Improves problem solving and innovation. • Stronger risk management processes. • Increases collaboration and knowledge sharing. • Higher levels of employee engagement and satisfaction. • Improves overall organisational performance and competitive advantage.	• Encourages professional growth through ongoing learning and development opportunities. • Fosters creativity, empowering and rewarding employees to innovate and solve complex challenges effectively. • Encourages a supportive environment where employees feel comfortable taking risks, sharing ideas and learning from mistakes. • Promotes knowledge transfer, enabling employees to leverage organisational expertise and experiences for mutual growth.	Views a company as • enhancing patient-centric learning and continuous improvement, leading to improved practices, ultimately protecting patients • fostering a culture of compliance and quality improvement, aligning with regulatory standards • encouraging innovation within the company, allowing for the development and implementation of new solutions to address challenges effectively • facilitating efficient knowledge transfer throughout the organisation, enabling employees to stay informed about best practice

Research Output	Anticipated Positive Impact of Research Output			
	Patient	Biopharmaceutical Company	Biopharmaceutical Employee	Regulatory Health Authority
			• Enhances skills, competencies and job satisfaction for employee career progression and fulfilment within the organisation.	and emerging trends in the industry • promoting a learning and continuous improvement culture. The PFLEx2 model helps to build organisational resilience, enabling the company to navigate challenges and changes in the industry more effectively.

Table 9.1: Mapping of research outputs, beneficiaries and anticipated positive impact

The research outputs described represent an exploration of learning excellence within the biopharmaceutical industry, culminating in organisational changes, cultural behaviours, tools and a transformative model designed to drive positive change. The benefits of these research outputs extend to patients, the biopharmaceutical industry and regulatory health authorities. By implementing the ALECT tool, these companies can optimise their training programmes, ensuring compliance with regulatory standards while enhancing the employee learning experience. Health authorities can leverage the insights that the research outputs provide to foster collaboration with biopharmaceutical companies and promote best practice. Adopting the PFLEx Model within these organisations can lead to improved patient safety, enhanced regulatory compliance and greater organisational resilience in the face of evolving industry challenges. Biopharmaceutical employees, meanwhile, can expect to experience a more supportive and inclusive work environment, characterised by a willingness to unlearn and relearn, reduce bias and enhance psychological safety. Implementing the ALECT tool enables employees to access purposeful and effective training programmes, fostering professional development while ensuring alignment with organisational goals.

Patients are the ultimate beneficiaries of the research outputs. By implementing the PFLEx Model and optimising training programmes using the ALECT, patients can expect to receive safer and more effective treatments. The emphasis on continuous learning and innovation within biopharmaceutical companies ensures that products are developed and delivered with patient safety as a top priority. Additionally, by promoting a culture of learning excellence, organisations strive to learn from their mistakes, reduce

errors, improve organisational performance and enhance overall patient experiences. Ultimately, the anticipated positive impact of these research outputs ranges from improved patient care and regulatory compliance to enhanced employee engagement and organisational performance. By embracing a culture of learning excellence and leveraging innovative tools and models, stakeholders across the industry can contribute to the improvement of the patient experience.

CHAPTER 10: CONCLUSION AND AREAS FOR FUTURE WORK

The exploration undertaken in this research study has laid the foundation for future endeavours that apply and extend the insights gained from the 3D Patient-focused Learning Excellence Model. Future work should focus on further refinements, pragmatic in approach, that can be implemented by all companies, regardless of the business model and the product pipeline being developed. The following items are areas of future work to consider:

- **Extending the use of the 3D PFLEx Model by conducting research in industries beyond pharmaceuticals.** Future work could examine how the principles of patient-focused learning excellence can be adjusted and implemented in various organisational settings, identifying shared traits and distinctive challenges. It could seek to identify opportunities for cross-industry learning in order to gain valuable insights and elements of best practice, understanding how other industries approach organisational learning and using these insights to enhance and improve the 3D model.
- **Conducting an in-depth case study to dive deeper into the organisational performance analysis.** Future case study work could include refining metrics, exploring additional or refined approaches and behaviours, and utilising the data to comprehensively understand the influence of patient-focused learning excellence on improved organisational performance outcomes. It could develop and integrate performance metrics aligned with the 3D model into the

organisational strategy, offering business-aligned performance indicators to assess the effectiveness of the patient-focused learning excellence approach.

- **Exploring methods to embed patient-focused learning behaviours in enlightened leader competency models, addressing organisational challenges.** A focused effort could be placed on aligning leadership behaviours with the learning model principles and support by creating key behaviour indicators (KBIs) specific to leadership roles to gauge the effective integration of patient-focused learning behaviours into leadership development programmes. These KBIs will serve as benchmarks for evaluating leadership performance in fostering a culture of continuous improvement and patient-focused learning excellence.
- **Researching and developing detailed guidance for different organisational maturity levels, ensuring a seamless and effective implementation.** A focus on developing scalable learning paths and continuous improvement mechanisms which are adaptable to diverse organisational capabilities and goals to ensure successful implementation. Additionally, the user guidance should showcase practical examples of successful 3D model implementation through case studies in organisations at various maturity levels.

The future work outlined above is aimed at propelling the **3D Patient-focused Learning Excellence Model** beyond theoretical exploration, towards practical application, enabling organisations to embrace a culture of continuous improvement and patient-focused learning excellence.

10.1 Conclusion

In conclusion, a biopharmaceutical company's transition from a two-dimensional compliance-focused training model to a three-dimensional patient-focused learning excellence paradigm may not be the sole cure for complex issues such as drug shortages and recurring regulatory non-compliance. However, this transformation can significantly contribute to improved organisational performance factors such as reducing patient risks, decreased recurring incidences of failure by being open to learning from mistakes and improved ownership of learning through active sponsorship by enlightened leaders. Incorporating the guiding principles of *adult learning theory* enhances engagement and personalisation, fostering increased knowledge acquisition. Embracing *organisational learning theory* cultivates a continuous culture of learning, contributing to adaptability, knowledge sharing and innovation, while *open systems theory* aligns training with corporate strategy, enhancing organisational agility. Experiential learning cycles and reflective practices enrich programmes, developing practical skills and abilities through learning-by-doing.

The three-dimensional PFLEx Model strategically positions learning as a dynamic contributor to organisational resilience, agility, innovation and improved performance for biopharmaceutical organisations. It is hoped that this model can assist organisations with aspiring to and achieving this improvement, ensuring that patients can trust in the reliable supply of quality products.

REFERENCES

Abrams, J., & Zweig, C. (1991). Meeting the shadow: The hidden power of the dark side of human nature. Penguin Group (USA).

Aguinis H., & Kraiger, K. (2009). Benefits of training and development for individuals and teams, organizations, and society. Annual Review of Psychology. https://doi.org/10.1146/annurev.psych.60.110707.163505

Al-Abri, R., & Al-Hashmi, I. (2007). The learning organisation and health care education. *Sultan Qaboos Univ Med J*., *7*(3), 207-14.

Argyris, C. (1977). Double loop learning in organizations. *Harvard Business Review*, (September-October).

Argyris, C. (1985). *Strategy, change and defensive routines*. Pitman.

Argyris, C. (1991). Teaching smart people how to learn. *Harvard Business Review*. **https://hbr.org/1991/05/teaching-smart-people-how-to-learn**

Argyris, C., & Schön, D. (1974). *Theory in practice increasing professional effectiveness*. Jossey-Bass Publishers.

Argyris, C., & Schön, D. (1978). *Organizational learning: A theory of action perspective*. Addisson-Wesley.

Ballman, E., Calnan, N., Ford, K., Frederick, T., Pearson, M., & Schwalbe-Fehl, M. (2017). *ISPE cultural excellence report*. ISPE.

Bersin, J. & Chamorro-Premuzic, T. (2018). *4 ways to create a learning culture on your team*. Forbes. **https://hbr.org/2018/07/4-ways-to-create-a-learning-culture-on-your-team**

Bersin, J. (2013). *How corporate learning drives competitive advantage*. Forbes. **https://www.forbes.com/sites/joshbersin/2013/03/20/how-corporate-learning-drives-competitive-advantage/?sh=5b58233617ad**

Black, K. (2010). *Business statistics: Contemporary decision making* (6th ed.). John Wiley & Sons.

Bloom, B. S. (Ed.). (1956). *Taxonomy of educational objectives* (Vol. 1: Cognitive Domain). McKay.

