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RESEARCH ARTICLE

IMPORTANT PROJECT MANAGEMENT KNOWLEDGE AREAS FOR SUCCESSFUL DELIVERY OF PROJECTS IN PHARMACEUTICAL INDUSTRY

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Abstract

In current business environment, the delivery of business outcomes is dependent upon the success of projects and this is the way how project management strategies drive organizational success. Project management is an art as well as science. It is an art because of soft skills including problem solving, leadership, proper communication and managing expectations while it is science because it consists of a systematic approach which uses a standard methodology. The art of project management can be developed through experience and practice. In current business environment of constant change and increasing complexity, Project management is equally divided between art and science and a successful project manager utilizes both the skill sets to effectively manage the projects. It has been evident from literature support and other sources that application of Project Management skills and knowledge has been focussed on industries like Infrastructure, IT, Communications and Defence but there is lack of information supporting use of Project Management in Pharmaceutical Industry. As a Pharma Project Management professional, my interest was in identifying the $PMBOK's knowledge areas and Pharma specific knowledge areas which are important for successful delivery of projects in Pharmaceutical Industry. To analyze this, I distributed an anonymous questionnaire online to a group of pharmaceutical project management professionals. This paper describes some of the key points of the research data obtained.
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Keywords: Projects, Project Management, Pharmaceutical Industry, $PMBOK (Project Management Body of Knowledge), PMBOK's knowledge areas – Time, Cost, Quality, Scope, Communication, Integration, Risk, Human Resources and Procurement

Introduction

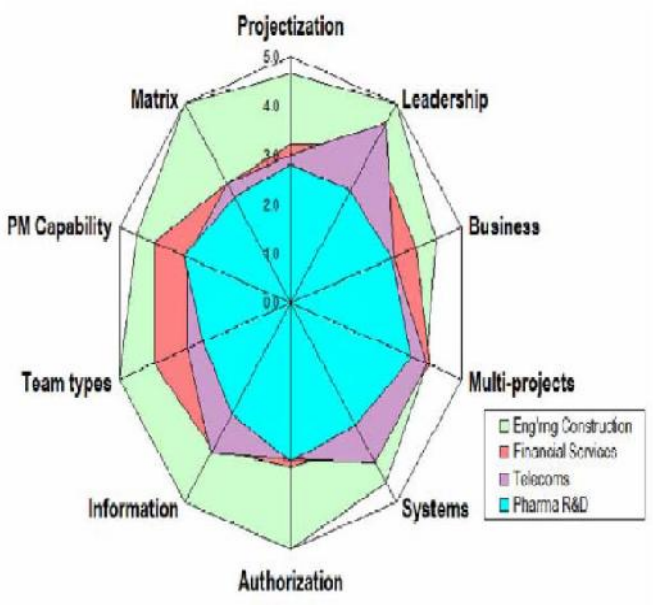
For Pharmaceutical industry, project management is the key for addressing quality, compliance and unique regulatory needs of the industry. The process of drug development, analytical research, clinical research, together with the critical factor of time to market can capitalize on project management techniques. These techniques can be effectively applied to scheduling, costing, quality assurance, risk management and control of the process for bringing a drug to market in a cost-efficient way.

In Pharmaceutical Industry the market has become much more competitive and regulatory, political, social and economic pressures have become much more intense. Lot many Pharmaceutical companies face recall of one of their drugs, lawsuits from competitors or customers. Product quality and time to market are other important factors in Pharmaceutical Industry that must be well managed through careful process to reduce the risks. So, key challenges with this industry are quality and schedule, both of which are directly addressed by

the tools and techniques used in project management.

A survey on maturity of Project Management in Biopharmaceutical Industry [Cooke-Davis, T (2005)] shows that Project Management in Pharmaceutical Industry is lagging behind other Industries. The radar diagram presented below shows this comparison between Pharmaceutical Industry and other Industries, where Project Management is well established.

Figure 1. Cooke-Davies, T (2005), Project Management Maturity in the Biopharmaceutical Industry. How does it Compare with Others?



To continue the work in this direction further, I stepped forward to identify the PMBOK's knowledge areas and Pharma specific knowledge areas used by experienced project managers to achieve project success in Indian Pharmaceutical Industry. I started this activity by first identifying the key knowledge areas only and determining the ways in which these knowledge areas can be applied to Pharmaceutical Projects. The methodology for my way forward is presented below.

