Exploring the Role of Knowledge in the Pharma Workplace of the Future: An Interactive Workshop Exploring Culture, KM and OpEx

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Abstract

This article presents a summary of an interactive workshop facilitated by Nuala Calnan and Stephanie Friedrichsen during the conference: 'ICH Q9(R1): The Next Frontier' held in Technological University Dublin, Ireland, on 1 June 2023. The summary was prepared by the workshop facilitators in conjunction with Martin Lipa who was a participant at the workshop. The article is written to give a high-level overview of the discussions which took place during the workshop and is not intended to be a complete representation of all the activities, insights and findings.

1. Introduction

This article is a high-level summary of the discussions and outputs of a workshop which was conducted during the 'ICH Q9(R1): The Next Frontier' conference held in Technological University Dublin, Ireland, on 1 June 2023. The workshop was facilitated by two of the authors of this paper, Nuala Calnan and Stephanie Friedrichsen. The third author, Martin Lipa, was an attendee at the workshop. The workshop was designed to explore the role of knowledge in the pharma workplace of the future, specifically focusing on Culture, Knowledge Management (KM) and Operational Excellence (OpEx).

In order to set the scene for the workshop, the conference Keynote speaker delivered opening remarks which are summarised in the section 2 of this paper. Section 3 describes the context and the process employed during the workshop, while the remaining sections present some of the key discussion topics and insights that emerged during the workshop, and from post-workshop reflections.

2. Summary of the Opening Remarks for the Workshop

Dr Ed Hoffman, retired NASA Chief Knowledge Officer, and a keynote speaker at the conference, opened this workshop session. In his opening address at the conference, featured in another paper in this Level 3 Special Edition, he proposed that there are three key factors that successfully drive work: knowledge, relationships, and strategy. His belief is that the workplace of the future is moving from a position where expertise and knowledge grown over a thirty+ year period in specific individuals to a situation where there is constant change and evolving dynamics. Organisations will have to tackle how to build trust, manage risk, and work cross-functionally in teams to survive and thrive in today's complex and rapidly changing world.

The workplace of the future continues to evolve at an ever-accelerating pace. Within the pharma industry we live this evolution daily as our workplaces continue to change through the following:

- Frequent innovations (and at a faster pace)
- Automation through robotics, informatics, data visualisation
- Application of new technologies (artificial intelligence (AI), ChatGPT, virtual or augmented reality).
- Shifts in work skillsets, capabilities, culture, virtual connections, and the "office" space
- Quality management maturity expectations (and others!).

Throughout these changes, adaptation continues to be critical to embracing our accelerating evolution, and yet, some things do not change about the industry's mission (or expectations of patients and regulators) as follows:

- We must continue to deliver a safe, effective, reliable supply of medicine

- Decisions still need to be made and knowledge has to flow

- New knowledge identifies new risks to control

- The road to continuous improvement never ends; and

- Humans continue to be…human… and will continue to find error pathways not previously seen or identified.

While we make incredible advances, technology is not a replacement for people, culture, or decision-making. This means that as we move into the future, we should embrace the new challenges, while not losing sight of the mission (to deliver safe effective medicines to patients every time).

3. Workshop context, process and findings

The "Pharma Workplace of the Future" workshop aimed to explore the role of knowledge in the future workplace through creating and sustaining a culture that nurtures learning and growth grounded in the complimentary disciples of knowledge management (KM) and operational excellence (OpEx). The intention was to initiate a discussion on the measures, mindsets, and behaviours that the Pharma industry should nurture as it moved into a new era.

Workshop participants were organised into two sessions (workshop 1 and 2), each of which discussed two themes (themes A and B) as follows:

1. Interactive Workshop 1 explored:
    A. The role of knowledge management in the Pharma Workplace of the Future

    B. Nurturing a Smart Culture: What does "Good" look like to cultivate learning and growth?
2. Interactive Workshop 2 explored:
    A. The "How" – Leveraging the approaches and tools available within your workplace for excellence
    B. Ready for the Future: Reflections and Learnings from the workshops.

