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SIGNIFICANCE OF PROJECT MANAGEMENT IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

In recent years, the Pharmaceutical market has become much more competitive and the political, regulatory, social and economic pressures more intense. There are no certainties in the field of drug development. Pharmaceutical companies investigate hundreds or even thousands of target molecules in the quest for candidates with interesting potential therapeutic effects. If companies are to maximize their financial investment and allocation of resources then project management will be the key to success. New approaches to solving productivity problems, such as collaborations, are a step forward but they will require careful management to ensure that potential benefits are realized..

Key words: *Project Management, Pharmaceutical, Generics, Drug development*

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INTRODUCTION

Project Management has been a well known tool and well established technique outside the pharmaceutical sector for many decades. Infact people mainly associate the word 'Project Management' with civil engineering, software and IT projects. But from the last decade it has become increasingly important within the Pharmaceutical Industry as well. Although this industry is a latecomer in the discipline of Project Management, but due to increasing global demand for drugs, increase in the ageing population, medical advances, competition among generic drugs, increasing regulatory requirements, health innovations and the wave of mergers in late 1990s and early 2000s, it is no longer possible to manage pharma business without it. Therefore, we can say that Project Management has become an important part of the Pharmaceutical Industry in current scenario.

Pharma Industry & Project Management

It is the mission of the Pharmaceutical research companies to take the path from understanding a disease to bringing a safe and effective new treatment to patients. But there are concerns about the side effects from drugs which make it

much more risky to roll out any blockbuster drug. So, the more likely scenario in future will be that such drugs will be gradually exploited over a range of therapeutic applications. This will greatly dilute the economic benefit of the blockbuster effect by slowing down value creation and through increasing cost and complexity of drug development. The whole area of risk management will become far more important even than before. US President Obama also wants to encourage the expansion of the generics market making further inroads into the traditional terrain of big pharma. He has addressed the regulatory and economic provisions for drug development, their purchasing and pricing. And these changes will put more pressure indirectly on the management of Pharmaceutical companies. That means, pharma companies will have to do a lot more. This suggests that project management processes will have to be ever sharper for companies to succeed.

There are a significant number of drugs coming off-patent in the coming years resulting in more pressure on Pharma companies. Pharmaceutical companies therefore need to be managed more strategically because the companies will have limited resource, which they can plough back into R&D due to pressures on average margins. Even more pressure will be placed on completing projects within timelines as well as to control, if not to reduce, cost.

As a result of increase in the competition in Pharma market, internal pressure has already intensified to deliver much faster and to reduce time to market. Therefore, more and more pharma companies are looking towards project management to accelerate drug development and particularly the clinical research part of the process.

Pharmaceutical Project Management includes strategic, organisational, operational and also the financial perspectives as against the traditional Project Management. Strategic thinking is an essential part of managing projects in the pharma industry, which is defined as the creative and relentless pursuit of options for action which leverage resources and produce shareholder value more easily and in less time. Business projects often materialise as a result of formal strategy development.

Thorough problem diagnosis, looking at a diversity of options (not only which projects to do but how to do them), managing stakeholders, dealing with uncertainty, trading-off not merely tangible but less tangible value, creating a strategic vision for the project, identifying key implementation difficulties are the key areas of contemporary process of Project Management which is ideally suited for Pharma Industry and covers all perspectives like strategic, organisational, operational and financial.

Before beginning the Pharma Project, the company should have clear vision on following three points:

i. Why are we doing this pharma project?
ii. What value do we hope to get out of it ?
iii. How can we avoid the problems that occur during this project?

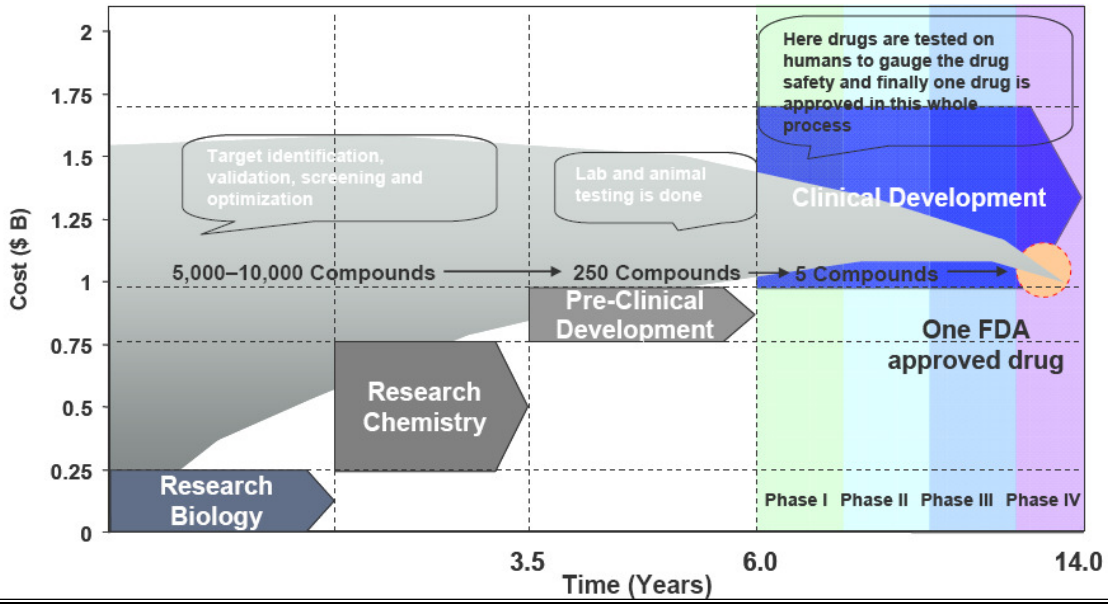
The day to day operations in a Pharma company involve multi-project, multi-product environment, often across geographies and it is a challenge to determine which projects have a strong value proposition. The pharma industry is expected to improve its productivity as the number of new products reaching the market has been decreasing over last few years and the industry requires to change the way it runs its projects. These circumstances have led to an increasing need for effective project managers in the pharma industry. It is the project manager who gathers information about any problem in a project in order to understand the issues as clearly as possible. The project manager retains the 'big picture' and therefore is in the optimum position to consider how the decision will affect the overall project.

