Management of Pharmaceutical Project and Their Complications

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Abstract

Project success is a collaborative effort involving team members, project managers, and upper management. Establishing a program-management practice that defines clear objectives, roles, responsibilities, and accountability, while fostering open communication, significantly contributes to project outcomes. The journey of product development in the pharmaceutical industry is fraught with numerous challenges. Effectively managing inherent risks at each stage of new product development is crucial. Integrating risk management into the product development process is the key to reducing both time and costs. While project management has long been acknowledged as a driving force behind successful risk management in other industries, its introduction to the pharmaceutical industry is a relatively recent development, and it continues to evolve. This article highlights the challenges associated with project management in the pharma industry.

Keywords: Pharmaceutical industry, Project managers, Project management.

Introduction

It is widely recognized that the research-based pharmaceutical industry serves as the primary source of modern pharmaceutical products. Innovative medicines play a vital role in controlling healthcare costs. The global healthcare landscape demands that the pharmaceutical industry develops medicines that can save and improve the lives of millions of people at a reduced cost.[1]The cost of healthcare worldwide is experiencing an exponential rise, surpassing the growth rate of the consumer price index. Projections indicate that the estimated healthcare expenditure, which stood at seven trillion US dollars in 2011, will double in the next decade. Several factors contribute to these soaring healthcare costs, including an aging population with chronic conditions, monopolistic practices within healthcare providers, and the development of novel and intricate therapies.[2] The pharmaceutical industry itself faces obstacles in achieving profitability. Intensified competition in the development of generic drugs, stricter regulatory

requirements, and rising research and development (R&D) expenses for innovative new drugs necessitate a restructuring of strategies to minimize internal costs. During this lengthy process, to bring a new product to market, effective coordination among various internal functional groups, such as R&D, regulatory, legal, finance, supply chain, sales, and marketing, as well as external partners, is crucial. Efficient collaboration between these different functional units is paramount to success.[3]

Project management assumes greater responsibility for risk management and the implementation of risk mitigation plans. The pharmaceutical industry has started adopting this approach over the past two decades. The concepts of project management and the best practices associated with it are continuously evolving within the pharmaceutical industry.The time required to obtain authorization for product launches has increased, thereby influencing the economics of drug development. Pharmaceutical companies are now facing the pressure to expedite the drug development process to compensate for the extended wait for regulatory approval. Recognizing the significance of concentrating efforts on a single product while pursuing parallel development, the pharmaceutical industry is increasingly embracing project management strategies.[4]

Challenges of Project Management

Project management encounters greater challenges when faced with unforeseeable or unknown-unknown risks. Presence of both known risks (known-unknowns) and unknown risks (unknown-unknowns) lead to disruptive turbulence and uncontrollable chaos within a project. enhancing team flexibility becomes crucial in navigating unforeseen risks. This allows the project team to quickly adapt and respond to unexpected challenges. Additionally,

effective communication and obtaining buy-in from key stakeholders play a vital role in managing these risks successfully.[5]

Project Management & its factors

Project management consists of several components that contribute to the successful execution and completion of a project. These components include:

- Project Planning: This involves defining project objectives, scope, deliverables, timelines, and resources required. A comprehensive project plan outlines the tasks, dependencies, and milestones necessary for successful project execution.
- Project Organization: Establishing the project team structure and roles is crucial. This includes identifying key stakeholders, selecting team members with appropriate skills and expertise, and assigning responsibilities.
- Risk Management: Identifying, assessing, and mitigating risks throughout the project lifecycle is essential. Project managers analyze potential risks, develop contingency plans, and monitor risks to minimize their impact on project outcomes.
- Communication Management: Effective communication is vital for project success. Project managers ensure clear and consistent communication among team members, stakeholders, and relevant parties. They facilitate collaboration, provide updates, and address any issues or concerns.
- Scope Management: Managing the project scope involves defining and controlling what is included and excluded from the project. Project managers ensure that project scope remains aligned with the agreed-upon
- objectives and deliverables, and they handle any scope changes or deviations.

- Time Management: Project schedules are created and managed to ensure tasks are completed on time. This involves setting realistic timelines, monitoring progress, identifying critical paths, and adjusting schedules as needed to meet project deadlines.
- Cost Management: Monitoring and controlling project costs is essential to ensure that the project remains within budget. Project managers track expenditures, manage resources efficiently, and make adjustments to prevent cost overruns.
- Quality Management: Ensuring project deliverables meet the required quality standards is crucial. Project managers establish quality assurance processes, conduct regular quality checks, and address any issues or deviations from quality requirements.
- Stakeholder Management: Identifying, engaging, and managing stakeholders throughout the project is important. Project managers identify stakeholders' needs, expectations, and concerns, and actively involve them in decision-making processes to gain their support and address any potential conflicts.
- Procurement and Vendor Management: For projects involving external vendors or suppliers, project managers oversee procurement processes, contract negotiations, and vendor performance management. They ensure timely delivery of goods and services while maintaining quality and cost control.

