Efficient Technology Transfer in Pharmaceutical Industry Through a PLM-based Collaborative Platform

Abstract

Pharmaceutical drug development is an extremely long and arduous process involving high technology transfer costs. Not surprisingly, the average cost of 'discovering' a drug is estimated at US$2.87 billion. In addition, drug development processes such as, recipe management, material and equipment handling and batch processes are fragmented at most companies, making it difficult to improve efficiencies and streamline the process.

Given the complex nature of the drug discovery process, pharmaceutical manufacturers need to digitize their processes to effectively manage the information flow. A Product Lifecycle Management (PLM) based collaborative platform, will help them ensure reduction in costs and timelines across the product lifecycle - from drug development to pharmaceutical manufacturing.

PLM-based recipe restructuring aligned with the ISA-S88 standard utilizes reusable library components in sync with standard industrial taxonomy. The result: harmonization of processes, enabling manufacturing efficiencies and faster time-to-market. A collaborative PLM platform can improve manufacturing efficiency by nearly 40% and reduce paperwork by around 30%.

From Lab to Launch – The Challenges on the Road to Drug Development

The drug development process from R&D to commercial manufacturing involves a series of interdependent steps. The long-drawn process often lasts more than a decade and on average, costs approximately US$2.87 billion. The process starts with identifying targets and drug candidates in the R&D stage. Thereafter, the active pharmaceutical ingredient (API) is formulated into a drug product, followed by a series of physio-chemical and toxicological evaluations. The formulated drugs go through clinical trials and are pushed into marketing after regulatory approvals.

The discovery of pharmaceutical drugs is often slowed down by various strategic, tactical, and operational challenges (as illustrated in Figure 1). Technology transfer of standard experimental procedures at various levels, from R&D to pilot to manufacturing is still a largely manual process. Challenges can be further aggravated by industrial sites straddling multiple geographies and governed by different regulations. The lack of consistency in terminologies and standard taxonomy employed in methodologies across various sites mandates the need for an efficient recipe management model, which is reproducible and acceptable across geographies.

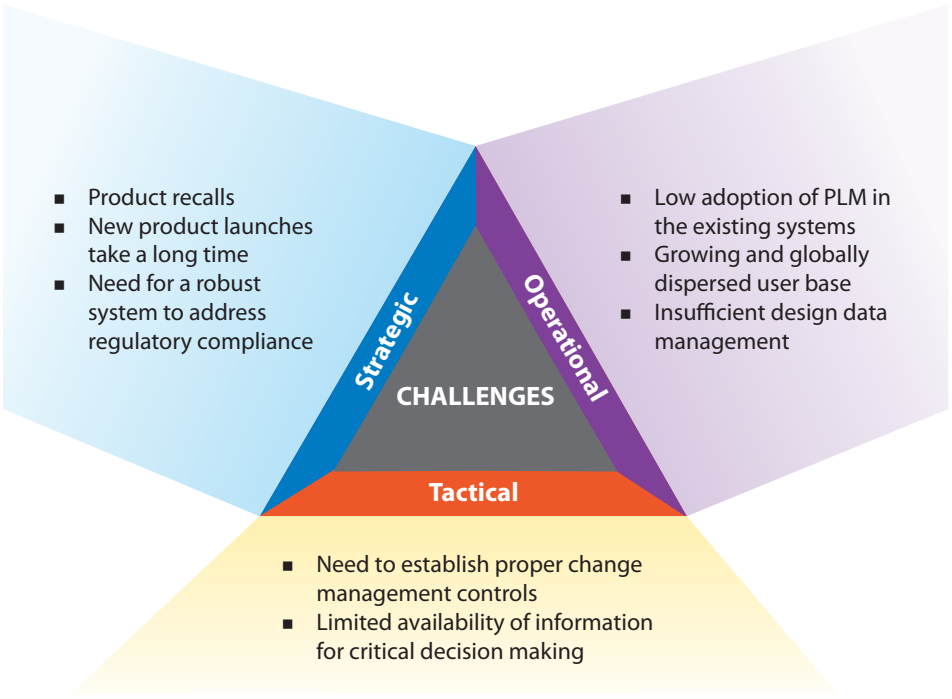

Figure 1: Strategic, tactical, and operational business challenges in drug development

A technology package designed for the rigors of drug development and approvals ideally consists of four major parts - protocols, people, materials, and external resources or agencies (as illustrated in Figure 2).

