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Role of Project Manager in Pharmaceutical Industry

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ABSTRACT

Today's fast-paced competition requires efficiency in all aspects of business. The identification of risks at the right stage and an effective mitigation plan are key factors for success, both financially and technically. The complex drug-development process from lab to launch includes management of several business processes, such as technical development using quality by design, regulatory strategy, clinical studies, and supply chain. These processes are affected not only by many circumstantial factors but also by each other. The inherent uncertainties during the evolution of any of these processes require constant change in plans. If the risks associated with the uncertainties are not managed in a timely and effective manner, the complexity of the situation increases dramatically and it subsequently becomes cost prohibitive for the developing industries to move forward. Although project management has been known to drive industrial success through effective risk management in other industries, it has only been introduced to the pharma industry in the last decade and is continuously evolving. This article identifies challenges in project management in the pharma industry. The analysis of critical factors, such as the roles of project managers and stakeholders, team communication, and key business processes, helps to identify strategies for addressing these challenges. This process can help put pharma companies on the road to success in launching a quality product that can improve quality of life.

Keywords – Project Manager, Pharmaceutical industry, Product management , Complexity and stakeholders

I. INTRODUCTION

Project Manager in The Pharmaceutical Industry

Project manager in the pharmaceutical industry serves an important role as it not only strategizes an organization's marketing strategy of products but also implements it. Right from pre-launch and launch campaigning of products to post-launch marketing aspects are handled thoroughly by the vertical called 'Project manager in the pharmaceutical industry'.

Every product in the pharmaceutical industry goes through typical 4 phases of the life cycle which are Introduction, growth, saturation, and decline or stable phase. Product management in the pharmaceutical

industry plays a vital role in all 4 phases of the product life cycle. It is responsible for the top line (gross revenue generation) along with the sales team and bottom line (EBITA which is revenue before interest, taxes, depreciation, and amortization) targets of a pharmaceutical organization. This is a liberal domain which gives a vast experience of cross-functional teams. The doors of other domains like sales, learning, and training, R & D team, along with hierarchical growth options, will open. The other professionals from clinical research, pharmacovigilance, production, and quality control can also join this segment if they successfully acquire innovation, creative and marketing aptitude.[1]

Depending upon the size and revenue of the organization, the hierarchical structure of the product management in the pharmaceutical industry may differ. Typically, it consists of.

- ✓ Product executives (1 or 2 years experience) or sometimes management trainee (fresher),
- ✓ Associate product manager or product manager (3 to 5 years experience),
- ✓ Group product manager (5 to 8 years experience),
- ✓ Marketing manager (9 to 12 years experience),
- ✓ General manager (12 to 15 years experience),
- ✓ Director or VP marketing or sales and marketing, (1 5 to 18 years experience)
- ✓ President of sales and marketing (19 to 22 or more years of experience)

Skill sets of Product Management in the Pharmaceutical Industry

- ✓ Product Knowledge
- ✓ Creativity and analytical skills
- ✓ Market research and intelligence to tap competitor analysis
- ✓ Good communication skills
- ✓ Ability to work and liaise with cross-functional teams
- ✓ Team building
- ✓ Forecasting and visionary approach
- ✓ Sales management and leadership skills

1. Project Management in the Pharmaceutical Industry, along with the sales team is responsible for achieving the top line and bottom line revenue target of an organization.
2. Brand establishment, brand building, and brand consolidation is the forte of the Project Management/ Product management of the Pharmaceutical Industry.
3. Creates a platform for new product launch and market penetration strategy and ensures implementation.
4. On the basis of market research, intelligence, and competitor mapping, Product Management in the Pharmaceutical Industry carves a niche strategy of product establishment in the pharmaceutical industry by creating good networking and liaising with healthcare professionals, KOLs, and hospitals and ensures implementation by the sales team.

Elements of Pharmaceutical Project Management :
Generally there are six elements which can be considered for project management.

- ✓ Project Definition
- ✓ Project team and organization
- ✓ Project planning, scheduling and control
- ✓ Problem solving and decision making using proto-type
- ✓ Senior management review and control
- ✓ Proactive and real time change management

