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Review Article

INTEGRATION OF PROJECT-PRODUCT LIFECYCLE IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

One meaningful and holistic approach to today's current challenges within the pharmaceutical industry is to focus on Product Lifecycle Management (PLM). PLM has provided many pharmaceutical organizations with the ability to get products to market quicker, ensure greater regulatory compliance and efficiencies while reducing development costs. A product life cycle is a conceptual map of - where a product's sales are and where they may be headed. However, it has no comment on what to do with the product. If a company believes its product is entering the decline phase, it will probably create a plan to either rejuvenate the product or cease production, but that is not inherent in the product life cycle. Thus, comes the concept of project life cycle (PLC), which is all about action. A project life cycle maps out the steps needed to complete a project with specific targeted results. Although these two lifecycles are talked about separately but if integrated can be of greater use to an organization.

Keywords: Product Lifecycle Management (PLM), Project Life Cycle (PLC).

INTRODUCTION

The evolving nature of pharmaceutical industry has fuelled interest in the discipline of PLM as a way of sustaining growth and profitability in the pharmaceutical industry. The product life cycle represents the amount of revenue a drug product generates over time, from its inception to the point where it is discontinued. The four stages of a product's life are development, growth, maturity and decline. On the other hand, a pharma project life cycle (PLC) measures the work that goes into a project from beginning of drug development to its launch in different markets. The phases in project life cycle are initiation, planning, execution and closure.

Integrating the two life Cycles i.e. Project Life Cycle and Product Life Cycle for a Pharmaceutical Project gives a better understanding of drug product throughout the project life cycle. It also helps in minimizing the time & cost of drug product development along with maximizing the revenues. In this paper we have developed a framework which integrates both the cycles and depicts how this integration can be useful.

Pharmaceutical Product Lifecycle

In Pharmaceutical Industry product lifecycle begins with the development of pharmaceutical product or drug product. ICH Q10 Guideline, which is globally accepted, divides the drug product lifecycle into following four stages:

- Pharmaceutical Development: This activity may involve development of -
  - Drug substance(s)
  - Formulations

Fig. 1- *Stages of Pharmaceutical Product Lifecycle*

- Investigational products
- Delivery system(s)
- Manufacturing process followed by its scale-up
- Analytical method

- Technology Transfer: Technical know-how is transferred from one site to another for-
  - New products (from Development to Manufacturing sites)
  - Marketed products (from Manufacturing to Testing sites)
- Commercial Manufacturing: Manufacturing pharmaceutical products on large scale may involve-
  - Acquisition and control of materials
  - Provision of facilities, utilities, and equipments
  - Production (including packaging and labelling)
  - Quality control and assurance
  - Release of drug product
  - Storage of drug product
  - Distribution of drug product

The above mentioned elements overlap each other and together form a quality system, as represented below diagrammatically:

Fig.2- *Pharmaceutical Quality System*

- Product Discontinuation: Once a product attains maturity in the market and similar product with better specification enter the market, the old product may be discontinued. However, during this process following things need to be ensured-
  - Retention of documentation
  - Sample retention
  - Continued product assessment and reporting

Pharmaceutical product lifecycle duration & cost is different for an investigational drug product or new drug product and a generic drug product. The estimates as per literature review are tabulated below.

Table1- Duration & cost for investigational drug product & generic drug product

Drug Product Type	Time (Years)	Cost (Million $)
Investigational/New drug product	12-15	1300
Generic drug product	3-5	3.5

Pharmaceutical Project Life Cycle

A Pharmaceutical Project undergoes one or more of the following phases of project life cycle:

- Feasibility: During feasibility phase, a business case is identified and it captures following points-
  - Description of the problem or opportunity e.g. disease requiring attention
  - List of alternative solutions available like various forms of formulations which can be developed for a disease
  - Analysis of business benefits, costs, risks and issues e.g. Sales forecast of a drug product
  - Description of preferred solution like overcoming patent and regulatory challenges
  - Summarized plan for implementation e.g. plan for drug development

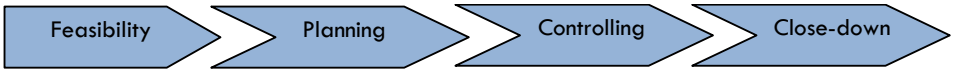

***Fig. 3**- Project Phases of a Pharmaceutical Project*

The purpose of a feasibility study is to assess the likelihood of each alternative option and achieve the benefits outlined in the business case. The feasibility study also investigate whether the forecast costs are reasonable, the solution is achievable, the risks are acceptable and the identified issues are avoidable.