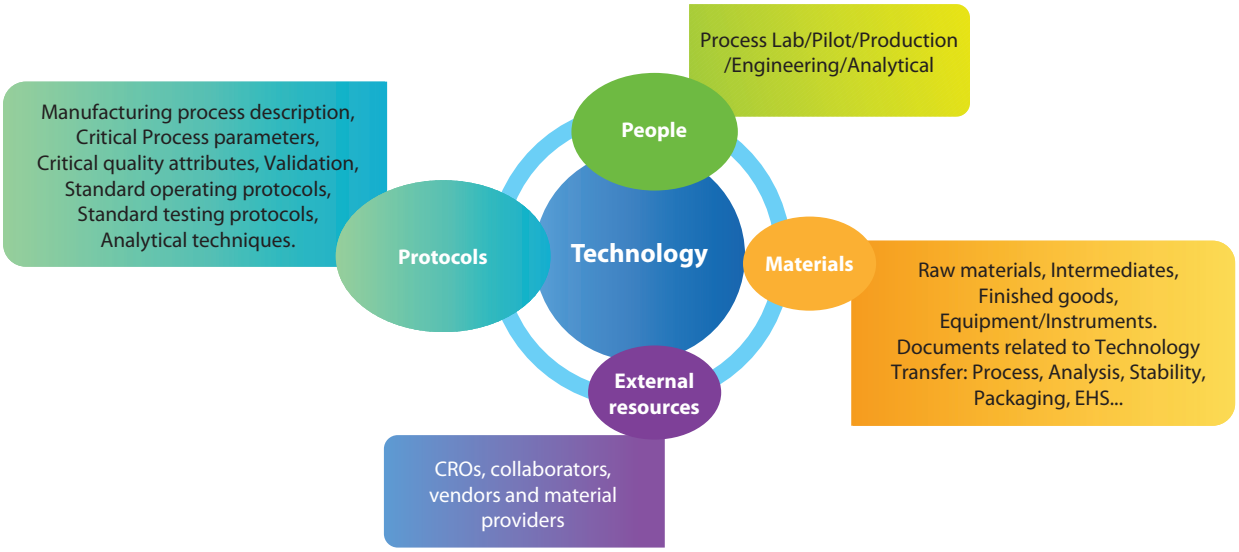

Figure 2: Components of the Technology package of drug development process

A Collaborative PLM Platform Approach Holds the Answers

The challenges in the drug discovery process lead to a lack of uniformity in the way observations are recorded during the process development stage. As a result, recipes are short on granular details, leading to non-reproducibility of the technology package across sites. The recipe drafting process is not standardized across the industry. It undergoes redrafting at various stages to suit the geographical site requirements. In addition, the need for human input for explaining the prepared recipes and processing technology transfer, combined with the variation in the available infrastructure at various sites, results in restructuring and re-standardization of the procedure.

Besides, paper-based documents lead to difficulties in traceability of process development procedure, causing delays in trouble shooting in the case of technology transfer failure. Clearly, there is an urgent need for a collaborative platform to bring various interdependent components of a technology package together, enabling them to work in harmony.

This is where a collaborative PLM platform can add significant value.

Multi-site production companies require an efficient recipe development model with a robust modular structure: one that is shared among local laboratories and plants. Pharmaceutical companies are rapidly adopting the ANSI/ISA-S88 standard that provides a consistent set of standards and terminology for batch control and defines the physical model, procedures, and recipes in process control and automation. Companies are embarking on initiatives to create a modular structure-based transformation process for the development and transfer of recipes for future products.

A PLM solution can help reduce process variability and batch recipe development time. The use of PLM eliminates human errors in the recipe creation and management process and guarantees effective communication, capturing all the ANSI/ISA-S88 data, including flows and parameters, in a single format. This provides a mechanism for content reuse, which is critical to recipe harmonization. In essence, PLM efficiently addresses the business need for efficient content management, execution and visualization, and reduction of time to market.

Figure 3 illustrates the As-Is and To-Be scenarios for accelerating the drug development process leveraging PLM.

As-Is	To-Be
Lack of structure in manufacturing recipe	ISA-S88 based recipe
Process and product parameters not connected to execution / regulatory filings	Consistency in content management
Islands of automation, lack of integration between information systems	ISA-S95 based integration of information systems
Non-availability of production and analytical information in real time	Access to production and analytical information in real time

Figure 3: As-is and To-be scenarios for accelerating the drug development process

Recipe Re-structuring: Using PLM-based Platform Aligned to ISA-S88 Standards

Recipe restructuring based on ISA-S88 standard consists of the steps summarized in Figures 4a and 4b. As a first step, materials and equipment are classified into re-usable libraries based on the recipe generated at the R&D level and categorized based on physiochemical properties. They are allocated to various sites depending on utilization. For instance, R&D sites, pilot, and commercial manufacturing plants and so on.