Methodology

The investigation was started with the help of questionnaires that focused on how project managers perceive the use of PMBOK's knowledge areas, other Pharma specific knowledge areas in their day to day activities and which among them do they think are important for success of a Pharmaceutical project. Prior to distribution of the questionnaires, it was subjected to content validity test and reliability test. After passing these tests, it was distributed online to 30 Project management professionals in Big (Sales > Rs. 2000 crores) and Medium (Sales between Rs. 450-1999 crores) Pharmaceutical companies in various parts of India, to reduce the influence of a single company. The results were gathered in a manner that guaranteed respondent's anonymity and no such questions were asked that would identify the individuals. The data gathered is presented in simplest manner to focus on results of questionnaires.

Results

The outcome of the questionnaire reflects some of the interesting and enlightening results. The questionnaire was distributed to 30 Project Management professionals while responses were received from only 17 professionals; a response rate of approximately 56.7%.

From the responses received, 70.5% of respondents had more than 5 years of experience in Pharmaceutical Industry and 47% of them have more than 5 years of experience in Pharmaceutical Project Management. The level of experience of the respondents gives additional confidence in the validity of the survey results.

Before joining Project Management department, 41% of the respondents worked in one or the other department of Pharmaceutical R&D while 23.5% came from Production/Manufacturing. This result emphasises the fact that existence of specific Project Management department is not too old in Pharmaceutical Industry and it originated imbibing the talent from different departments of R&D and Production.

It was found that within the Indian pharmaceutical industry 70.5% of project management professionals make use of knowledge areas like Regulatory guidelines, good manufacturing practices and good Quality management practises for managing Pharmaceutical projects.

88% respondents said that by using project management tools and techniques, there was a higher rate of project success while only 12% were of the view that implementation of Project Management has moderate or low impact on success of projects in their organisation.

To correlate the use of project management knowledge areas with the success of a pharmaceutical project, Pearson's product moment correlation was used on the primary data gathered through questionnaires. When respondents were asked about the use of PMBOK's knowledge areas, following findings were observed:

83% respondents reported that Time, Cost and Quality are among the important factors for success of a Pharmaceutical Project

67% were of the view that clarity in project scope is must for success of a Pharmaceutical Project

49% believed that proper and clear communication is necessary to make pharmaceutical project successful.

From the results obtained, it has been observed that Risk Management contributes only 16% towards success of a Pharmaceutical project, which is very poor and needs more attention in Pharmaceutical Industry.

The knowledge areas which are considered as least contributors in success of a pharmaceutical project are Integration and Procurement Management with only 5% reporting level. These areas still demand focus and proper implementation in Pharma Industry.

Thus, based on above points, it could be derived that Time, Cost and Quality are considered as three most important knowledge areas for success of a Pharmaceutical project.

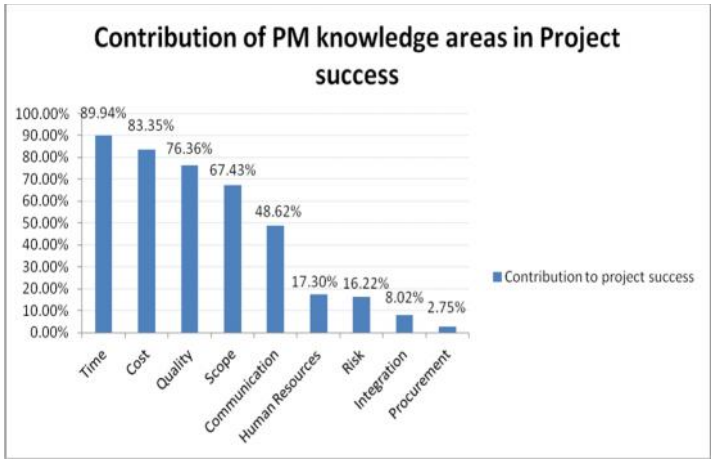
Key Knowledge Areas

The responses obtained through questionnaires were subjected to Pearson's product moment correlation analysis to establish the relation between project management knowledge areas and project success. Provided below is the percentage contribution of each knowledge area in project success of a Pharmaceutical Project in Indian Pharma Industry.