The workshop participants (n ~ 60) included representatives from many sectors of pharma including academia, regulatory and industry. Discussion questions were designed by the workshop facilitators to stimulate conversations on topics such as: knowledge management, cultures of quality and excellence, operational excellence, and the future of knowledge in the workplace.

Participant perspectives were written on sticky-notes (one thought/perspective per note) and these were captured on a large board during the session. These perspectives were grouped into preliminary themes followed by a brief group discussion.

Subsequent to the workshop, the facilitators conducted a more detailed analysis to capture the insights for each of the 4 subsets of the workshop (i.e., workshop 1A, 1B, 2A and 2B) which are presented graphically below for the first 3 workshops, and in a table format for the final workshop.

Workshop 1

Workshop 1 / Theme A: The role of Knowledge Management in the Pharma workplace of the future

Background information shared by the workshop facilitators

> *"In the current era, business activities are becoming increasingly dominated by **knowledge workers** and the widespread utilization of **complex digital systems** for storing the ever-growing knowledge generated in different types of enterprises."*
>
> - ISPE Good Practice Guide to Knowledge Management
> in the Pharmaceutical Industry

ICH Q10 defined knowledge management fifteen years ago in 2008 as "a systematic approach to acquiring, analysing, storing and disseminating information related to products, manufacturing processes and components." Other industries embrace a more holistic definition of KM, such as that provided by APQC as "a systematic effort to enable information and knowledge to grow, flow and create value. The discipline is about creating and managing the processes, approaches, and enablers to help knowledge to flow to the right people at the right time and help them share and act on knowledge to improve organisational performance" [1].

Although these definitions have been in place for some time, and most workers in pharmaceutical organisations have heard of the term 'knowledge management', KM continues to be poorly understood and adopted. Furthermore, what is not as well- known in pharma, or widely discussed, is why knowledge management is introduced into organisations as a discipline – and what the goals of these efforts entail.

Questions posed by the facilitators to stimulate discussion

The following questions were posed by the facilitators, and the participants were encouraged to interact with one another in a discussion on at least one of the following:

- *What does KM look like in your workplace?*

- *What are the goals of KM at your Organisation?*

- *What are the common methods/tools deployed?*

- *What are common measurements of success?*

Participant perspectives

Participant responses were recorded on sticky-notes and were grouped into themes by the facilitators after the workshop. These are summarised and shown in Figure 1.

Note: A complete listing of all participant inputs for all session collected from the participants is presented in the Appendix.
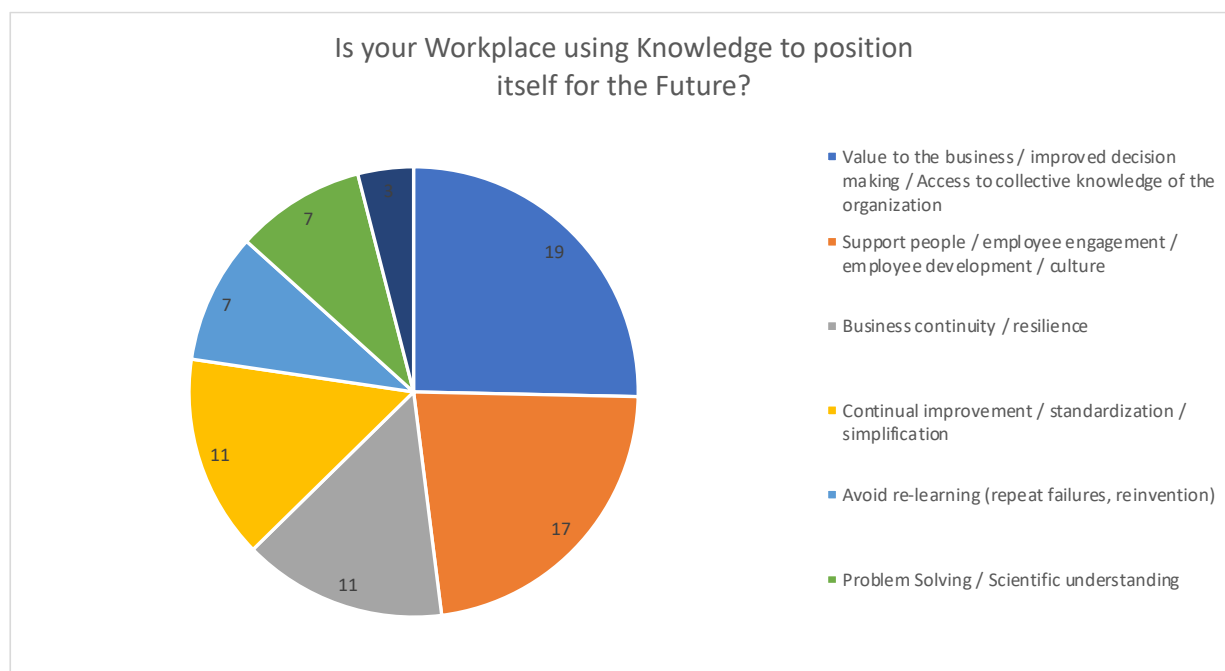