If the outcome of feasibility is positive, a new project is planned. Project manager along with project team is nominated and project objectives, scope, deliverables are defined in form of Project Charter. When project charter is made, project resources, project budget, risks, issues and constraints are also listed. This paves way for next phase of project life cycle which is planning. Thus, starts the journey of a new project.

Planning: Following plans are created and maintained in Project database for tracking of Pharmaceutical project while it is in operational phase -

- Project plan (development & manufacturing activities/tasks, their dependencies and timeframes)
- Resource plan (scientists, equipments and raw materials required)
- Financial plan (cost of manpower, equipments and materials)
- Quality plan (drug product quality, assurance and control measures)
- Risk plan (potential risks during drug development and actions to mitigate those risks)
- Acceptance plan (drug product specifications)
- Communication plan (inform stakeholders timely)
- Procurement plan (raw materials for drug product development from external suppliers)

Controlling & Co-ordination: This is the longest phase of the project in terms of duration. It involves implementing the plans created during the project planning phase. While each plan is being executed, a series of management processes are undertaken to monitor and control the deliverables of the project. This includes identifying change, risks and issues, reviewing deliverable quality and measuring each deliverable produced against the acceptance criteria. In a Pharmaceutical project following activities are grouped under this phase-

- API Development (monitoring activities related to development of Active Pharmaceutical Ingredient)
- Formulation Development (monitoring activities related to development of formulations using Active Pharmaceutical Ingredient & excipients)
- ICH Stability (technology transfer to manufacturing site & manufacturing drug product in larger quantities)
- Clinical Development (Bioequivalence & toxicity studies)
- Regulatory Procedure (Regulatory submission and approval of drug product by Regulatory Agency)

Once all of the above listed activities have been completed and the product is launched, the project is ready for closure.

Close-down: This is winding-up of the project and specifically determines-

- Whether all of the project completion criteria have been met
- If there are any outstanding project activities, risks or issues
- If all project deliverables and documentation are handed over to the customer
- If supplier contracts are terminated and project resources are released
- If the closure of the project is communicated to all stakeholders and interested parties

Integration of Project-Product Lifecycle in a Pharmaceutical Industry

From above discussion, it is seen that a Project Life Cycle is contained in a Product lifecycle and can be diagrammatically represented as follows:

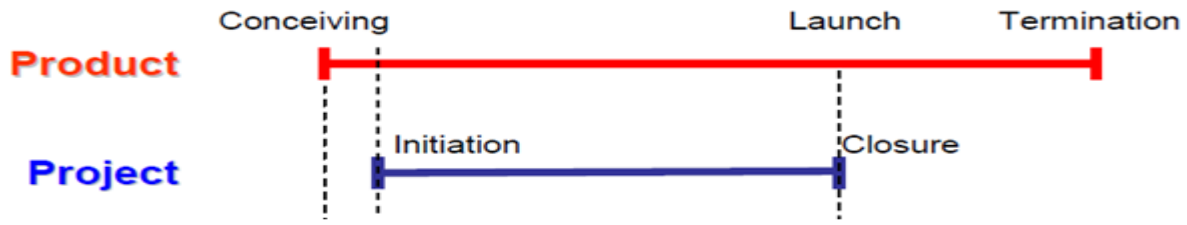

***Fig.4**-Fusion of Product-Project Life Cycle*

If we map Project and Product lifecycle we see that Project-Product Lifecycle Management is a combined effort aimed at developing a methodology for fusing the product to be developed with the project. More specifically, this fusion is intended to develop an underlying holistic conceptual model based on a shared ontology with a pharmaceutical environment for an integrated project and product lifecycle support. This will enhance drug product quality and project lifecycle management capabilities, yielding significant cuts in time-to-market, project risks, and product disqualifications.