Bloor, M., Frankland, J., Thomas, M., & Robson, K. (2001). *Focus groups in social research*. SAGE Publications. **https://doi.org/10.4135/9781849209175**

Boblin, S. L., Ireland, S., Kirkpatrick, H., & Robertson, K. (2013). Using Stake's qualitative case study approach to explore implementation of evidence-based practice. *Qual. Health Res*. *23*(9), 1267-75. **https://doi.org/10.1177/1049732313502128**

Boyd, C. O. (2000). Combining qualitative and quantitative approaches. In P. L. Munhall & C. O. Boyd (Eds.), *Nursing research: A qualitative perspective* (2nd ed.) (pp. 454-475). Jones & Bartlett.

Boydell, T. H. (1976). *A guide to the identification of training needs* (2nd ed.). BACIE.

Brady, J. (2015). Risk assessment: Issues and challenges. *Pharmaceutical Engineering 35*(1), 10-20. **www.ispe.gr.jp/ISPE/07_public/pdf/201506_en.pdf**

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2). 77-101.

Brodie, P. (2007). Assessment in work-based learning: Investigating a pedagogical approach to enhance student learning. *Assessment & Evaluation in Higher Education*, *32*(1), 11-19.

Brown, B. (2018). *Dare to lead: Brave work. Tough conversations. Whole hearts*. Random House.

Brown, J. (2002). Training needs assessment: A must for developing an effective training program. *Public Personnel Management 31*(4, Winter).

Bryant, A. (2020). *Double loop learning for surviving & thriving: Learning, self-leadership.* **https://www.selfleadership.com/blog/double-loop-learning-survive-thrive**

Callahan, J. L., & De Dávila, T. D. (2004). *An Impressionistic Framework for Theorizing About Human Resource Development*. Human Resource Development Review, 3(1), 75-95. **https://doi.org/10.1177/1534484303261229**

Calnan, N. (2014). *Protecting the Patient: Enhancing the Quality of Pharmaceutical Products.* [published doctoral thesis]. Technological University Dublin.

Chodron, P. (1996). *When things fall apart: Heart advice for difficult times*. Shambhala Publications, Inc.

Choo, C. W. (1996). The knowing organization: How organizations use information to construct meaning, create knowledge and make decisions. *International Journal of Information Management*, *16*(5), 329-340. **https://doi.org/10.1016/0268-4012(96)00020-5**

Coff, R. W. (1997). Human assets and management dilemmas: Coping with hazards on the road to resource-based theory. *Academy of Management Review*, *22*, 374-402.

Collins, J., Langlotz, T., & Regenbrecht, H. (2020). *Virtual reality in education: A case study on exploring immersive learning for prisoners*. University of Otago.

Creswell, J. W., & Poth, C. (2018). *Qualitative inquiry and research design: Choosing among five approaches*. Sage Publications, Inc.

Crossan, M. M., Maurer, C. C., & White, R. E. (2011). Reflections on the 2009 AMR Decade Award: Do we have a theory of organizational learning? *The Academy of Management Review*, *36*(3), 446-460. **http://www.jstor.org/stable/41319180**

Crotty, M. (1998). *The foundations of social research: Meaning and perspective in the research process*. SAGE Publications Ltd.

Denzin, N. K. (1970). *The research act: A theoretical introduction to sociological methods*. Aldine.

Dweck, C. (2016). What having a growth mindset actually means. *Harvard Business Review*.

Edmondson, A. (2018). *The fearless organization: Creating psychological safety in the workplace for learning, innovation, and growth*. Wiley.

Edmondson, A., & Moingeon, B. (1998). From organizational learning to the learning organization. *Management Learning*, *29*(1), 5-20. **https://doi.org/10.1177/1350507698291001**

ELM Learning. (2022). *What is a learning organization? A complete guide*. **https://elmlearning.com/blog/what-is-a-learning-organization/**

EMA. (2023). *European Medicines Agency: Good Manufacturing Practices*. **https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice**

European Commission. EudraLex: The rules governing medicinal products in the European Union. Volume 4: EU Guidelines for good manufacturing practice for medicinal products for human and veterinary use. Chapter 2: Personnel. EU 2.10 and EU 2.11.

Fiol, M., & Lyles, M. (1985). Organizational learning. *The Academy of Management Review*, *10*(4), 803-813. Academy of Management. **https://www.jstor.org/stable/258048**

Ford, D. J. (2011). *How the brain learns*. **https://trainingindustry.com/articles/content-development/how-the-brain-learns/**

Friedli, T., Basu, P. K., & Calnan, N. (2017). *St. Gallen FDA quality metrics research final report.* University of St. Gallen.

Fugate, T. (2018). *Reviewing FY2017 FDA 483s: Training failures or a learning paradigm?* Pharmaceutical Online. **https://www.pharmaceuticalonline.com/doc/reviewing-fy-fda-s-training-failures-or-a-learning-paradigm-0001**

Gallant, J. (2016). *Power up your CGMP training: How to make it more relevant, meaningful, & engaging*.. **https://www.pharmaceuticalonline.com/doc/power-up-your-gmp-training-how-to-make-it-more-relevant-meaningful-engaging-0001.** Pharmaceutical Online.

Garavan, T., Hogan, C., Cahir-O'Donnell, A., & Gubbins, C. (2020). *Learning & development in organizations: Strategy, evidence and practice*. Oak Tree Press.

Garavan, T., McCarthy, A., Lai, Y., Murphy, K., Sheehan, M., & Carbery, R. (2020). Training and organisational performance: A meta-analysis of temporal, institutional and organisational context moderators. *Human Resource Management Journal*.

Garavan, T., McCarthy, A., Lai, Y., Nicholas, C., Carbery, R., Gubbins, C., Sheehan, M., & Saunders, M. K. (2021). Putting the *system* back into training and firm performance research: A review and research agenda. *Human Resource Management Journal*.

Garavan, T. N. (1991). The contribution of open systems theory to understanding organizational learning, innovation and change. *Journal of European Industrial Training*, *15*(2), 17-27.

Garvin, D. A. (1993). Building a learning organization. *Harvard Business Review*, (July-August). **https://hbr.org/1993/07/building-a-learning-organization**

Garvin, D. A., Edmondson, A. C., & Gino, F. (2008). Is yours a learning organization? *Harvard Business Review*.

Gibbs, R. (2020). Four positive effects of fostering a learning organization. Forbes. **https://www.forbes.com/sites/forbescoachescouncil/2020/06/05/four-positive-effects-of-fostering-a-learning-organization/?sh=188555a82b09**

Gladstein, D. (1984). Groups in context: A model of task group effectiveness. *Administrative Science Quarterly*, *29*(4), 499-517.

Gundumogula, M., & Gundumogula, M. (2020). Importance of focus groups in qualitative research. *International Journal of Humanities and Social Science (IJHSS)*, *8*(11), 299-302.

Grant, A. (2021a). *Think again*. Penguin Random House.

Grant, A. (2021b). Work Life with Adam Grant Podcast. [Audio podcast]. Transmitter Media. **https://podcasts.apple.com/us/podcast/is-it-safe-to-speak-up-at-work/id1346314086?i=1000529425087**

Guba, E. G. (1990) "The alternative paradigm dialog," *The paradigm dialog*. doi:10.1080/1357527032000140352.

Guba, E. G. and Lincoln, Y. S. (1994) "Competing paradigms in qualitative research," in Denzin, N. and Lincoln, Y. (eds) *Handbook of qualitative research*. Thousand Oaks, CA: Sage, pp. 105–117.

Guzer, B., & Caner, H. (2014). The past, present and future of blended learning: An in-depth analysis of literature. *Procedia – Social and Behavioral Sciences*, *116*(2014), 4596-4603.

Haddad, G. (2019). *Quality risk management: The development of a role-based competency model for the biopharmaceutical sector* [published doctoral thesis]. Technological University Dublin.

Halmaghi, E. (2018). From the traditional organization to the learning organization. *Journal of Defense Resources Management*, *9*(1), 98-103. **http://www.jodrm.eu/issues/volume9_issue1/12_Halmaghi.pdf**

Harvard Business School. (n.d.). *Amy C. Edmonson bio*. **https://www.hbs.edu/faculty/Pages/profile.aspx?facId=6451**

Health Canada. Good manufacturing practices guide for drug products (GUI-0001). Personnel C.02.006 5(e)). **https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001/document.html**

Hedberg, B. (1981). How organizations learn and unlearn. In P. C. Nystrom & W. H. Starbuck (Eds.), *Handbook of organizational design* (pp. 8-27). Oxford University Press.