From the above representation it is observed that top three project management knowledge areas based on their contribution towards project success in Indian Pharmaceutical Industry are:

1. Time Management (~90%)
2. Cost Management (~83%)
3. Quality Management (~76%)

Figure 2: Representation of contribution of Project Management (PM) knowledge areas in Project Success



As seen in the above bar chart, the response towards percentage contribution of Human Resource, Risk, Integration and Procurement Management is very poor and these knowledge areas demand more attention in Indian Pharmaceutical Industry during execution of a project.

Discussion

Provided below is a review and discussion about the knowledge areas which are collectively described as being key to project management in Indian Pharmaceutical Industry. The grouping is based on the questionnaire results regarding knowledge areas that are important for project success. These knowledge areas include: Time, Cost and Quality.

Time Management

Time management remains and shines as the most important knowledge area for overall success of a Pharmaceutical project. Execution of activities in timely manner is a key responsibility of the project manager. This is because, extra resources can be leveraged, customer expectations can be managed, but if the project is delayed by an unacceptable period of time, the impact could be widespread. With poor time management of a project, other projects can suffer the consequences by getting delayed, robbed of resources or placed under increased pressure in relation to time to make up for the delays in the earlier project. The importance of time management can be visualised if we imagine the typical phases of pharmaceutical development

projects to be the stages of a relay race – if the time taken to complete one stage is delayed, the next runner must put strain on their resources or take a short cut in order to remain competitive. Additionally, time management is very important for Pharmaceutical companies to avail the advantage of first market entry (especially incase of generic drugs) as it brings huge share in the market as compared to its competitors.

Cost Management

Cost is another factor which plays important role in success of a Pharmaceutical company. If the company manufactures medicines at a cheaper cost as compared to its competitors, it can sell more and increase its earnings.

Crucial information related to cost management was identified in an examination by Jacob and Kwak [5] on evaluation approaches for selection of a project for pharmaceutical R&D. It was found that there is a requirement to reduce the costs associated with the development of a new pharmaceutical product, by reducing the risk of getting a wrong product candidate chosen for development. This approach is described as movement from Project Management thought of doing the project right to one of doing the right project. The selection of the right product candidate is important because it takes between US $350 million and $500 million to bring a new drug to market. Before that it is required to screen over 5000 compounds to produce one marketable drug. Therefore, it has been suggested to have a high quality of information about the project during the early phases because the decisions made during the project lifecycle will be based on the quality of information available.

Quality Management

Regulatory authorities support an effective pharmaceutical quality system to enhance the quality and availability of medicines around the world in the interest of public health. Implementation of ICH Q10 throughout the product lifecycle should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities. Quality is one of the most important aspects of Pharmaceutical project management. It should be inherent in everything that is produced. If the project manager waits until the end of the project to determine if the quality was met, then it is too late to make corrections that could have been identified earlier. A quality management plan describes how the project management team will implement its quality policy. It will not only address the quality requirements of the project but must also address the policy and procedures of the existing corporate quality plan reviewed during the Initiation Phase.

Each product in a Pharmaceutical company goes through following lifecycle:

- Pharmaceutical Development
- Technology Transfer
- Commercial Manufacturing
- Product Discontinuation

Elements of a Pharmaceutical Quality System

There are four elements of a Pharmaceutical Quality System as described in ICH Q10. They are:

- Process performance and product quality monitoring system
- Corrective action and preventive action (CAPA) system
- Change management system
- Management review of process performance and product quality

The elements described above might be required in part under regional GMP regulations but are covered in Q10 because Q10 model's intent is to enhance these elements in order to promote the lifecycle approach to product quality. These elements should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages. Throughout the product lifecycle, companies are encouraged to evaluate opportunities for innovative approaches to improve product quality.

Conclusion

The responses gathered and analyzed statistically provide an insight into the knowledge areas which contribute towards project success in a Pharmaceutical Industry. It depends on company to company how project managers implement the use of these knowledge areas in their day to day activities. By focusing on the project management knowledge areas mentioned in this research paper, project managers in Indian Pharmaceutical sector

can hopefully realize improvements in overall project success rates. This focus can also enhance the ability of the project manager to maintain increased levels of control over the project's scope, duration, cost and quality – all key factors in achieving overall project success. This is a step forward in raising the level of maturity of project management in Indian Pharmaceutical industry and underlines the important role project management can play in creating and supporting successful Pharmaceutical companies in India.

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