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"Transitioning organisations from a data quagmire to knowledge nirvana through the digital thread"

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Transitioning organisations from a data quagmire to knowledge nirvana through the digital thread

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Abstract

Historically, organisations have managed product data in a combination of Microsoft Office, Sharepoint and Document Management Systems. In this paper, we explore how different technologies can be leveraged to create digital product profiles, and in doing so structure data to enable effective knowledge management.

Introduction

As with many industries since the pandemic started, the Life Science industry has had to reinvent itself in a number of different ways, and, while reinventing "ways of working" it also progressed the development of vaccines and led the charge as the world battled with COVID.

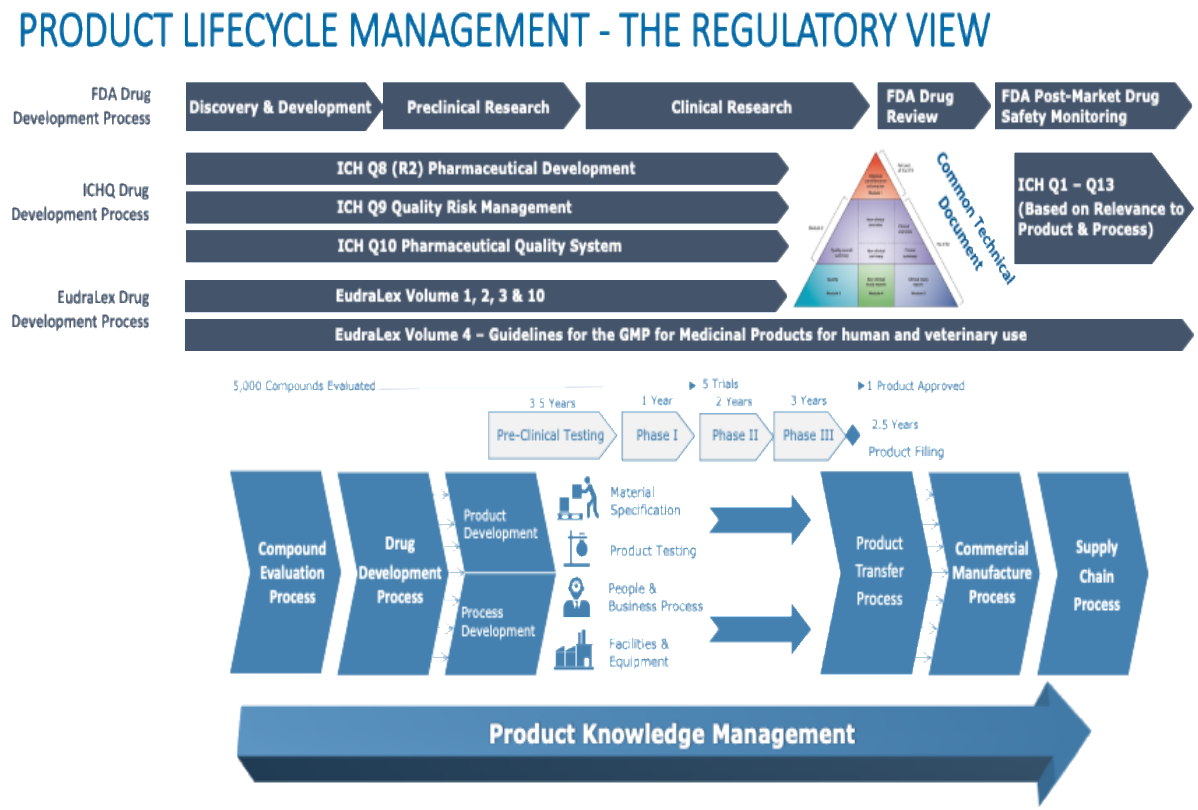
However, before mRNA and viral vectors became conversations at the dinner table, the industry had already started the "new science" evolution. Personalised medicine, such as cell and gene therapy, continues to push the industry from treatment-based care to curative. Similar to the tech start-up model in Silicon Valley, Life Science is being disrupted by new small and more agile companies. With this disruption the boundaries of innovation are being expanded at a rate of change that has not been seen before. Chimeric Antigen Receptors, Oncolytic Virus, Antibody-Drug Conjugates are bio-engineering on new levels.

The Challenge

While it is an incredibly exciting time to be working in the sector, companies are still plagued by the legacy of being digital laggards. For all of the advances in science, the enabling units have struggled to keep pace. R&D, Manufacturing and Supply continue to operate in a

somewhat siloed fashion, and manual processes and procedures are often the default mode of operation. This tendency to be overly reliant on manual processes is constraining the business as companies come under pressures with products becoming more complicated to develop and manufacture. In addition to product complexity, speed to market has been redefined by the pandemic which has set a benchmark for all future treatments.