Hillson, D. (2013). *The A-B-C of risk culture: How to be risk-mature* [Conference session]. PMI® Global Congress 2013—North America, New Orleans, LA. Project Management Institute.

HSGAC. (2023). *US Senate Committee on Homeland Security and Governmental Affairs: Short Supply the health and national security risks of drug shortages.* **https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf**

Ibarra, H., & Scoular, A. (2019). The leaders as a coach. *Harvard Business Review*.

ICH. (2005). *Quality Risk Management Q9, ICH Harmonised Tripartite Guideline 1-23*. **https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-3.pdf**

ICH. (2008). *Pharmaceutical Quality System Q10, ICH Harmonised Tripartite Guideline*. Geneva. **https://database.ich.org/sites/default/files/Q10 Guideline.pdf**

ICH. (2014). *Final concept paper Q12: Technical and regulatory considerations for pharmaceutical product lifecycle management* **chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://database.ich.org/sites/default/files/Q12%20Concept%20Paper.pdf**

Jackson, B. A., Baker, J. C., Cragin, K., Parachini, J., Trujillo, H. R., & Chalk, P. (2005). What is organizational learning? In *Aptitude for destruction, volume 1: Organizational learning in terrorist groups and its implications for combating terrorism* (pp. 9-16). RAND Corporation. **http://www.jstor.org/stable/10.7249/mg331nij.9**

Jacobs, R. L., Jones, M. J., & Neil, S. (1992). A case study in forecasting the financial benefits of unstructured and structured on-the-job training. *Human Resources Development Quarterly*.

Janoska, L. (2017). *What is the Cone of Experience?* **https://obsidianlearning.com/blog/2017/07/what-is-the-cone-of-experience.html**

Kahneman, D. (2013). *Thinking fast and slow*. Farrar, Straus and Giroux.

Kane, P. (2018) *A Blueprint for Knowledge Management in the Biopharmaceutical Sector*. [published doctoral thesis]. Technological University Dublin.

Katz, D., & Kahn, R. L. (1966). *The social psychology of organizations.* Wiley.

Kim, Y., & Ployhart, R. E. (2014). The effects of staffing and training on firm productivity and profit growth before, during and after the Great Recession. *Journal of Applied Psychology*, *99*(3), 361-389.

Knowles, M. S. (1980). *The modern practice of adult education – From pedagogy to andragogy.* The Adult Education Company.

Knowles, M. S. (1990). *The adult learner: A neglected species*. Gulf Publishing Co.

Korte, R. (2012). Exploring the social foundations of human resource development: A theoretical framework for research and practice. *Theory and Conceptual Articles.* SAGE Publications.

Kurt, S. (2020). *Kolb's experiential learning theory & learning styles*. **https://educationaltechnology.net/kolbs-experiential-learning-theory-learning-styles/**

Kvale, S., & Brinkmann, S. (2009). *Interviews: Learning the craft of qualitative research interviewing*. Sage.

Levitt, B., & March, J. G. (1988). Organizational learning. *American Review of Sociology*, *14*.

Lipa, M. J., O'Donnell, K., & Greene, A. (2020a). Knowledge as the currency of managing risk: A novel framework to unite quality risk management and knowledge management. *Journal of Validation Technology*, *26*(5).

Lipa, M. J., O'Donnell, K., & Greene, A. (2020b). Managing knowledge and risk – A literature review on the interdependency of QRM and KM as ICH Q10 enablers. *Journal of Validation Technology*. **https://www.ivtnetwork.com/article/managing-knowledge-and-risk-%E2%80%93-literature-review-interdependency-qrm-and-km-ich-q10-enablers**

Lipa, M.J. (2021) Unlocking Knowledge to Benefit the Patient: How Connecting KM and QRM Can Strengthen Science and Risk-Based Decision Making. [published doctoral thesis]. Technological University Dublin.

Maguire, M., & Delahunt, B. (2017). *Doing a thematic analysis: A practical, step-by-step guide for learning and teaching scholars* (Vol. 3). Dundalk Institute of Technology.

Maxwell, J. (2004). *Qualitative research design: An interactive approach* (2nd ed.). Sage.

Mayer, R. E. (2009). *Multimedia learning* (2nd ed.). Cambridge University Press.

McKinsey & Company. (2014). *Mature quality systems*. **https://www.mckinsey.com/business-functions/operations/our-insights/mature-quality-systems**

MDIC. (2015). *MDIC case for quality program, maturity model research report*. **chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://mdic.org/wp-content/uploads/2015/06/MDIC-Deloitte_Maturity-Model-Research-Report_June-2015.pdf**

Myers, G., & Macnaghten, P. (1999). Developing focus group research: Politics, theory and practice, 173-185. Sage.

Nadler (1989). *Even Failures Can Be Productive*. New York Times.

Northern Arizona University. (2018). *Adult learning theory (andragogy) – An overview of adult learning theory and definition of andragogy*. Northern Arizona University.

Nyumba, O., Wilson, T., Derrick, K. C. J., & Mukherjee, N. (2018). The use of focus group discussion methodology: Insights from two decades of application in conservation. *Methods in Ecology and evolution*, *9*(1), 20-32.

Patton, M. Q. (1990). *Qualitative evaluation and research methods*. SAGE Publications, Inc.

Pfeffer, J., & Sutton, R. I. (2000). *The knowing-doing gap: How smart companies turn knowledge into action*. Harvard Business Press.

Pharmaceutical Group of the European Union (PGEU). (2022). *Medicine shortages PGEU survey 2022 results*. **chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.pgeu.eu/wp-content/uploads/2023/01/Medicine-Shortages-PGEU-Survey-2022-Results-1.pdf**

Pharmafield. (2010). *The learning organisation – Is the pharma industry willing to learn?* PF Media. **https://pf-media.co.uk/in-depth/the-learning-organisation-is-the-pharma-industry-willing-to-learn/**

Porter, D. (2017). *Why training for compliance doesn't work (and what does)*. Pharmaceutical Online. **https://www.pharmaceuticalonline.com/doc/why-training-for-compliance-doesn-t-work-and-what-does-0001**

Powar, R. K. (2010). *The learning organisation – is the pharma industry willing to learn?* Pharmafield. **https://pf-media.co.uk/in-depth/the-learning-organisation-is-the-pharma-industry-willing-to-learn/**

Ramnarine, E. (2021). *Solving the continual improvement and innovation challenge for the benefit of patients: How an effective pharmaceutical quality system (PQS) and risk-based approach could transform post-approval change (PAC) management* [Published doctoral thesis]. Technological University Dublin.

Richter, L. (2022). *Shadows of missed opportunities in learning excellence*. Institute of Validation Technology (IVT).

Richter, L., & Calnan, N. (2020). *Building effective CGMP training designed for the adult learner*. Institute of Validation Technology (IVT).

Richter, L., & Greene, A. (2019a). *Understanding adult learning principles, cGMP training modalities and the biopharmaceutical regulatory landscape*. Institute of Validation Technology (IVT).

Richter, L., & Greene, A. (2019b). *Applying adult learning principles in cGMP training*. Institute of Validation Technology (IVT).

Rittel, H. W. J., & Webber, M. M. (1973). Dilemmas in a general theory of planning. *Policy Sciences*, *4*(2), 155-169.

Robertson, R. (2022). *Pros and cons of instructor-led training*. RoundTable Learning. **https://roundtablelearning.com/pros-and-cons-of-instructor-led-training/**

Robson, C. (2002). *Real world research: A resource for social scientists and practitioner-researchers* (2nd ed.). Blackwell Publishing.

Rooney, P. (2005). *Researching from the inside – does it compromise validity? A discussion*. Technological University Dublin. **https://arrow.tudublin.ie/cgi/viewcontent.cgi?article=1004&context=ltcart**

Rutherford, A. (2019). *The elements of thinking in systems*. Kindle Direct Publishing.

Samman, R. A., & Ouenniche, J. (2016). Continuous quality improvement programs – Part I. *Source: The Journal of Developing Areas*, *50*(4), 39-66. College of Business, Tennessee State University. **https://www.jstor.org/stable/10.2307/26415515**

Saunders, M., Lewis, P., & Thornhill, A. (2019). *Research methods for business students*. (8th ed.). Pearson Education.

Schein, E. (2017). *Organizational culture and leadership*. Wiley.

Schön, D. A. (1983). *The reflective practitioner: How professionals think in action*. Basic Books.