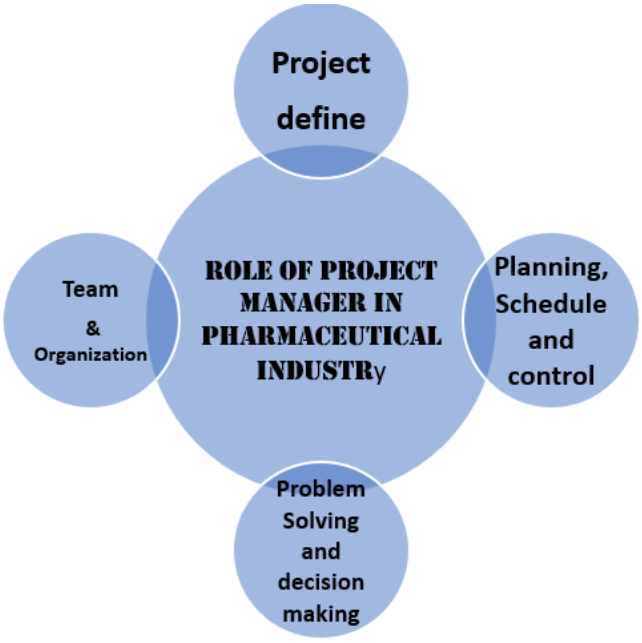


Figure 1: Key elements of project manager in pharmaceutical industry

PROJECT DEFINITION:

The first element of a project management framework is used to define project scope and objectives. It outlines what is within and not within the project boundaries, the business case and market need, the technologies to be used to solve that business case, and the initiation, selling and sponsoring of the project objectives define target status at the end of the project, reaching of which is considered necessary for the achievement of planned benefits. They can be formulated as S.M.A.R.T.

- Specific,
- Measurable (or at least evaluable) achievement,
- Achievable (recently Acceptable is used regularly as well),
- Realistic and
- Time terminated

In pharma industry objectives are dependend on some objects such as management/authority, development, registration, supply chain, QA , patent, market and also parallely time and cost.

Management/ Authority will run the project. Development department develop the product through galenical, analytical, clinical study etc. Registration is required for the launching of the product which will do the respective department .Supply chain department will provide raw material necessary for the development through active and excipient sourcing. QA will assure the quality of the product according to marketting authorization. For business purpose patent right is to be ensured. Marketting department will deal with the market to launch the product. Here, if we broadly segment the objective, that will be development of the product and then launching in the market. All these jobs have to be performed within time frame & budget.For the evaluation of a project some factors are important to consider depending on risk/benefit. Then top management takes the decision whether the project can be started or rejected. Projects need to be performed and delivered under certain constraints. Traditionally, these constraints have been listed as "scope or work requirements- cost, performance ,""time-to market," and "resources".
These are also referred to as the "Project Management Triangle ,"were each side represents a constraint. One side of the triangle cannot be changed without affecting the others.

The business case for a new product project should include the following:

- An evaluation of the market and customer needs including appropriate market research studies
- An analysis of the competition including their potential products and strengths and weaknesses
- A technical assessment of the capability of the organizations it relates to the product competing in the market
- A statement of alignment to the organization's business strategy
- A preliminary evaluation of the financial opportunity of the new product, which may include use of return on

Investment, discounted cashflow and internal rate of return, net present value, and break-even time.[2,3]

PROJECT TEAM AND ORGANIZATION :

A team is a small number of people with complementary skills who are committed to a common purpose, performance goals, and approach for which they hold themselves mutually accountable.

A project team can be divided in two parts- core team and support team. Core team members are from different functions of an organizations who have significant authority & responsibility in the organization and have both specialist/technical both specialist/technical & generalist/business skills.Support teams are group of team from different functions. A member of core team can be a leader of support team.

In a project management team ,every member have specific job. To manage the project efficiently, every member must have specific responsibility & proper authority to perform his/her job. The project team must have a chart which visualizes where every member is located in project management network. It shows the role of team members and other relationships (to sub-teams or to external units etc.)

Each team member-

- Ensures functional expertise on the project
- Represents functional perspective on the project
- Ensures functional deliverables are met
- Proactively raises functional issues that impact the team.

PROJECT PLANNING, SCHEDULING AND CONTROL :

Different method can be considered for planning of project management such as Work Breakdown Structure (WBS), Critical Path method, Project Evaluation and Review Technique (PERT). The Work Breakdown Structure (WBS) is a tree structure, which shows a subdivision of effort required achieving an objective; for example a program, project, and contract.

The WBS may be hardware, product, service, or process oriented. In a project of contract, the WBS is developed by starting with the end objective and successively subdividing it into manageable components in terms of size, duration, and responsibility (eg. Systems, subsystems , components, tasks, subtasks, and work packages) which include all steps necessary to achieve the objective.

The Work Breakdown Structure provides a common framework for the natural development of the overall planning and control of a contract and is the basis for dividing work into definable increments from which the statement of work can be developed and technical, schedule, cost, and labor hour reporting can be established.

An example, for pharmaceutical project following points can be considered in WBS: Project masterplan, Evaluation of project through analysis of objectives-scope-timeframe etc, Development Strategy- Pre-formulation study/formulation/clinical study/ analytical study/stability testing/cost effective process development etc, Raw material sourcing, Dossier compilation & Registration, QA program, Launch to market and then closure.