Figure 1: Is your workplace using knowledge to position itself for the future?

Facilitators post-workshop reflections

Within pharma these responses and associated outcomes point to why one should introduce knowledge management. All these items have in common a connection to enhanced performance, and ultimately risk reduction, through optimisation of knowledge flow, or a focus to improve individual competency or capability of the organisation to deliver on its mission. Whether one is trying to improve performance outcomes, or trying to improve efficiency and effectiveness through the right knowledge to the right person at the right time, an organisation must establish the right culture. There is no real distinction between managing knowledge as an

asset *versus* process effectiveness and/or efficiency. But how does the industry cross that bridge of understanding how to effectively use knowledge in the future? The answer is perhaps found in our organisational culture – which was next explored by the workshop participants.

Workshop 1 / Theme B: Nurturing a smart culture

Background information shared by the workshop facilitators

> *"A formal cultural excellence program seeks to **enhance organizational capability** and **performance outcomes** through increased **employee engagement**, the use of **systematic improvement processes** and **rigorous proactive performance management practices.***
>
> - ISPE Advancing Pharmaceutical Quality Guide to Cultural Excellence

Questions posed by the facilitators to stimulate discussion

The following questions were asked by the facilitators, and groups were encouraged to interact with one another.

- *How does your organisation manage the balance between maintaining a culture of quality and striving for a culture of excellence?*

- *How does your workplace culture nurture / enable:*
    - *Management to support learning and growth*
    - *Employees to routinely engage in learning and growth*
    - *A continuous Improvement mindset*
    - *Empowerment and Accountability behaviors*
    - *Honest Dialogue.*