See, Z. S., Lee, X. X., Brimo, A., Thwaites, H., & Goodman, L. (2018). *MOOC for AR VR training: Obstacles, challenges and usability* [Conference paper].

Senge, P. (2006). *The fifth discipline. The art & practice of the learning organization*. Penguin Random House.

Sluss, D. (2020). Becoming a more patient leader. *Harvard Business Review*. **https://hbr.org/2020/09/becoming-a-more-patient-leader**

Somaya, D., Williamson, I., & Lorinkova, N., (2008). Gone but not lost: The different performance impacts of employee mobility between cooperators versus competitors. *The Academy of Management Journal*. **http://dx.doi.org/10.5465/AMJ.2008.34789660**

Srinivasan, A., & Kurey, B. (2014). Creating a culture of quality. *Harvard Business Review*, (April), 23-26.

Stake, R. E. (1995). *The art of case study research*. University of Illinois at Urbana-Champaign.

Stata, R. (1989). Organizational learning – the key to management innovation. *Sloan Management Review*, Spring Edition.

Tang, Y., (2020). *Unlocking agility: Building learning capabilities within a consumer healthcare organization*. [Published thesis]. University of Pennsylvania.

Teddlie, C., & Tashakkori, A. (2010). Overview of contemporary issues in mixed methods research. *Sage handbook of mixed methods in social and behavioral research*, *2*, 1-44.

Tedlock, B. (2000). Ethnography and ethnographic representation. In N. K. Denzin, & Y. S. Lincoln (eds.), *The handbook of qualitative research* (2nd ed.). Sage Publications.

Tharenou, P., Saks, A., & Moore, C. (2007). A review and critique of research on training and organization level outcomes. *Human Resources Management Review*. **http://dx.doi.org/10.1016/j.hrmr.2007.07.004**.

Tierney, M. (1994). On method and hope. In A. Gitlin (ed.), *Power and method*. Routledge.

Training Industry. (2023). *The 70:20:10 Model for Learning and Development*. **https://trainingindustry.com/wiki/content-development/the-702010-model-for-learning-and-development/**

US Congress. (2012). *Food and Drug Administration Safety and Innovation Act*. **https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-safety-and-innovation-act-fdasia**

US FDA. (2019). *Drug shortages: Root causes and potential solutions. A report by the Drug Shortages Task Force*. **https://wayback.archive-it.org/7993/20191216101654/https:/www.fda.gov/media/132059/download**

US FDA. (2018). *Part 211 current good manufacturing practice for finished biopharmaceuticals. Subpart B. Organization and Personnel. 211.25 Personnel qualification*.

US FDA Code of Federal Regulations. Title 21, Volume 4. 21CFR211.25.

US FDA Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality (OPQ). (2022). *Quality management maturity: Essential for stable U.S. supply chains of quality pharmaceuticals*. **https://www.fda.gov/media/157432/download**

US FDA. (2022). *Report to Congress: Drug Shortages CY 2022*. **https://www.fda.gov/media/169302/download**

US FDA Office of Regulatory Affairs (ORA). (2020). *Inspection observations*. **https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations**

Usher, R., & Bryant, I. (1989). *Adult education as theory, practice and research: The captive triangle*. Routledge. **https://doi.org/10.4324/9780203802656**

Vesper, J. L. (2015). Incorporating risk assessment into the formative evaluation of an authentic e-learning program. *British Journal of Educational Technology*.

Vesper, J. L. (2018). *Regulatory GMP expectations for learning, training, & performance in pharma/biopharma*. Pharmaceutical Online. **https://www.pharmaceuticalonline.com/doc/regulatory-gmp-expectations-for-learning-training-performance-in-pharma-biopharma-0001.**

Vesper, J. L., & O'Donnell K. (2016). Current challenges in implementing quality risk management. *Pharmaceutical Engineering Magazine*. **https://ispe.org/pharmaceutical-engineering/ispeak/current-challenges-implementing-quality-risk-management**

Vesper, J. L., & Sandle, T. (2018). CGMP in practice: Regulatory expectations for the biopharmaceutical industry. DHI/PDA Books.

Vinther, A. (2016). Drug shortage is a "wicked problem", PDA Letter.

Waldron, K. (2018). *Managing risk to the patient: Recoding quality risk management for the pharmaceutical and biopharmaceutical Industries* [published doctoral thesis]. Technological University Dublin.

Waldron, K., Greene, A., & Calnan, N. (2014). Quality risk management: State of the industry – Part 1. Has the industry realized the full value of ICH Q9? *Journal of Validation Technology 20*(4). **http://www.ivtnetwork.com/article/quality-risk-management-state-industry%E2%80%94part-1-has-industry-realized-full-value-ich-q9**

Welty, G. (2009). Developing a continuing CCGMP training program. *Journal of GXP Compliance*, *13*(4, Fall), 86-96.

Wenger, E. (2000). Communities of Practice and Social Learning Systems. *Organization*, *7*(2), 225-246. **https://doi.org/10.1177/135050840072002**

Whitehead, A. N. (1929). *The aims of education*. Simon & Schuster

Whitten, N. (2002). Duties of the effective project sponsor. *PM Network*, *16*(12), 16.

Woodcock, J. (2019). *To Help reduce drug shortages, we need manufacturers to sell quality — not just medicine*. **https://www.fda.gov/news-events/fda-voices/help-reduce-drug-shortages-we-need-manufacturers-sell-quality-not-just-medicine**

World Health Organization (WHO). (2013). *WHO guidelines on quality risk management*. **https://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex2TRS-981.pdf**

Yeasmin, S., & Rahman, K. F. (2012). *Triangulation' research method as the tool of social science research.* Semantics Scholar. **https://www.semanticscholar.org/paper/'Triangulation'-ResearchMethod-as-the-Tool-of-Yeasmin-Rahman/22381bd84a8b9b8fb68a6301a8e2fb4026ab9272**

Yin, R. (2018). *Case study research and applications: Design and methods*. Sage Publications, Inc.

Yu, L. X., & Kopcha, M. (2017). The future of pharmaceutical quality and the path to get there. *Int. J. Pharm*., *528*(1-2), 354-359. **https://doi.org/10.1016/j.ijpharm.2017.06.039**.

APPENDIX 1: COMPANY A CASE STUDY SPOTLIGHT

Case Study Spotlight

Company A Profile

The company represented in this case study is a biopharmaceutical company with a varied portfolio of products. Company A is headquartered in the United States. The current portfolio of Investigational Medicinal Products (IMPs) and commercially marketed products is entirely manufactured through external vendors.

Company A Business Need:

In 2020, the company observed performance issues emerging within its third-party vendor network as its portfolio expanded. This was identified in their trended performance metrics and confirmed by audit data.

The following problem statement was proposed;

The organisation has an external supply network that is fragile in some areas as demonstrated by the performance of some critical 3rd party vendors.

Company A Improvement Project Objectives:

Develop an improved process for identifying, assessing, and evaluating third party vendor risks comprising new processes, tools, and training interventions to ensure a more sustainable oversight and risk management process.

This new 3pVRMO process will include integrating defined organisational learning components to improve organisational performance in the third-party supply network.

Existing Company Performance Measures for Vendor Management Oversight

Company A monitored vendor management performance metrics on a monthly cadence. The key performance measures below were used to determine the effectiveness of the existing vendor oversight and risk management program.

Metric	Definition
On Time in Full (OTIF)	A supplier's ability to fulfill its delivery commitments.
On Time Batch Release	A supplier's ability to meet the predefined batch release timelines as determined between the *contract give* and the *contract receiver*
Production Yield	Percentage of good product retrieved after manufacturing process
Production Deviation Rate	The number of deviations per manufacturing lot
On Time CAPA Closure	The number of Corrective/Preventive Actions closed within the predetermined timeframe
On Time Deviatio Closure	The number of manufacturing deviation instances closed within the predetermined timeframe
Effective Communication	Qualitative measure of communication behaviours between the *contract give* and the *contract receiver*

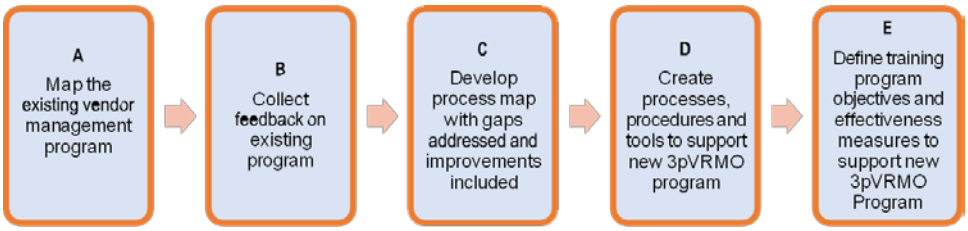
Trend data in 2020 confirmed the need for improvement and leadership committed to sponsoring the design and development of a robust program to strengthen the critical 3pVRMO program proactively. A cross functional team was assembled to lead the improvement project to ensure a diversity of perspectives of key stakeholders was embraced.