PROBLEM SOLVING AND DECISIONMAKING USING PROTOTYPES:

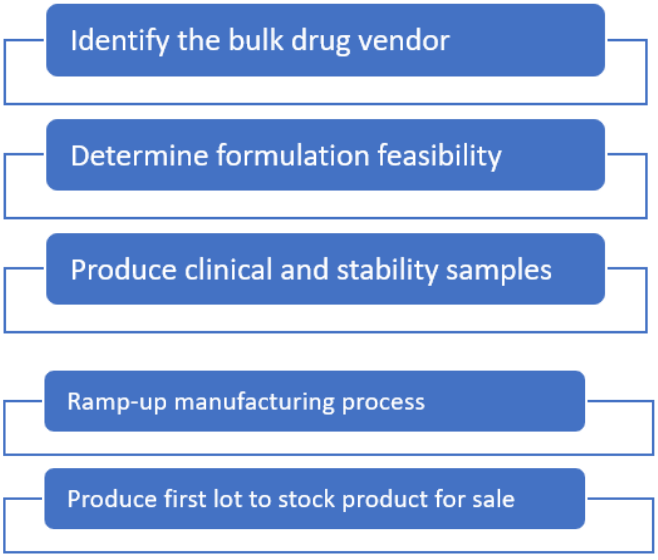
Pharmaceutical development projects consist of different phases, technology transfer processes, milestone and problem solving issues. To understand the progress of projects, these constraints need to be understand to visualize the project status and for communication purposes. For examples

- The phases of clinical development for a pharmaceutical development Project: phase I, II, III, IV and post-marketing;
- The technology transfer from research to development and from to manufacturing.

- The major milestones of a pharmaceutical project: FDA submission and first lot to stock ;
- The use of different product prototyping cycles and their value towards solving problems , communicating results, and making progress.

For a technology transfer processes, two types approaches can be used-sequential and overlapped. In sequential approach, upstream group waits for completion of work before starting next step and after completion of work communicate with downstream group. Simply, this is called one after one work. In overlapped approach, different work can be performed parallel and can be taken input from down stream groups. Communicating with cross functional groups, different work can be completed more successfully.

Another basic building block of any product development project is design–build–test cycles. These cycles use prototypes to serve as a focal point for problem solving, testing, communication, and conflict resolution. Using these cycles provides feedback on decisions made so far and identifies issues that need to be resolved. Examples of the prototyping cycles for a clinical development project are



SENIOR MANAGEMENT REVIEW AND CONTROL:

Senior management provides the sponsorship, championship, and funding for the pharmaceutical development projects that new product teams are working on. They need to be involved and understand the importance of the project, its link to business strategy and growth, the risks and issues that the project is facing, and the status of the project. This understanding is important throughout the life of a project particularly at the start of the project.

Senior management involvement, especially at the start of the project, is key to successful project outcomes. Some process guidelines to assure management involvement are as follows:

- Senior management should define strategic direction that will be used to drive new product development.

Senior management should define the new product project olio and the aggregate set of projects that will achieve their strategic objectives.

- Senior management should be actively involved in assigning the type of project team and type of project, i.e., where this project falls in the portfolio.
- Senior management should develop and support a project review process that encourages early involvement in the project to validate the business assumptions and decrease project surprises

Roles and Responsibilities of Project Manager in The Pharmaceutical Industry

The primary role of Project Manager in the pharmaceutical industry is to manage the existing project line of the pharmaceutical organization, brand establishment and brand building and also new

project launching and strategy for pipeline products and execution.

Below are Roles Assigned to Product Management in the Pharmaceutical Industry

Providing training, product knowledge, direction to the field sales team to ensure that they are well equipped with scientific and communication skills both.

1. Product Management in the pharmaceutical industry has to work with cross-functional teams like medical affairs, learning and development team, R & D team (Research & Development) in the process.
2. Developing brand plans/strategies for the product range along with market penetration strategy along with market research and competitor analysis.
3. SWOT analysis of product line (strength, weakness, opportunities, and threats) and guiding sales team to tap the opportunities and growth in the product sale.
4. Creating brand inputs for promotion like VA, LBL, Newsletter, flipcharts, or digital campaigns like website or app launch or webinar series, etc.
5. Conducting meetings, scientific symposia, CMEs, conferences, and ensuring brand visibility in the target audience segment of the pharmaceutical industry, which are healthcare professionals and hospitals.
6. Motivating sales team members by organizing training camps, award ceremonies, and recognition programs.
7. Product forecasting, New product pipeline strategy, new product pre-launch, and launch strategy and post-launch, new initiatives for product growth strategy.