- Integration Management: Project integration involves coordinating all project components, ensuring they work together seamlessly. Project managers integrate the various project management processes and monitor overall project progress and performance.

These components of project management are interconnected and require ongoing monitoring and adjustment throughout the project lifecycle. Skilled project managers employ these components to effectively plan, execute, and control projects, ultimately achieving the desired project outcomes.[6-7]

Factors of a Project Success

Determining project success involves more than simply meeting time and budget constraints. While delivering a project on time and within budget is a clear indicator of success, projects that fall short of these criteria may still yield valuable lessons and opportunities for long-term business profitability. As a result, when measuring project success, two key components should be considered: technical success and business success. Evaluating these aspects helps in developing comprehensive metrics for assessing project success. Now, let's delve into the critical factors that significantly influence project success. As mentioned earlier, the roles of the project manager and stakeholders, team communication, and effective business processes play pivotal roles in achieving project success.[8]

Figure 1: Critical factors affecting project success (*Source: self*)

The roles of the project manager and stakeholders, team communication, and effective business processes play pivotal roles in achieving project success:
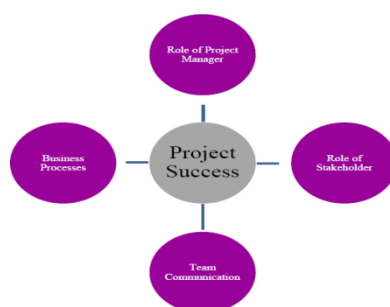
1. Project Manager and Stakeholders: The competence, leadership, and decision-making abilities of the project manager greatly impact the project's outcome. Engaged and supportive stakeholders who actively participate in the project and provide necessary resources and guidance contribute to success.
2. Team Communication: Open and effective communication among team members is crucial for project success. It ensures clarity, alignment, and collaboration, enabling smooth progress and timely resolution of issues.
3. Business Processes: Well-defined and efficient business processes contribute to project success. This includes clear project scope, effective planning and execution, proper risk management, and adherence to quality standards and regulatory requirements.
4. By addressing these critical factors and emphasizing the importance of the project manager-stakeholder relationship, fostering effective team communication, and establishing robust business processes, organizations can enhance their chances of achieving project success.[9]

Conclusion

The collective efforts of team members, project managers, and upper management are vital for project success. Senior leaders' support in providing resources and talent, coupled with a well-defined program-management practice, sets the foundation for success. Flexibility, risk mitigation, and effective communication further enhance project outcomes. By embracing these practices and fostering a collaborative environment, projects are positioned for success and can achieve their desired objectives.

References

1. Adams R, Tranfield D, Denyer D. A taxonomy of innovation: configurations of attributes in healthcare innovations. International Journal of Innovation Management. 2011; 15(02): 359-392.
2. Anderson N, Dreu C, Nijstad BA. The routinization of innovation research: A constructively critical review of the state-of-the-science. Journal of Organizational Behavior. 2004; 25: 147-173.
3. Agarwal R, Sambamurthy V, Stair RM. The evolving relationship between general and specific computer efficacy: An empirical assessment. Information Systems Research. 2000; 11(4): 418-430.
4. Smith D, Langlois E,Lazau M. An empirical investigation of the adoption behavior of technological service innovation. Journal of management and marketing research.2010; 3.
5. Matthing J, Sanden B,Edvardsson B. New service development: learning from and with customers. International Journal of Service Industry Management. 2004; 15(5): 479-98.
6. Gibis B, Artiles J, Corabian P, Meiesaar K, Koppel A, Jacobs P, Serrano P. Menon D. Application of strengths, weaknesses, opportunities and threats analysis in the development of a health technology assessment program. Health Policy. 2001; 58: 27–35.
7. Bell E,Bryman A. Business Research Methods (3rd edition) Oxford University press.2011.
8. Cohen D, McDaniel RR, Crabtree BF, Ruhe MC. A practice change model for quality improvement in primary care practice. Journal of Healthcare Management. 2004; 49(3): 155.
9. Francis D, Bessant J. Targeting innovation and implications for capability development. Technovision. 2005; 25: 171-183.