Company A Learning Culture Gap Assessment

A gap assessment was performed to determine the gaps between Company A's culture and the expected skills for a Culture of Learning. The findings from the gap assessment are documented in the thesis in Chapter 6 and were leveraged in building the 3pVRMO program.

Define the Scope of the New Process and Associated Roles/Responsibilities

Before the new training program could be designed, the new 3pVRMO process had to be defined through understanding the existing program gaps. Once this was understood processes and procedures could be created and supporting training content designed. The following process was developed to complete this step. The case study outcomes of process A -E are in the subsequent figure.



A. Map the existing vendor management program

- Risk Assessment Templates (for selection of the vendor and continued maintenance of the contractual relationship)
- Risk Management Plan Template (to document steps being taken by the Contract Giver to monitor the identified risks with the Contract Acceptor)

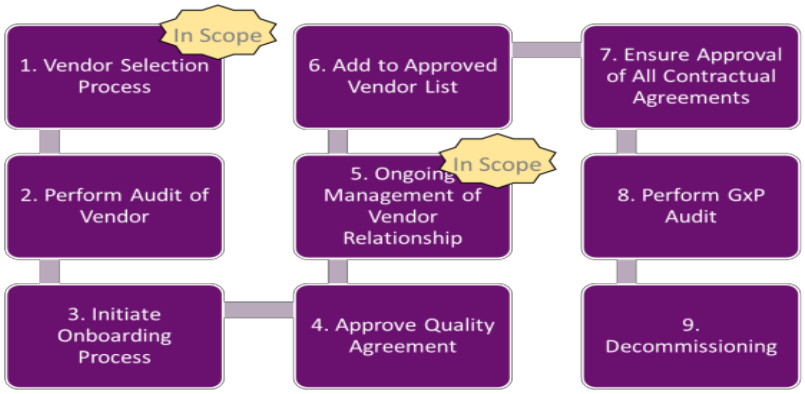
B. Collect feedback on existing program

- There was no standardized process or tools for performing risk assessments to select or manage the vendor.
- There was no training or education available so that new people could pick up the tools and perform a risk assessment.
- There were no job aides to guide a user in understanding when to perform the risk assessment or how to develop a risk management plan.
- The organisation was unable to explain the business benefits to performing the risk management processes.
- There was no connection between performing a risk assessment and measuring performance of the vendor.
- Existing training curriculums across Company A were comprised of 80% read and understand procedures, with the remaining training items deployed as self- directed e-learning modules.

C. Develop process map with gaps addressed and improvements included

- The team identified two critical areas in the end-to-end process where risk management practices were needed as a priority. (1) Vendor Selection, (2) Ongoing Management of Vendor Relationships.
- These two areas were prioritized as "in scope" for the redesigned 3pVRMO Process and Training Program.

Future State Process Map for New 3pVRMO Process (focus areas highlighted as In Scope



D. Create processes, procedures and tools to support new 3pVRMO program

- Through a series of pilot sessions run over a number of weeks, the team proceeded to define and create the FOUR new procedures and tools required to support the new 3pVRMO program.
- Vendor Risk Management & Oversight Procedure (SOP): Define the vendor risk management process, scoring criteria, tools, templates and roles and responsibilities.
- Vendor Selection Risk Assessment Tool: A risk assessment for the selection process that allows the user to leverage standardized risk categories and scoring criteria to determine the best vendor amongst multiple options.
- Operational Risk Assessment Tool: A risk assessment that is built to manage the relationship with the selected vendor (operational risk assessment) which allows any risks identified during selection process to be carried over and managed. The tool has standardized risk scoring and predefined risk categories
- Risk Management Plan Template: A risk management plan that is an executive summary document capturing the risk monitoring plan for open & high risks and documents the current overall risk profile of the vendor.

E. Define training program objectives and effectiveness measures to support new 3pVRMO program

- These objectives would serve as the foundation for designing the training modules and curriculum that would result in a comprehensive 3pVRMO training program.
- The training objectives are defined in the subsequent figure.

3pVRMO Training Program Learning Objectives

Provide an overview of the end-to-end vendor management program.	Ensure consistent application of the Selection Risk Assessment and the Operational Risk Assessment.
Risks must be assessed for mitigations or monitoring based on the application of standardized risk scoring.	Mitigations and monitoring plans are executed per the Operational Risk Assessment and the Risk Management Plan.
The Risk Management Plan is designed based on the outputs of the risk assessment and the assigned Risk Profile.	The Operational Risk Assessment and Risk Management Plan are revised per scheduled risk review.

3pVRMO Training Program Effectiveness Measures

Measure	Target
Each new vendor has a Selection Risk Assessment (where applicable), an Operational Risk Assessment and Risk Management Plan reference in the onboarding change control record	No overdue/incomplete Selection Change Controls
Existing vendors are transitioned to the new Operational Risk Assessment and Risk Management Plan templates and process per transition plan	Adherence to Plan
Risk review of each Operational Risk Assessment and Risk Management Plan is completed on time	Adherence to Schedule for addition to the GMP Approved CO List
Each Selection Risk Assessment meets the standard of the SOP	Rework – Number of rejected Quality approvals in the Change Control
Each Risk Management Plan meet the standard of the SOP	Rework - Number of rejected Quality approvals in the Electronic Document Management System

☑ Risk-Based Training Needs Assessment

Once the formal scoping exercise for the new process was complete and the objectives of the associated training program were defined with corresponding effectiveness measures, the next step of the PFLEX 0 Model could be applied by performing a **risk-based training needs assessment of the trainees.** Results are in the subsequent table.

Role	Responsibilities to Achieve Objective	Risk Level
Vendor Selection Risk Assessment Owner	Leads theSelectionRisk Assessment development with SME participations.	**High**
	Approves the Selection Risk Assessment	**Medium**
Vendor Selection Team	Participates as an SME in the development of the Selection Risk Assessment	**Medium**
	Provides input to the selection of the vendor.	**Medium**
Quality Assurance	Participates as an SME in the development of the risk assessments	**Medium**
	Participates as an SME in the risk review of the risk assessments	**Medium**
	Approves the Selection Risk Assessment	**Medium**
	Approves the Risk Management Plan	**High**
Operational Risk Assessment Owner	Leadsthe development of the Operational Risk Assessment, authoring and approving the Risk Management Plan.	**High**
	Leads identification of risk mitigations and/or risk monitoring plans.	**High**
	Leads the risk review activitiesfor the risk assessments.	**High**
	Communicates high risk and risk mitigations to the appropriate governance team.	**Low**
Operational Team	Participates as an SME in the development and risk review of the risk assessments.	**Medium**
	Provide input tothe risk mitigation and/or risk monitoring plans.	**Medium**

Based on the outcome from the risk-based training exercise, the team developed the final training course recommendations (modality, objective and roles) to address the high-risk activities in the table below.