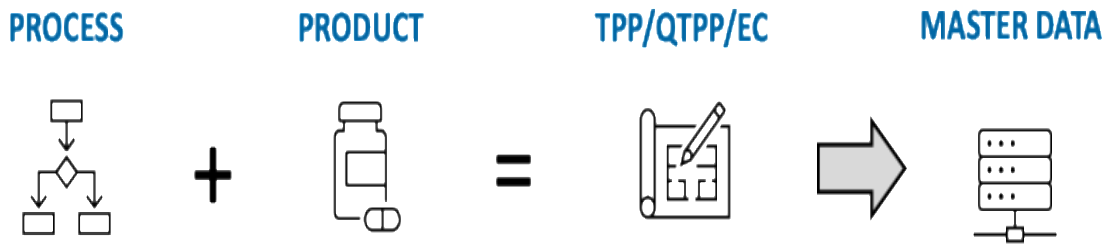
As the industry looks forward to a new horizon it needs to look back at an old challenge: Product Lifecycle Management. To date, as drugs are brought to market, they work through a series of distinct development phases and business units. From starting out in research, companies need to consider how products can be developed safely at scale and speed while ensuring complex regulatory and business requirements are adhered to. Historically, development and commercialisation processes have not leveraged the full potential of technology and data. For example, technology transfer is governed via manually executed procedures and recorded as static word or pdf files in a Data Management System (DMS). This makes it a challenge for companies to ensure data integrity and to gather business intelligence.



Driving forces for PLM & the Digital Thread

Product Lifecycle Management (PLM) and Digital Thread which are both interchangeable, and are widely adopted frameworks within other industries. The automotive, aviation and electronics industries have used these concepts to drive transformational changes within their organisations. While not new to those working in Life Science, their adoption has been somewhat limited with the exception of medical devices. One of the main reasons for this being the nature of PLM for biopharmaceutical products is different i.e.

PLM f(x) Product Specifications + Process Design = TPP/QTPP/EC[1] → Master Data.



The relationship of product and process data to create target product established conditions is a level of complexity PLM solutions have not dealt well with previously. These quality characterisations are imperative to ensure product safety and efficacy. Product profiles are made up of complex and diverse data sets including materials, equipment, business workflow etc., a subset of which then needs to be managed as master data to support operational execution.

From a regulator perspective, ICH Q12 (Technical and Regulatory Considerations for the Pharmaceutical Product Lifecycle Management – November 2019), and the FDA's publication of the Q12 Annex for industry May 2021, are clear indications regulatory and quality organisations see the potential for PLM to harness the power of process and product data. The following quote is extracted from the FDA guidance document:

[1] TPP = Target Product Profile, QTPP= Quality Target Product Profile, EC = Established Conditions

> *"A holistic view of the manufacturing process and control strategy is necessary when considering Established Conditions since the output of one unit operation is the input for subsequent operations."*

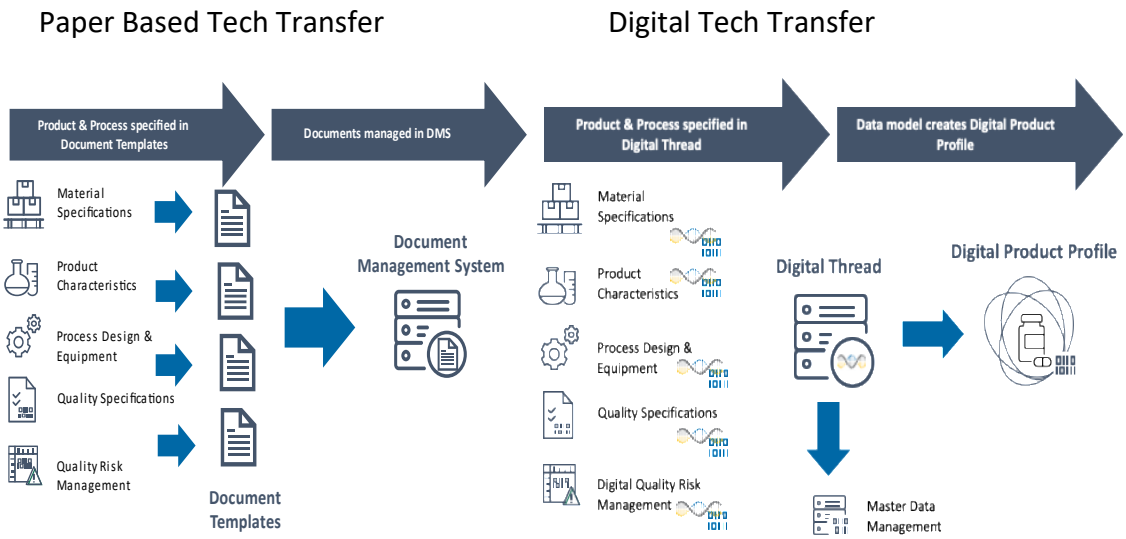
Given the increasingly complex nature of the business processes, the utilisation of data will be key to ensuring regulatory compliance. Having a system that can enable users to view and manage data sets in a business context will not only address the quality requirements, but also ensure organisations can optimise life cycle activities through research, development, tech transfer, manufacturing and supply.