Figure 4a: Recipe Re-Structuring Using PLM Platform Aligned to ISA-S88 Standard

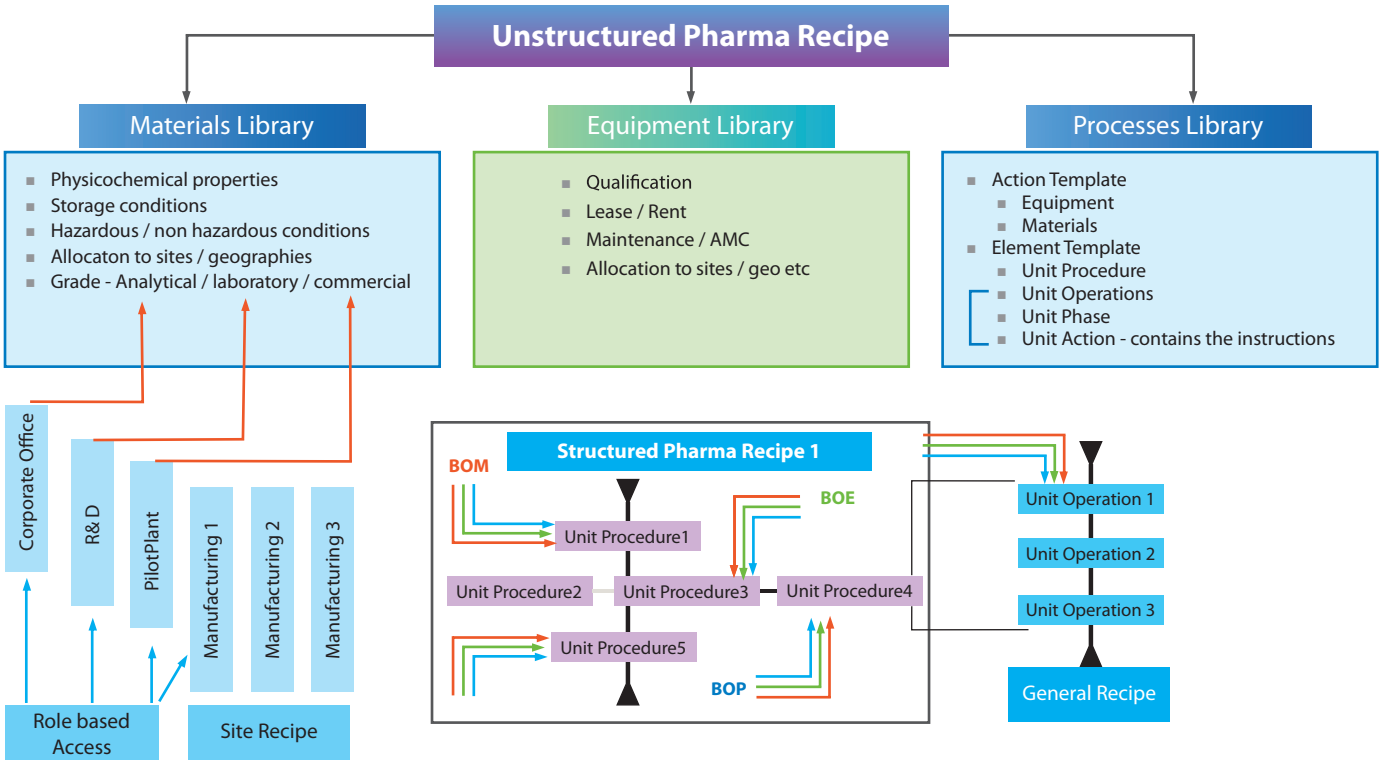

Figure 4b: Recipe Re-Structuring and Role Based Access in Organizational Structure

The process flow is then broken down into action and element templates, which are further organized into unit procedures. Dissecting the recipe into unit procedures allows generation of reusable components, which can be reproduced in various recipes across the production chain. Utilization of identical unit procedures across manufacturing units and sites leads to uniformity in terminology and eliminates inconsistency, thereby facilitating reproducibility across industrial sites.