Design of Five Critical Training Programs to Address the High-Risk Training

Ref.	Critical Training Course Title	Training Modality	Training Course Objective(s)	WHO SHOULD ATTEND		
				Vendor Selection Risk Assessment Owner	Operational Risk Assessment Owner	QA Owner
1	**GMP Vendor Management Overview**	vILT + Knowledge Assessment	The participants will be able to describe the requirements, responsibilities, and key deliverables for the Vendor Risk Management process. This will be a prerequisite for the additional courses needed.	X	X	**X**
2	**Facilitation of Vendor Selection Risk Assessment**	OJT/Skills Assessment	The Vendor Selection Risk Assessment Owner will demonstrate how to facilitate and document risks in the Selection Risk Assessment using the template with Selection Team participation.	X	X	
3	**Facilitation of Operational Risk Assessment**	OJT/Skills Assessment	The Operational Risk Assessment Owner will demonstrate how to facilitate and document risks in the Operational Risk Assessment template with Operational Team participation.		X	
4	**Authoring the Risk Management Plan**	OJT/Skills Assessment	The Operational Risk Assessment Owner will demonstrate how to author a Risk Management Plan using the templates.		X	
5	**Approving the Risk Management Plan**	vILT + Knowledge Assessment	The QA role will demonstrate an understanding of how to review and approve the Risk Management Plan using the templates.		X	X

☑ **Designing Course Content Using the ALECT Approach**

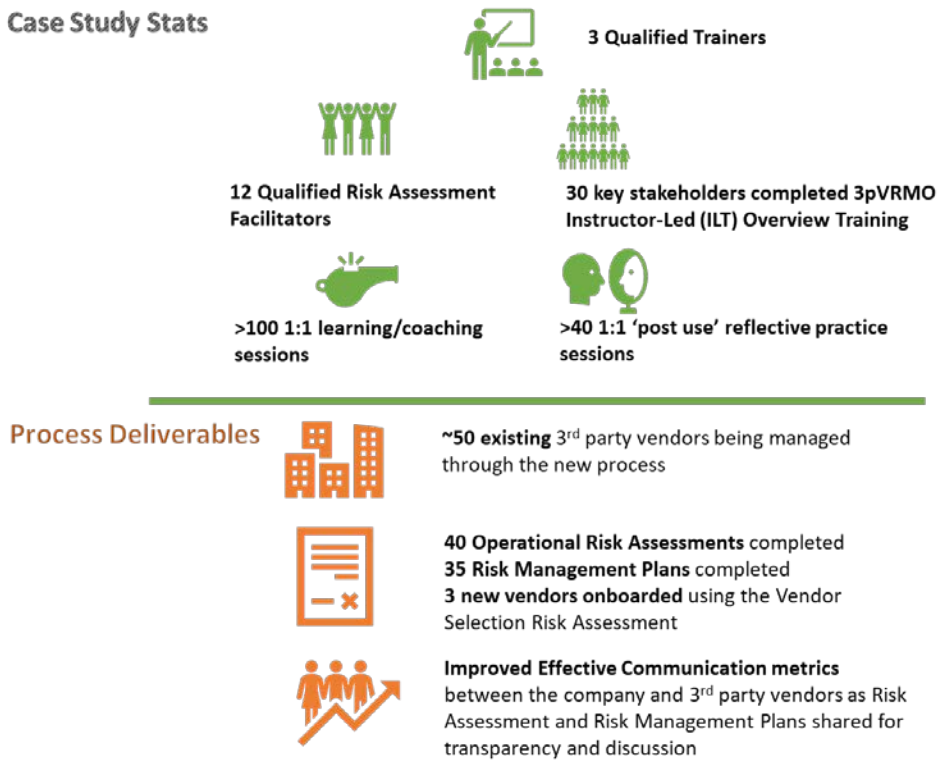
The next step in the process was to design detailed course content using the Adult Learner Effective CGMP Training (ALECT) tool. The example shown is for the Vendor Selection On-the-Job Training (OJT) Course.

Requirement	Information
Problem Statement	The role of leading the Vendor Selection Risk Assessment with SME participations was deemed high risk through the Risk Based Training Needs Assessment.
Regulatory Requirement	Personnel are trained and/or otherwise qualified in the procedures and methods they use, and, in the tasks, they perform.
Course Objective	• Demonstrate guiding the team in risk identification using the Evaluation Questions in the Vendor Selection Risk Assessment template with minimal intervention from the trainer • Demonstrate guiding the team in using the risk scoring definitions provided in the Vendor Selection Risk Assessment template with minimal intervention from the trainer • Describe how to document rationale for each applicable Evaluation Question to support the Scoring Criteria per the Selection Risk Assessment template. The trainer reviews and accepts the rationales.
Course Title	Vendor Selection Risk Assessment on the Job Training
Who Should Attend?	Vendor Risk Assessment Owners
Training Modality	On the Job Training with 1:1 coaching sessions as reflection practices
Course Outline	• First session: o Facilitator to review Vendor Selection Risk Assessment Template and Evaluation Questions with learner. o Review governing procedure requirements and work instruction guidance. o Review completed example with learner and address any questions. o Provide guidance and tips for facilitating a team and review the micro-learning: *How to Write a Risk Description*. o Final preparation discussion for learner to facilitate session. • Second session: o Review output of Vendor Selection Risk Assessment completed by learner and provide feedback and guidance for any corrections. o Address coaching session with learner regarding performance with facilitation, progress completing the template and feedback from participants o Address if future sessions are necessary and provide opportunities for subsequent coaching sessions to review final output.
Other comments	N/A
Adult Learning Concepts	
Adult learners are aware of self	• This training did not provide a self-assessment opportunity, or something similar, to help guide the learner to focus on areas they needed to improve
Past experiences are critical	• Learners were provided opportunities to share past experiences regarding the Vendor Risk Management process.
Adults are purpose driven in learning	• This course addressed a critical initiative for the company to improve management of vendors. • The instructor and learner develop an environment for sharing experiences. • The learner was given opportunities to practice techniques using examples in the course.
Adults have a readiness to learn	• The training material addressed how this course fit into the larger strategy of improving the vendor management program.
Adult learners have internal motivation	• The learner was given some opportunities to practice techniques. • The learner was encouraged for the second session to bring an actual working example of a risk assessment and work through it with the instructor for a coaching opportunity.
Mistakes are valuable	• The course incorporated an activity for the learner to struggle and learn from mistakes by having them facilitate on their own and bring back challenges to discuss with the instructor.
Adult learners want an active role in curriculum development	• Learners were encouraged to drive the coaching discussions and get what information they needed from the instructor to focus and individualize the learning event.
Concrete Experience	• Learner was provided with templates and evaluation forms that may have challenged what they had done in their past roles at other companies.

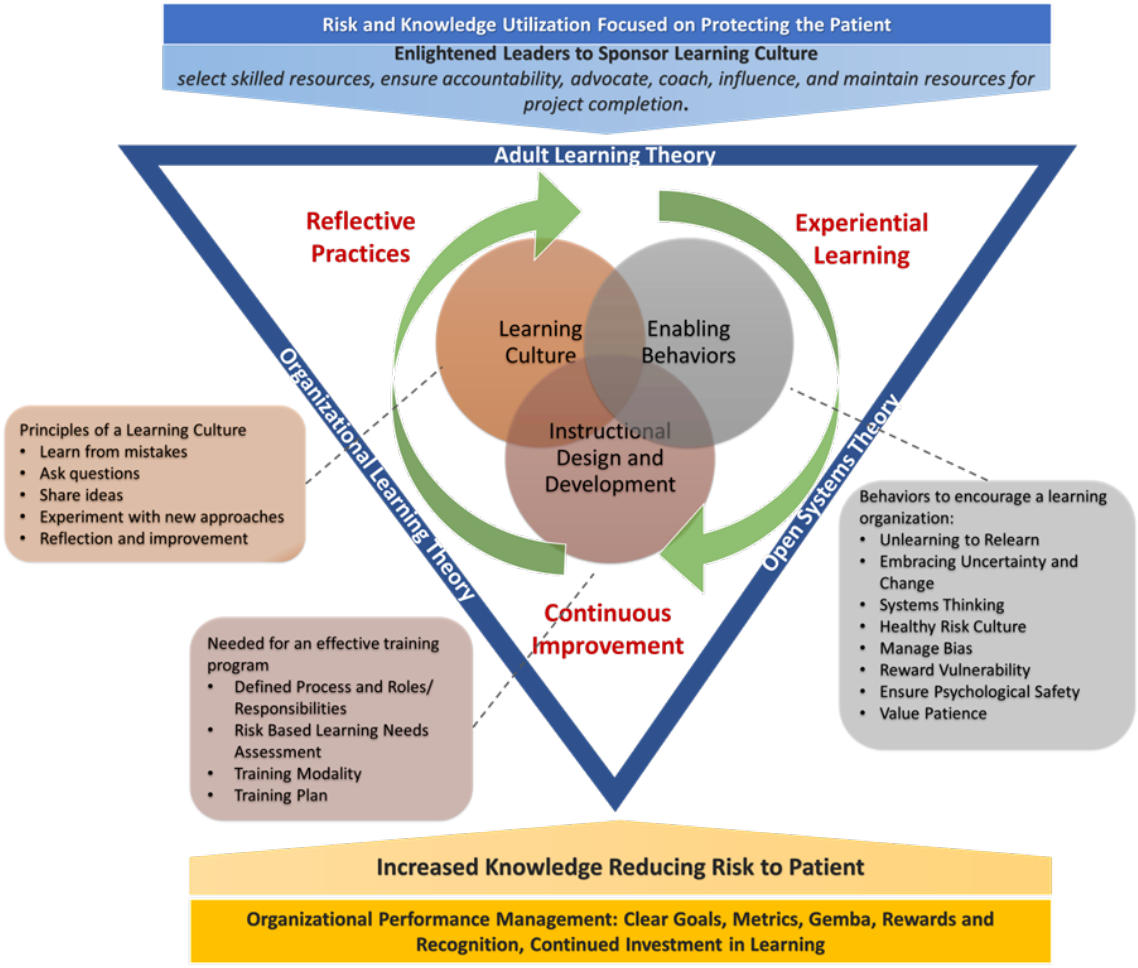
☑Case Study Outcome

The implementation of the 3pVRMO program, accompanied by robust processes, tools, and comprehensive training, has yielded significant performance improvements for Company A. The program's emphasis on proactive risk management has not only minimized potential issues but has also fostered a culture of continuous improvement and learning. A trainee in the program, shared her perspective on the impact of the risk management plan, stating, "The risk management plan is like a knowledge management tool for us. It retains the history of the risk decisions made during our relationship with the vendor, providing valuable insights into our risk mitigation strategies." This sentiment underscores the program's effectiveness not only in risk reduction but also in serving as a knowledge repository that aids in informed decision making.