The Digital Thread for Life Science is a product and process information framework that enables users to define and manage all associated data and knowledge to create a digital product profile.

Practically applying the Digital Thread

The practical application of the digital thread concept in technology transfer enables companies to specify and manage products and process design in a new and innovative way. Rather than populate document templates, such as control strategies, process definition, quality control test plans etc., the digital thread enables the business to record data in a knowledge management framework.

The image below provides a conceptual overview as to how paper-based tech transfer compares to a digital thread-based tech transfer.



The illustrations below provide an overview of product journeys in a pre and post digital environment.

Sending Site, A

Documentation transferred

Receiving Site, B

CONTINUOUS ITERATIVE MANUAL PROCESS

Phase 0: Site Selection

- Multi site product fit evaluation (paper based). Difficult to facilitate due to manual nature of previous tech transfers.
- Down selection of site completed.

Phase 1: Product Fit

Defining:

- Materials & equipment specifications.
- Product/process characterization (QTPPs & ECs).
- Quality specifications (e.g. QCTP).

Reporting:

- Tech transfer team are creating multiple different documents & reports, (e.g. control strategy, process descriptions, etc).
- Documents are managed via SharePoint and governed via DMS.

Receiving:

- Receiving site team starts to fit product to site processes.
- This process from defining to receiving can be subject to multiple iterations and change. Manual nature of process and documentation impedes efficiency.

Phase 2: Product/ Process Configuration

Product/Process Config:

- Design and build of business process (e.g. EBRs, equipment recipes, master data config etc.)
- Translation of product/process specifications into systems.

Process validation:

- Commissioning, qualification and validation of the product and process.

Phase3: Qualified Recipe to Manufacture

Unintended changes:

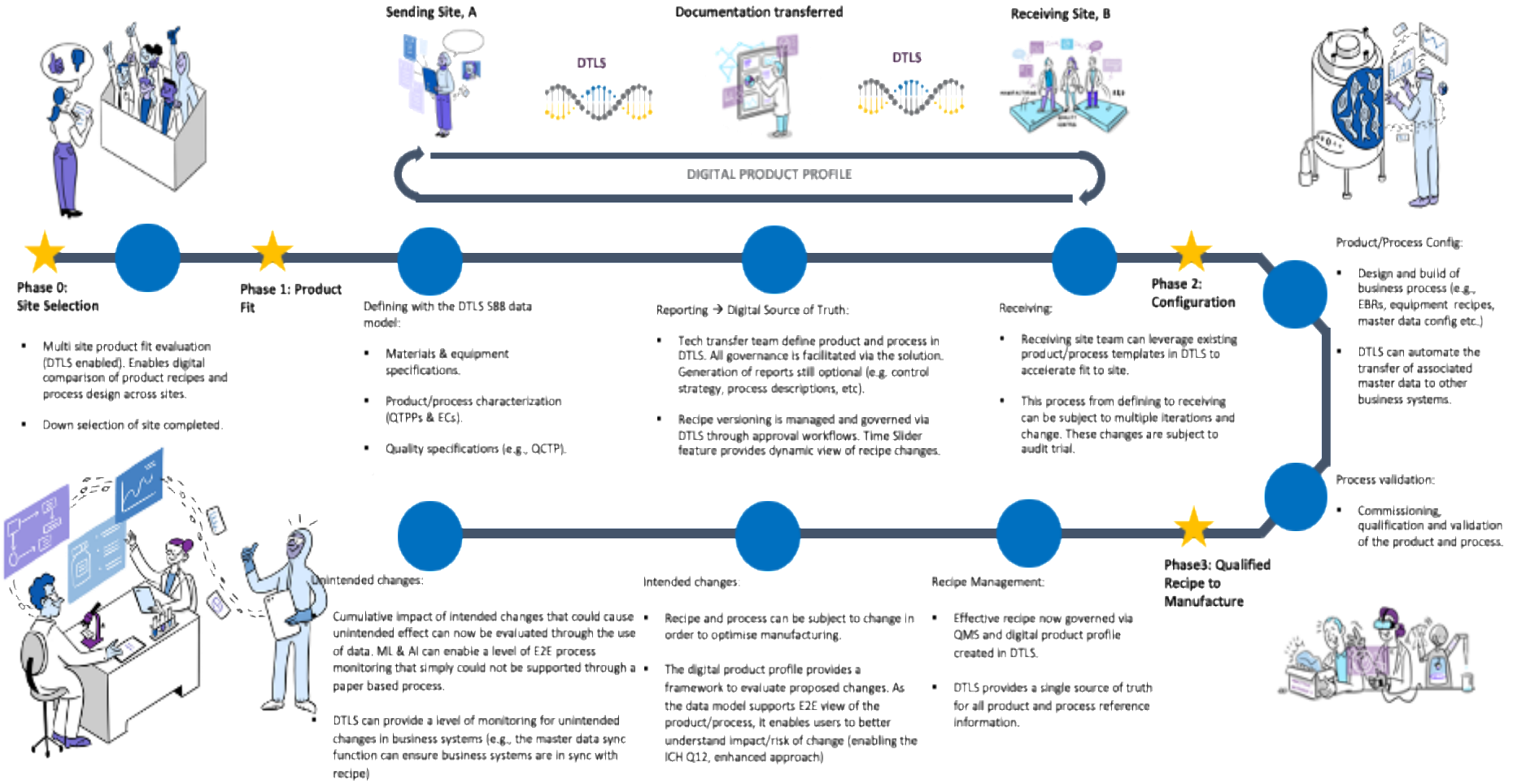
- Cumulative impact of intended changes that could cause unintended effect. It can be difficult to evaluate the E2E impact of changes because the product/process is defined in paper.
- It can be challenging to govern unintentional changes as the business systems may fall out of alignment with documented product/process specifications.