Solution Architecture for the Collaborative Platform

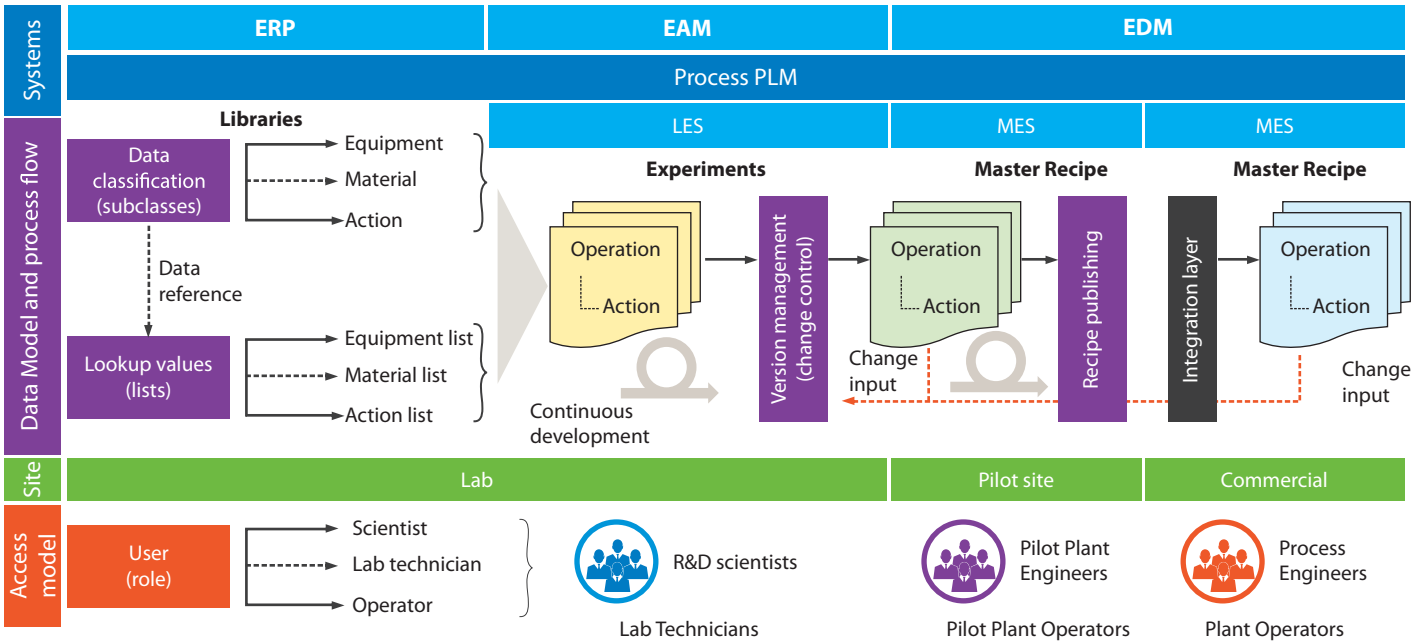

Figure 5: Architecture of Collaborative PLM Platform

The collaborative platform (architecture illustrated in Figure 5) ensures seamless integration of data received from Lab execution systems with the PLM platform. The seamless interconnectivity ensures consistency in taxonomy at various levels, driving faster information transfer and execution. It also ensures uniformity in the way observations are recorded during the process development stage to retain granular details, resulting in reproducibility at the receiving end.

Reimagining PLM for Evolving Digital Pharma Needs

While on the product front, pharma companies are renowned for being innovative and discovering drugs to heal stubborn ailments, their manufacturing processes have been lagging on the technology adoption front for decades. With the industry striving to accelerate development time in response to global economic challenges, new capabilities such as product and process data management, collaboration, and analytics are emerging as top priorities.

PLM offers a holistic approach to optimize drug manufacturing processes and product quality and industry players are taking note. Leading pharma companies such as Sanofi, GlaxoSmithKline PLC, Johnson & Johnson and Novartis AG are leveraging PLM to redefine operational efficiencies in drug development and reduce time to market. However, the key factor in successfully implementing PLM-based collaborative solutions is to use the right design and solution architecture as it can differ from other industries and even from one pharmaceutical company to the other. Collaborating with a technology firm with expertise in drug development, manufacturing, and system integration can help establish a digital thread from R&D to manufacturing, creating a truly connected manufacturing enterprise.

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