The stats below represent the improved performance measures resulting from implementation of the 3pVRMO program.



APPENDIX 2: PATIENT-FOCUSED LEARNING EXCELLENCE USER GUIDE



Risk and Knowledge Utilisation Focused on Protecting the Patient

Case Study Reflection: *While Company A did have a strong patient-focused culture, it was lacking in connecting patient focused risk assessment outputs, changes in the regulatory landscape, lessons learned and near misses with its learning and development programme. This resulted in a gap in connecting the training programmes to organisational risk and integrating key lessons learned throughout the lifetime of the programme when making major improvements.*

Goal of this stage of the PFLEx Model:

Proactively manage risks while leveraging knowledge to enhance patient safety, minimise adverse outcomes and optimise the overall quality of the patient experience. It reflects a commitment to a patient-centric approach where risk is acknowledged, assessed and mitigated within the broader framework of providing safe and efficacious therapies.

The implementation action plan for this step of the PFLEx Model involves the following:

1. Ensure the organisation's risk management programme actively identifies and assesses potential risks that could impact on patient safety and ensure that patient safety risks are inherently linked to the L&D programmes.
2. Ensure these risks are communicated regularly to all parties involved in the development, manufacture and distribution of drug products.
3. Incorporate a process to actively learn about, and from, patient communities through 1:1 interaction, patient forums or patient speakers visiting the company, ultimately incorporating this information into knowledge management and training programmes.
4. PFLEx should facilitate a system for continuous monitoring of the identified risks and the effectiveness of L&D mitigation strategies. It should be prepared to adapt and refine approaches based on feedback from the learners, emerging information, changes in the regulatory landscape or evolving patient needs.

Intended output from this step of the PFLEx Model:

By translating the concept of ***risk and knowledge utilisation focused on protecting the patient*** into these actionable steps, an organisation can systematically integrate risk management and knowledge management practices into its L&D operations, ensuring a patient-centric approach to managing and transferring knowledge.

Enlightened Leaders to Sponsor a Learning Culture

Case Study Reflection: *The sponsor only held the team accountable to a timeline but needed to appreciate the deliverables and the work the team was putting into the training programme development and deployment. If an enlightened learning leader sponsor had been in place who mentored, coached, fostered a psychologically safe environment and promoted the team's work, the project outcome would likely have been positively impacted. The company represented in the case study did not have guidance for describing an enlightened learning leader's sponsorship role or behaviours. A competency model is needed to measure leadership performance. If the focus of success for the leader had shifted from measuring the due date for the project to being accountable for the behaviours of an enlightened leader as a sponsor, the interaction between the team and the sponsor would have been more productive.*

Goal of this stage of the PFLEx model:

To be a strong sponsor, leaders need to demonstrate certain skills and behaviours. They should have a deep understanding of the importance of learning and development, and how it relates to the organisation's strategic objectives.

Enlightened leaders should also be able to communicate this message to employees and regularly reinforce that learning is a priority through their own behaviours. Enlightened leaders should lead by example and prioritise their own learning and development. This not only demonstrates a commitment to learning, but also creates a culture where continuous learning is seen as an integral part of personal and professional growth. Effective sponsors of learning cultures should create an environment where employees feel safe to ask questions, share ideas and experiment with new approaches, where employees are rewarded for their successes, and where failures are seen as learning opportunities.

The implementation action plan for this step of the PFLEx Model involves the following:

1. **Leaders who actively sponsor a *learning culture* should be approachable and available to answer questions, provide feedback and offer support.**
2. **Resources, such as time and funding, to support learning initiatives, and should actively encourage employees to pursue their own learning and development.**
3. **Leaders accountable and responsible for the success of learning initiatives and hold themselves and others accountable for meeting learning objectives.**
4. **Employees open to new ideas and approaches and willing to experiment with new learning methods and technologies.**
5. **Leaders encouraging employees to reflect on their learning experiences, and to continuously improve their skills and knowledge.**
6. **Leaders fostering a safe and inclusive environment, encouraging open dialogue, active listening and respect for diverse perspectives. Creating a space where team members feel comfortable sharing their ideas and asking questions (Edmondson, 2018).**

7. **Leaders encouraging a mindset of continuous learning and improvement. Emphasising the value of mistakes as opportunities for learning and innovation. Encouraging team members to take intentional risks and learn from both successes and failures (Dweck, 2016).**
8. **Employees actively promoting the exchange of knowledge, experiences and best practice among team members. Encouraging learning from one another through communities of practice, lessons learned and relevant resources (Wenger, 2000).**
9. **Leaders promoting a culture where team members are encouraged to think critically, challenge assumptions and explore alternative perspectives. Creating opportunities for constructive debates and discussions that stimulate learning (Argyris & SchѴðn, 1978).**
10. **Leaders seeking input and feedback from team members when making decisions. Involving them in the decision-making process to encourage ownership, engagement and learning (Senge, 2006).**
11. **Leaders fostering a culture of learning from both successful outcomes and failures, extracting lessons that can inform future decision making and improvements (Knowles, 1980).**

Intended output from this step of the PFLEx Model:

A strong sponsor of a learning culture is committed to creating a culture of continuous learning and actively supports and encourages employees to pursue their learning and development. They are accessible, supportive, accountable, innovative and reflective, and they lead by example, prioritising their own learning and development. Companies must build these behaviours into leadership competency models, linking performance reviews to the success of demonstrating these behaviours.

Embedding Adult Learning, Organisational Learning and Open Systems Theories as Guiding Principles

Case Study Reflection: *Modifying the model to better embed adult learning theory, organisational learning theory, and open systems theory would have further integrated these concepts across the various processes of the L&D programme. While these concepts were present in the risk-based training assessment, the ALECT tool and during the development of the training content, the holistic presence of these concepts throughout could have led to a more deliberate integration of these guiding principles through mindset, culture and instruction design, development and deployment.*

Goal of this stage of the PFLEx Model:

Incorporating the guiding principles from adult learning, organisational learning and open systems theories into the “outer walls” or framework of the PFLEx2 Model offers a holistic organisational development process. The guiding principles from the three theoretical frameworks are not standalone elements, but integral components that should permeate

every facet of the model, influencing its design, implementation and continuous improvement. Integrating these principles into the very fabric of the model establishes a comprehensive and dynamic approach to organisational learning and development, setting the stage for sustained success and innovation.

The Implementation action plan for this approach involves the following:

1. Designing learning programmes that align with *adult learning theory* involves incorporating various learning modalities, such as workshops, online modules, coaching sessions and on-the-job training, allowing employees to tailor the learning they need to meet the requirements of their role in the organisation and engage in ways that suit their individual learning styles.
2. Implementing tools such as the Risk-based Training Needs Assessment and the ALECT tool can provide opportunities to integrate these principles into learning sessions, improving the overall effectiveness of the learning programme.
3. Embedding *organisational learning theory* by implementing regular feedback loops such as post-training evaluations, lessons learned and debrief sessions as post-reflection opportunities contributes to continuous improvement.
4. Monitor industry trends, regulatory changes and current technological advancements to incorporate them into regularly updated training content and methodologies to align with external shifts, ensuring organisational responsiveness.