Participant perspectives

Participant responses were recorded on sticky-notes and were grouped into themes by the facilitators after the workshop. These are summarised and shown in Figure 2.
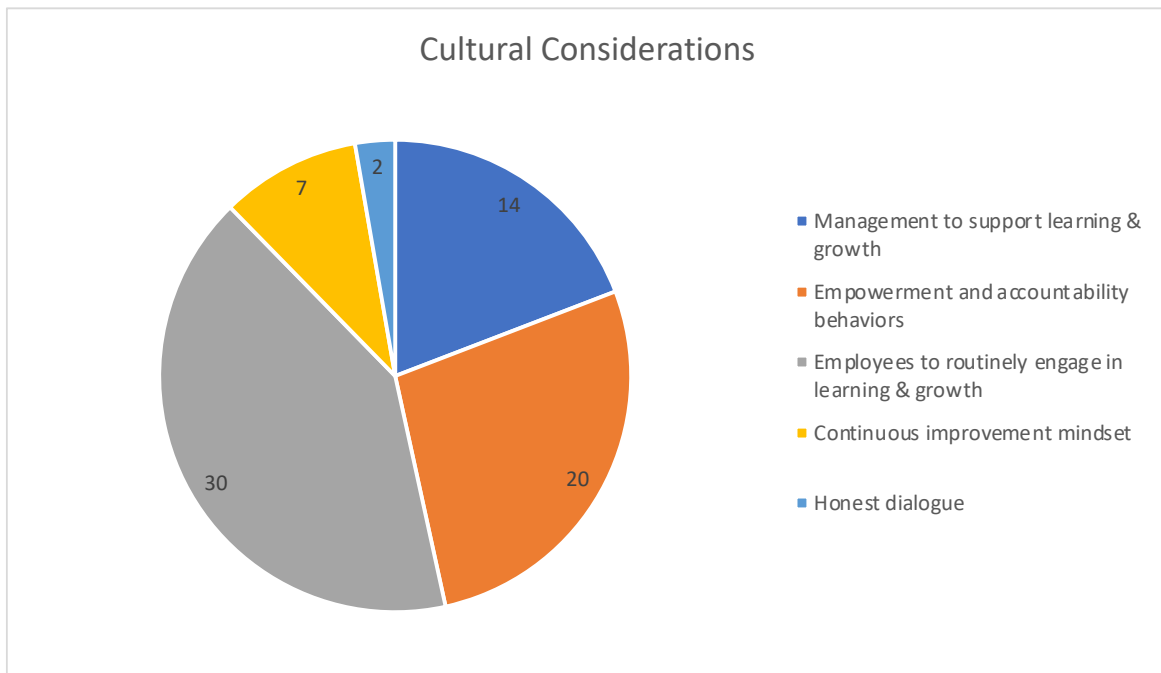
Figure 2: Culture of quality balanced with culture of excellence +

Facilitators' post-workshop reflections

It was clear that culture needs to start at the top and requires active change leadership – not just passive sponsorship – to drive change. This is in part achieved through the actions by leadership (e.g. engaging the shop floor to solve important problems, delegating decisions) and by embracing and modelling behaviours and mindsets that encourage empowerment and accountability as well as encouraging employees to routinely engage in learning and growth.

There were many helpful insights shared from the participants (presented in detail in the Appendix), including the practice of sharing knowledge and experiences across areas (both proactively and reactively as 'lessons learned'), very candid means of learning and a variety of other tactics to consider as a means of reinforcing and improving cultural excellence. The importance of sharing information about failures emerged as a prominent theme.

Facilitating the session, Nuala Calnan asked: "*Why are we so focused on measures of failure instead of measuring behaviors that result in success?"* If we focus on measuring failures instead

of measuring how we share and apply learnings from the failure, we may be preventing our people from getting it right the first time.

Workshop 2
Workshop 2 / Theme A: Exploring the 'how': leveraging approaches and tools available within the workplace for excellence

Background information shared by the workshop facilitators

> *Operational Excellence is a state of readiness attained as the efforts throughout the enterprise reach a state of alignment for pursuing its strategies—where the **corporate culture is committed to the continuous and deliberate improvement of company** performance **AND the circumstances of those who work there**—and is a precursor to becoming a **high-performance organization**.*
>
> - Paris Jr., Joseph F. State of Readiness: Operational Excellence as Precursor to Becoming a High-Performance Organization

The concept of operational excellence in pharma is by no means new to the industry. From the participants' responses, disciplines such as Lean (Toyota Production System) and Six Sigma are still commonly acknowledged vehicles for operational excellence.

Questions posed by the facilitators to stimulate discussion

Participants were asked to continue their discussions considering the following questions:

- *What is operational excellence at your workplace?*
- *What are the characteristics?*
- *Why OpEx? What are the goals?*
- *What are your common methods/tools?*
- *What are your common measurements?*