- Product executives (1 or 2 years experience) or sometimes management trainee (fresher),
- Associate product manager or product manager (3 to 5 years experience),
- Group product manager (5 to 8 years experience),
- Marketing manager (9 to 12 years experience),
- General manager (12 to 15 years experience),
- Director or VP marketing or sales and marketing, (1 5 to 18 years experience)
- President of sales and marketing (19 to 22 or more years of experience). [3,4]

Challenges In Project Management In The Pharmaceutical Industry

In the pharma industry, with added uncertainties from the process of scientific research, project management becomes more challenging. Project management in the pharmaceutical industry involves:

Scope management

Project planning, execution, and monitoring

Timeline and budget planning and management

Stakeholder management

Management of regulatory and compliance strategies

Environmental safety

Risk management

Team management

Challenges underlie each of these aspects of project management. The interdependencies between these elements make it even more complex. While the developed product may be effective for the intended use, it may require hazardous chemicals and ingredients in the production process. Any deviation from safety plans can create long delays in the project timeline.

While changes are inevitable, it is natural that the stakeholders may internally or externally resist implementing a change. Creating an environment that embraces change is key in managing the stakeholders. The project manager should continually evolve his or her style of approach in managing the stakeholders. Improving soft skills for effective communication is as important as improving listening skills. A policy of “no surprises” and open

communication is beneficial in preventing the delivery of erroneous information.

Recently, more industries are moving toward matrix organization. In a matrix organization, there are four key players of project management: project manager, functional managers, upper management, and project team members.[5]

While each of these components has its own role and responsibilities, interdependencies become inevitable. The project managers are challenged in keeping this interrelationship viable to benefit the project. In addition, project managers in the pharmaceutical industry encounter challenges in:

- Resource limitation
- Cross-functional team management
- Institution processes
- Cultural differences
- Customer management

With pressures to cut costs, resource limitation is a major concern in project execution. A limited pool of resources with desired technical expertise makes it even more difficult to execute the work plan and meet the timeline. At the product-development stage, engaging the cross-functional teams becomes a challenging task for the project manager. Often the team members also work on multiple projects. The team members' skills in prioritizing, realizing the importance of the tasks, and effective communication become crucial to the productivity of the matrix organization. Lack of communication between team members, and between team members and their functional managers, can create a chaotic situation within a project.

As businesses face continuous changes in customer needs and in regulatory, quality, and safety requirements, updating the business processes becomes an exhausting task to accomplish. Often, project managers fall in a challenging situation working with outdated processes. Upper management's support in establishing clear business processes will help the project manager and project team in accomplishing the project goal.

Managing cultural differences within the team, within the host businesses, and on the customer side is a challenge that the project manager encounters regularly. Customer management adds another layer of challenges in managing projects that involve intercompany collaboration and contract manufacturing organizations (CMOs). Ineffective management of the customer needs can yield scope creeps, increasing the project budget and causing delays. Establishing the customer expectation in alignment with the scope early in the process helps in satisfying the customers. Project management acts as the face for the host company to the customer and vice versa. This puts project management in a difficult situation when the customer expectation does not match the promises the host company offered as per the agreement. Working with the customer to develop of a clear scope definition in the early stages of the project is the desired approach to prevent any confusion.[6,7]

Complexity of Project Management In The Pharmaceutical Industry

Project management becomes more complex due to known risks (known-unknown) and unknown risks (unknown-unknown). Lack of effective risk management can result in turbulence (chaos) in the project that can be incontrollable. The use of available techniques, such as Program Evaluation and Review Technique (PERT) and Gantt charts, helps in identifying risks and developing a mitigation and contingency plan, which is beneficial in managing the known or foreseeable risks.

Project management encounters greater challenges at the occurrence of unknown-unknown or unforeseeable risks. Managing the newfound risks adds agility and branches to the decision tree during the project execution. These risks make contingency

planning more difficult with lack of known decision tree branches at the planning stage. The management of these risks requires an approach developed specifically for the project. For example, team flexibility, developing a new technical plan, and greater communication for buy-in by the key stakeholders need to be considered.[8,9]

II. Conclusion

The project managers share responsibilities in creating an environment conducive to project success. Support from senior leaders in providing the resources and desired talents in a timely fashion is crucial in executing a project successfully. A program-management practice that clearly defines the objective, roles and responsibilities, and accountability, as well as embraces open communication, contributes a great deal to the project. Adding flexibility and incorporating branches to the decision tree at key stages of project execution result in a competitive advantage. Proactive measures by the project manager to mitigate risks and create a culture of effective communication among stakeholders and team members are valuable factors in achieving project success.

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