Intended changes:

- Recipe and process can be subject to change in order to optimise manufacturing.
- Due to manual nature of recipe management via documents, it can be difficult to holistically assess impact of change. (ICH Q12, minimal approach vs enhanced approach.)

Recipe Management:

- Effective recipe now governed via QMS & DMS.
- Product and process documentation stored in DMS – can be difficult to maintain.


PRODUCT JOURNEY DIGITAL THREAD TECH TRANSFER
Sending Site, A
DTLS
Documentation transferred
DTLS
Receiving Site, B
DIGITAL PRODUCT PROFILE
Phase 0:
Site Selection
Multi site product fit evaluation (DTLS enabled). Enables digital comparison of product recipes and process design across sites.
Down selection of site completed.
Phase 1: Product Fit
Defining with the DTLS S88 data model:
Materials & equipment specifications.
Product/process characterization (CQTPPs & ECs).
Quality specifications (e.g., QCTP).
Reporting → Digital Source of Truth:
Tech transfer team define product and process in DTLS. All governance is facilitated via the solution. Generation of reports still optional (e.g. control strategy, process descriptions, etc).
Recipe versioning is managed and governed via DTLS through approval workflows. Time Slider feature provides dynamic view of recipe changes.
Receiving:
Receiving site team can leverage existing product/process templates in DTLS to accelerate fit to site.
This process from defining to receiving can be subject to multiple iterations and change. These changes are subject to audit trial.
Phase 2:
Configuration
Product/Process Config:
Design and build of business process (e.g., EBRs, equipment recipes, master data config etc.)
DTLS can automate the transfer of associated master data to other business systems.
Process validation:
Commissioning, qualification and validation of the product and process.
Phase3: Qualified Recipe to Manufacture
Unintended changes:
Cumulative impact of intended changes that could cause unintended effect can now be evaluated through the use of data. ML & AI can enable a level of E2E process monitoring that simply could not be supported through a paper based process.
DTLS can provide a level of monitoring for unintended changes in business systems (e.g., the master data sync function can ensure business systems are in sync with recipe)
Intended changes:
Recipe and process can be subject to change in order to optimise manufacturing.
The digital product profile provides a framework to evaluate proposed changes. As the data model supports E2E view of the product/process, it enables users to better understand impact/risk of change (enabling the ICH Q12, enhanced approach)
Recipe Management:
Effective recipe now governed via QMS and digital product profile created in DTLS.
DTLS provides a single source of truth for all product and process reference information.

By defining the product and process in a digital thread framework, teams are able to leverage the DTLS platform as a single source of truth. This provides the business with a series of benefits, as follows:

- Enables multiple users to quickly access a broad set of product and process data in an industry contextualised standard.

- The data model automates product genealogy making it easier to identify and track changes.

- Digitising process design enables the creation of templates which can be used to accelerate fit/gap assessments as products are transferred between sites.

- Having defined the product in a digital context it becomes easier to manage changes through the lifecycle post tech transfer.

- The digital thread supports quality management by automating the tracking of changes and risk management evaluation.

In closing, while the digital thread does not resolve all of the business challenges within lifecycle management, it is enabling organisations to transition from paper-based business processes to digital ways of working. By providing tech transfer teams with data frameworks that automate and simplify tasks, they can focus on higher-value activities. This should ultimately help companies to use data to drive knowledge.