Participant perspectives and discussion

Participant responses were recorded on sticky-notes and were grouped into themes by the facilitators after the workshop. These are summarised and shown in Figure 3.
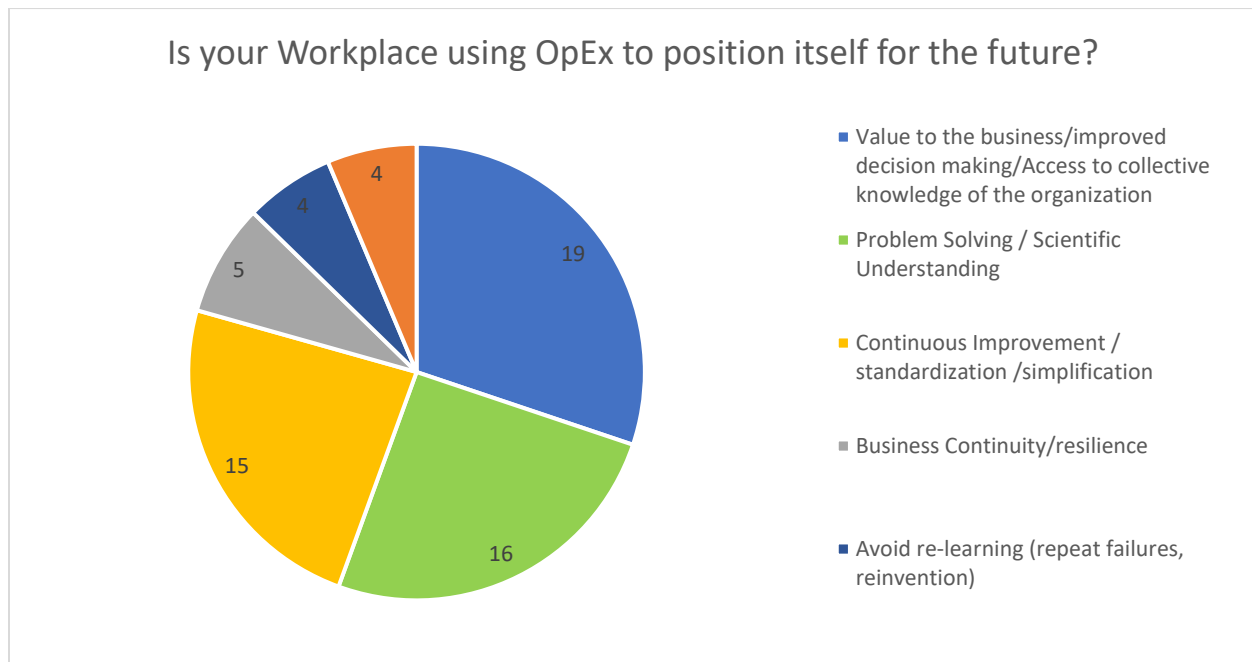
Figure 3: Is your Workplace using OpEx to position itself for the future?

Facilitators' post-workshop reflections

There is a clear acknowledgement within the themes that OpEx delivers value for the organisation and is accepted for enabling problem-solving and scientific understanding. Multiple Lean and Six Sigma tools were proposed as examples (e.g. 5S, Value Stream Mapping) to enable productivity gains, reduction of waste, to set prioritisation and focus the company's efforts.

Workshop 2 / Theme B: Key Takeaways on OpEx & KM:

Background information shared by the workshop facilitators

The facilitators opened the topic by suggesting: '*What is not frequently discussed is the connection between knowledge management, culture, and operational excelle*nce'.

Questions posed by the facilitators to stimulate discussion

- *Can you achieve, sustain, and build on operational excellence without improving knowledge flow, and vice-versa?*

- *Explore: Where do the methods, tools, and measures from OpEx & KM align?*
- *Is a culture of quality different from a culture of excellence?*
- *What is the role of KM & OpEx in the workplace of the future?*
- *What can you do to influence the culture of excellence in your organisation?*

Participant perspectives and discussion

Participant responses were recorded on sticky-notes and were grouped into themes by the facilitators after the workshop. A review of the participant responses reveals similarities across all three workshop areas as shown in Table 1 below:

Table 1: Top Three Themes in Knowledge Management, Culture, and OpEx Workshops

Knowledge Management	Culture	OpEx
Value to the business/ improved decision-making/ Access to collective knowledge of the organisation (19 responses)	Employees routinely engage in learning and growth (30 responses)	Value to the business/ improved decision-making/ Access to collective knowledge of the organisation (19 responses)
Support people / employee engagement / employee development / culture (17 responses)	Empowerment and Accountability Behaviors (20 responses)	Problem-Solving / Scientific Understanding (16 Responses)
Business Continuity/resilience (11 responses)	Management to Support Learning and Growth (14 responses)	Continuous Improvement / standardisation /simplification (15 responses)

Facilitators' post-workshop reflections

As noted by the facilitators during the workshops – the two ultimate reasons pharmaceutical companies deploy KM and OpEx are:

Reason 1: To improve individual competency or capability of the organisation to deliver on its mission

Reason 2: To Enhance Performance and Risk Reduction through optimisation of (knowledge or process) flow to achieve a balance of effectiveness and efficiency.

4. Closing comments

As we look at KM and Culture, the theme of focusing on people emerges. Supporting employees to engage, learn, grow, and develop is important. Even the OpEx goals of problem-solving and scientific understanding refers to empowering people and increasing individual competency which in turn enhances the capability of the organisation.

Interestingly, the most frequent responses by the participants for KM and OpEx focus on delivering value, enabling decision-making, and obtaining access to an organisation's collective knowledge. These themes further support the premise that KM and OpEX are disciplines that share common goals. Fundamentally, while different in methods and tools, KM and OpEx both start with the ability to recognise a problem or opportunity in the business and to bring a means of diagnosing and implementing improvements. The ISPE presentation of the *Good Practice Guide on Knowledge Management in the Pharmaceutical Industry* was referenced during the workshop [2], which further explores the commonalities between the disciplines (see Figure 4). Common goals and drivers imply there's an opening for synergy where we could leverage the best of both disciplines for our people and our patients.
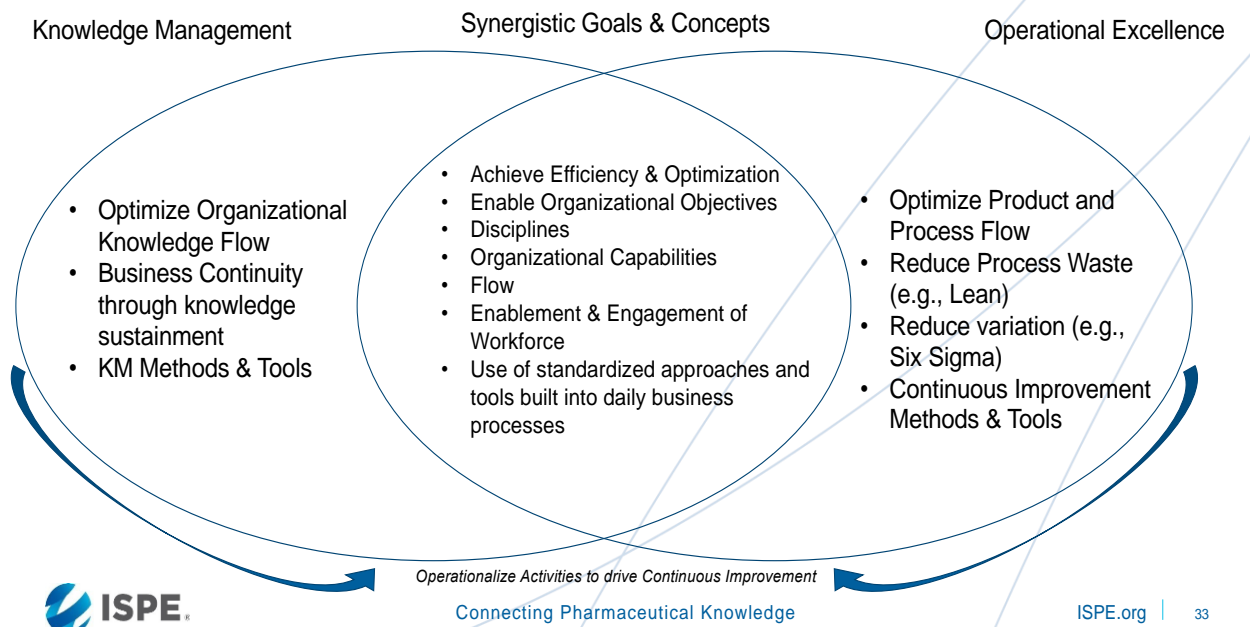
Relationship Between OpEx and KM