Significance of integrating Project-Product Life Cycle in Pharmaceutical Industry

Since, drug product specific and pharma project specific data are managed separately using different tools, they are not interlinked. This prevents free flow of vital information, at the required situation, in an appropriate format, to the right people, so that they can make the right decisions.

In case the relevant project and product data had been appropriately managed under a unified umbrella, the various data elements could be converted into valuable information at critical decision points. When some project data will be combined with the relevant product data, the calculated lifecycle cost would be more realistic, providing tangible benefits to all the stakeholders. Therefore, a framework with Project-Product Lifecycle management (PPLM) approach is derived, which requires both product and project data. This framework is obtained by Product Management PPLM Derivative process and Project Management PPLM Derivative process, respectively. The data could be extracted from appropriate management toolset. The PPLM outputs will be introduced back to the management teams, to be used as part of the Product-Project Management PPLM Derivative processes. The framework is diagrammatically represented below-

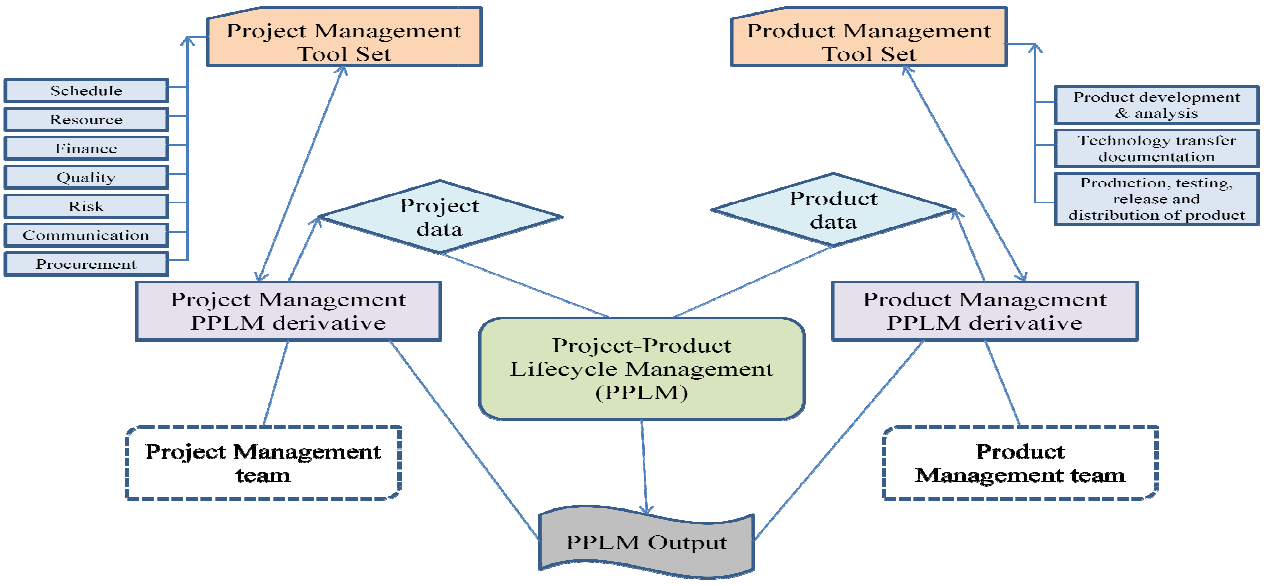

***Fig.5**-Project-Product Lifecycle Management (PPLM) Framework*

CONCLUSION

Pharmaceutical development is a complex process, which requires collaboration of multidisciplinary teams, coordination of processes, methods and tools, allocation of resources and utilization of adequate facilities. The development and Management of a Pharmaceutical product comprises of three different domains - product, project and organization, which are interlinked but use their own processes and toolsets. This conceptual separation hinders effective handling of the project and product lifecycle activities within the organization. Hence, integration of these domains will result in establishing relationship between project, product and organization. The Project-Product Lifecycle Management (PPLM) approach will potentially pave the way for organizations to attain superior product quality and advanced project and product lifecycle management capabilities, yielding significant cuts in total cost, time to market and risk.

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