Intended output from this step of the PFLEx Model:

Employees are more likely to actively participate and retain information when the learning experiences resonate with their preferences. This approach fosters a positive learning environment, leading to increased knowledge retention, skill development and overall satisfaction among learners. This continuous improvement mindset positively influences innovation and efficiency within the organisation, improving organisational performance in reducing re-work and the implementation of process improvement, enhancing efficiencies. An organisation that embraces open systems theory concepts is better positioned to adapt to external changes proactively. Employees are more attuned to industry developments, enabling them to apply the latest knowledge and skills. This adaptability positively influences the organisation's agility and competitiveness in a dynamic business landscape.

Bringing Together the Learning Culture, Enabling Behaviours, Instructional Design and Development Process

Case Study Reflection*: Modifying the model to integrate learning culture, enabling behaviours and instructional design and development would have provided an opportunity in the case study to work within an organisation that embraced, valued and rewarded the behaviours necessary to design, deploy*

and sustain a holistic learning programme designed to integrate a learning culture that ensured that the vendor risk management programme was improved and sustained, with external knowledge incorporated for continuous improvement.

Goal of this stage of the PFLEx Model:

Integrating a learning culture, enabling behaviours and instructional design and development within the "engine" of the PFLEx2 Model represents a comprehensive approach to organisational growth and performance improvement.

- Drawing from the principles of a *learning organisation*, the PFLEx2 Model encapsulates systematic problem solving, experimentation with new approaches and the assimilation of knowledge from individual experiences and external best practices.
- *Enabling behaviours* such as the willingness to unlearn and relearn, embracing uncertainty, ensuring psychological safety and valuing patience are woven into the model's fabric.
- Structured *instructional design and development* processes play a pivotal role, encompassing the definition of roles and responsibilities, risk-based training needs assessment, diverse training modalities and a rigorous training plan.

By integrating these elements, the model becomes a dynamic platform that not only cultivates a culture of continuous learning, but also provides the necessary tools and strategies for practical skill development and knowledge transfer throughout the organisation.

What sets this model apart is its holistic incorporation of principles often treated as separate entities. In many organisations, a learning culture, enabling behaviours and instructional design and development are approached in silos, missing out on the synergistic potential when combined. The PFLEx Model creates an environment where individuals feel empowered to learn from mistakes, leading to a reduction in repeat errors and a proactive approach to problem solving.

The implementation action plan for this approach involves the following:

- Conduct a comprehensive evaluation of the existing organisational culture to identify strengths and areas for improvement in learning and behaviour. Understanding that the current cultural landscape serves as a foundational baseline for targeted interventions. The evaluation provides an opportunity to see where these approaches are synergistic with other initiatives that may be ongoing for the organisation. For example, many of the behaviours defined in the PFLEx2 Model align well with quality culture, operational excellence, safety culture, knowledge management initiatives, etc.
- Regularly administer surveys to gauge employee satisfaction regarding perception of the learning environment, identifying successful aspects and areas requiring attention. Employee feedback becomes crucial for designing initiatives that resonate with and motivate the workforce.

- Conduct a thorough analysis of individual and organisational requirements. Tailoring training to specific needs ensures the content remains relevant and effectively addresses identified gaps. Using the Risk-based Training Needs Assessment and ALECT tool would be beneficial.
- Develop a behavioural competency framework aligned with desired enabling behaviours and integrate it into performance assessments and development plans.
- Develop a hiring strategy focused on identifying these behaviours with demonstrable evidence in future leadership candidates.
- Reward and recognition programmes should support the cultivation and sustaining of these behaviours throughout the organisation.
- Establish continuous improvement mechanisms, such as regular curriculum reviews, post-training evaluations and feedback loops to improve design and development. Continuous improvement ensures that the integration of learning principles remains dynamic and responsive to evolving needs.

Intended output from this step of the PFLEx Model:

By strategically implementing these actions, a biopharmaceutical company can foster a culture of continuous learning, enabling behaviours and practical instructional design and deployment processes, creating a dynamic learning environment that contributes to improved organisational performance and sustained success.

Deployment through an Experiential Learning Cycle

Case Study Reflection*: Integrating experiential learning into the model aligns with the feedback obtained from the survey results of participants in the vendor risk management programme. Survey responses highlighted the effectiveness of coaching and mentoring sessions, hands-on tool-based working sessions and reflective practices in delivering a comprehensive and practical learning experience. Most notably, the experiential learning process integrated into the vendor risk management programme received the highest positive feedback in the survey. This modification to the model presents a clear opportunity to shift away from compliance-centric training programmes and tick-the-box training activities.*

Goal of this stage of the PFLEx Model:

The *experiential learning cycle* enriches the PFLEx2 Model by providing a structured, hands-on approach to the real-world application of knowledge, aligning with a culture of learning. It informs the creation of learner experiences that incorporate reflective practice and invites coaching, enhancing learner engagement. This cycle reinforces a culture of continuous improvement, encouraging experimentation, reflection and adaptation of approaches. Inherent to the experiential learning cycle is encouragement to take risks, try new approaches

and learn from both successes and failures. The reflective phase prompts analysis, fostering a culture where mistakes are seen as valuable learning opportunities. Integrating the experiential learning cycle enhances skill development and problem-solving capabilities. Participants actively engage with challenges, apply knowledge and refine approaches based on feedback, contributing to a more agile and competent workforce and positively impacting on overall organisational performance.

The implementation action plan for this approach involves the following:

1. **Align instructional design methodologies with the experiential learning cycle.**
2. **Design and implement structured experiential learning activities such as coaching and mentoring to enhance the learning experience.**
3. **Incorporate reflection as a structured component of learning experiences.**
4. **Establish mechanisms for providing timely and constructive feedback after the completion of a learning experience.**
5. **Align experiential learning outcomes with performance management processes.**
6. **Leverage technology to facilitate virtual experiential learning opportunities.**
7. **Implement metrics to measure the impact of experiential learning on individual and organisational performance.**

Intended output from this step of the PFLEx Model:

By taking these actions, organisations can successfully integrate the experiential learning cycle into everyday learning opportunities, fostering a culture of continuous learning and learning from mistakes, improving adaptability and contributing to overall organisational success.

Organisational Performance Management

Case Study Reflection*: Before creating the vendor risk management programme, the case study team identified organisational performance metrics. Initially focused on measuring programme implementation, these metrics were designed to evolve with programme maturity, assessing output quality and re-working risk assessment output for effectiveness. The action list provided in this section would have guided the team to design metrics more intentionally, incorporating them as a project deliverable.*

Goal of this stage of the PFLEx Model:

Integrating proactive performance measurements into the PFLEx Model emphasises a forward-looking improvement methodology that goes beyond reactive responses. By incorporating clear metrics and real-time performance assessments, the model enables organisations to set precise goals, monitor progress and strategically align learning initiatives with overall business objectives. The synergy of proactive performance measurements with

Gemba, the philosophy of observing work in its actual place, ensures a grounded understanding of organisational dynamics. Rewards and recognition mechanisms are heightened through the data-driven insights provided by proactive measurements, fostering a culture of achievement and continuous improvement. Continued investment in learning is bolstered by the model's ability to identify areas for refinement and innovation, ensuring that resources are strategically allocated for sustained growth. The introduction of proactive performance measurements positions the PFLEx Model as an adaptive and results-driven framework, advancing the trajectory of organisational learning and excellence.

The implementation action plan for this approach involves the following:

1. **Clearly articulate learning excellence programme goals, aligning them with the overall business mission and vision of the organisation.**
2. **Define relevant leading KPIs that align with organisational strategic business objectives and learning outcomes. Utilise data analytics tools to gather, analyse and visualise performance metrics for informed decision making.**
3. **Encourage leaders to regularly engage in Gemba walks to observe and understand work processes at the ground level. Facilitate employee involvement in Gemba activities, promoting a collaborative approach to process improvement.**
4. **Develop programmes that acknowledge and reward individuals or teams achieving milestones and demonstrating the enabling behaviours for learning excellence. Align rewards and recognition with measurable achievements, reinforcing the connection between performance and acknowledgment.**
5. **Ensure a dedicated budget for ongoing learning initiatives, underscoring the organisation's commitment to employee development. Explore and invest in learning technologies that facilitate continuous skill development and knowledge acquisition, preferably identified using the model to determine the education and knowledge needs of the team.**

Intended output from this step of the PFLEx Model:

These actions collectively contribute to the seamless integration of clear goals, metrics, Gemba, rewards and recognition, and continued investment in learning into the organisational culture, fostering a dynamic environment of growth, accountability and sustained learning excellence.