Figure 4: Relationship Between OpEx and KM

There are, of course, other disciplines that share opportunity (or expectation!) of synergy with OpEx and KM, and all of which would acknowledge culture as a critical foundation – such as organisational change management, data and information management, analytics, and of course, as ICH Q10 expects of us, quality risk management.

One has to ponder that if the end goals are the same, then why do we keep these disciplines separate? Additional constraints contributing to the current state may be that, especially in large organisations, various management sciences are often organised into discrete "centers of excellence" each with their own priorities, thus creating artificial organisational boundaries between these complimentary disciplines. Furthermore, industry surveys on KM reporting lines [3] report that these are highly variable, thus contributing to further variability in the understanding and application of KM.

The Cambridge dictionary defines the collection of these disciplines as "management sciences", as follows:

The use of scientific methods and ideas to understand business and management problems and decisions, or the formal study of management; Management science is concerned with designing and developing new and better models of organisational excellence. [4]

In the workplace of the future the opportunity exists to harness the shared goals of these areas to deliver safe, effective, reliable supply of medicines to our patients while identifying and managing risks throughout a product's lifecycle. Opportunity presents itself if we bring these disciplines together to get the right method and tool in the right application at the right time.

This is especially relevant given the opening remarks by Dr Hoffman.

- **Knowledge** – including ensuring the right knowledge with know-how and collaborative capability, inclusion and open spaces of exchange
- **Relationships** – humans engage around relationships – and without trust, nothing happens
- **Strategy** - Where are we trying to go? What is our destination? What is the *mission*?

Considering the ever-increasing complexity of the world we live in, and the fact that the environment continues to accelerate and change, perhaps it is time that we intentionally leverage the synergies between the disciplines in management sciences to make the most of what the future offers for pharma, its employees, and the patients.

5. References

[1]   APQC, *Knowledge Management Glossary*. Houston, TX: APQC, 2019. [Online]. Available: https://www.apqc.org/resource-library/resource-listing/knowledge-management-glossary

[2]   ISPE, "Webinar: Knowledge Management Insights and More," ISPE Pharmaceutical Engineering.

[3]   Knoco Ltd, "Global Survey of Knowledge Management 2020-2021, including trends and analyses involving the 2014 and 2017 data," 2021. [Online]. Available: https://www.knoco.com/knowledge-management-survey.htm

[4]   Cambridge, "Management Science." Accessed: Aug. 24, 2020. [Online]. Available: https://dictionary.cambridge.org/us/dictionary/english/management-science

Appendix: Participant input captured on sticky-notes during workshop breakouts

Workshop 1 / Theme A participant input on sticky notes

- added value and return on investment
- allows for root cause of deviations
- avoid previous pitfalls - deviations, failed changes, projects
- avoid re-inventing the wheel
- break down silos
- build on knowledge
- business continuity
- business continuity of tacit experience
- Capture history - product knowledge, equipment knowledge, systems knowledge
- capture knowledge as it walks out door
- collate the collective wisdom of the team
- competitive advantage
- compliance
- consistency of knowledge use
- create a forward-looking culture
- create positive culture
- creative approach
- crisis resilience
- cross-functional to improvement of process that ultimately benefit the patient
- data vs. insights
- decrease uncertainty
- eliminate dependency on relationships
- employee retention
- expanding teams need background
- facilitate continuous improvement
- facilitate decision making
- gen Z - 2 years is a long time on the job
- happy employees
- help find solutions
- help new team members
- high turnover
- improve/enable business decisions
- improved profitability
- Improvement of greater understanding
- improvement of processes
- improvement of speed of learning
- increase availability of information
- know areas of risk

- knowledge retention
- knowledge sharing
- knowledge sharing gives purpose to create culture
- make better risk-based decisions
- make employee handover easier
- manage complex data
- manage complex information
- manage product lifecycle
- mapping knowledge location and gaps
- maximize effectiveness of training
- Measures of success instead of failure
- mitigate against loss of knowledge via attrition
- patient safety, quality decisions
- people confined knowledge
- prevent problems from reoccurring
- prevent repeat incidents
- problem solving
- problem solving through collaboration
- reduce non-conformances
- right information right time
- right information, right people, right time
- root cause identification
- share and record data driving decisions
- share different experiences for risk
- share good ideas (improvement)
- simple and effective technical transfer
- simplify repository of information
- single point dependency of knowledge - people leave, knowledge leaves
- standardization
- succession planning
- succession planning
- sustain project as people change
- thorough tech transfer of manufacturing and testing
- transfer tacit knowledge
- transform ideas into results
- transparency
- we aspire to be a learning organization

Workshop 1 / Theme B participant input on sticky notes

- align with corporate strategic plan
- all-team lunch
- be humble
- brave
- chats with lead team
- coffee chats
- continuous learning culture
- Create a community of belonging
- create white space for innovation
- cross projects
- demonstrate from the top
- department expo showing what is done in the area
- department open doors
- department rotation
- develop radical candor
- don't get defensive
- emails
- empower staff
- empower staff
- empowerment
- encourage and support initiatives
- encourage culture of learning
- encouraging curiosity
- find out what happens in other departments
- first team responsibility (safe space)
- from the top down
- global learning and growth program
- go to the line for issues
- graduate programs
- hard on ideas soft on people
- hold leaders accountable for development conversations
- inclusion in learning
- inclusion in training
- inclusion in training and learning
- integrated teams
- inter-team communications
- interactive small group sessions
- join ups/signs ups
- leaders and managers ask operator to solve
- lessons learned shared across areas
- linked in learning
- mentorship program
- my best mistake
- my development conversations
- news
- no blame
- No-blame culture
- on the job coaching (process mapping workshops)
- open
- open door discussions
- open door policy
- open to delegation
- operational excellence programs
- operations, QA, QC on same team
- own your career
- psychological safety to speak
- quiet Fridays to focus on learning
- reverse mentorship
- rewards
- right level of decision making
- rotations
- sharing of knowledge
- site in network meetings
- Three C's - curious compassion considerate
- Top-down feedback
- tour of duty in different areas
- transparency of knowledge
- two-way mentorship
- webinars
- what's in it for me
- white space
- willingness to learn
- workshop with stakeholders

Workshop 2 / Theme A participant input on sticky notes

- 5S
- capability tracking
- collective risk assessment
- compliance across all disciplines
- cost of goods
- create process improvement
- cycle time
- reduce time-between-batches
- decrease variation
- digital brainstorm
- eliminate waste
- empowerment
- encourage use of tools
- enhances impact assessment
- fishbone
- good business
- good business sense
- good process sense
- implement effective solutions which eliminate issues
- improve process
- improve productivity
- increase operational equipment efficiency
- increase productivity
- increase right first time
- right first time
- risk based decisions
- safety quality delivery cost SQDC
- set priorities
- simplify process
- simplify system processes
- sustainability
- system improvement
- turnaround time
- underscore all aspects of the business
- value stream mapping
- visualization of problems
- yield
- yield
- problem solving

- increase yield
- influence behaviors
- influence culture
- key process indicators
- knowledge sharing
- lean-six-sigma
- lean-six-sigma
- lean-six-sigma
- lean-six-sigma
- maintain delivery
- maintain quality
- maintenance prevention
- measure monthly performance
- operational excellence and quality for everyone
- plant utilization
- PPM defects
- practical process improvement
- process improvement
- process reliability
- quality inter-link
- quality risk management tools
- reduce cost
- reduce waste
- remove non-value-added activities