Drug Discovery & Development

In a Pharma company, the journey of a New Chemical Entity (NCE) from research laboratory to market or even introduction of generic version of an approved drug needs to be a time bound programme responsive to the market and patient needs. One needs to act within regulatory and patent boundaries and still be cost competitive. In short we can say that the drug development is a

multifaceted, multilevel activity and Project Management department basically works to keep the goals of all key stakeholders aligned so that the combined effort leads to realisation of organisational vision.

A pictorial representation of the drug discovery and development process along with the cost involved, in Pharmaceutical Industry is shown below:



Drug Discovery and Development Process

From the above figure it is clear that for every 5,000-10,000 compounds that enter the research and development (R&D) phase, ultimately only one receives the regulatory approval. In current scenario, for a drug to come to market from the time the target is identified is about 10-15 years. The pre-launch cost of development as per present estimate is around 800 million dollars and the capitalized cost comes out to be ~2 billion dollars. Both the cost and the time vary depending on the nature of the disease being targeted, the type of drug being developed and the nature and scope of the clinical trials required to gain regulatory approval. Success requires immense resources — the best scientific minds, highly sophisticated technology and complex project management.

The costly nature of drug development is due to large investments in R&D over extended periods of time as the fundamental research is carried out in universities and other research organisations. The pharmaceutical industry has the highest ratio of R&D spending to sales of any industry and this investment in R&D has been growing by about 13% per year over recent years.

The cost of developing drugs is rising, and this, combined with a perceived decrease in the productivity of R&D, has been one of the major reasons for the mergers and acquisitions among pharmaceutical companies over recent years, as they seek to find and exploit economies of both scale and scope in drug R&D. Clinical trials is the most expensive stage and accounts for at least 40% of costs.

Project Management Responsibilities

The Project Management department is a single department which can claim to be omnipresent in every function. It starts with participation in identification of research area, new research project, making an operation plan for the project, evaluating and constantly watching the financial commitments on the projects, comparing it with the potential market opportunities, questioning viability of the projects and recommending termination of non-viable projects, tracking and ensuring timely completion of milestone activities for the entire portfolio, identification of potential hurdles ahead of time and facilitation to mitigate the risks, bringing right people on the right forum

so that a right decision is taken, updating the senior management of the entire concept to launch activities, escalating the issues to right level where they can be resolved, and post marketing surveillance for cost reduction and optimisation of resource utilisation. All in all we can say that a project manger exhibits as a vertical integration within the company and all customers through effective communication, understanding and resolving constraints. To sum up Project Management is about 6 'C' and these are: Concept, Clarity, Consensus, Commitment, Control & Confirmation.

An effective Project Manager

A project manager has to be efficient enough to ensure that the project gets completed within stipulated time, at appropriate cost with adherence to quality and regulatory compliance and with very little hassles. The project manager's primary role involves planning for the scope within the assigned budget and timelines. All this needs to be achieved with appropriate buy-in from the project team members in order to create a more realistic plan. A well developed change control system will in turn assist the project manager to monitor the results as per the proposed plan and increase the possibilities of the project to be a success. Mature project manager practices allow for economically unviable projects to be killed early in the project life cycle. This could be presented by taking live example from a Generics Pharma company: The same product was sold in different geographies across the world. The batch size manufactured for different markets varied as per the market requirement of the product. But the Project Manager and the respective departments worked together to resolve this issue and came out with a solution as follows:

The batch size forecast for Active Pharmaceutical Ingredient (API) and for formulations given by Marketing & Sales team to API and Formulation team for manufacturing, was optimized by combining yearly forecasts of different markets. This not only reduced the number of batches, but the indirect benefit came from saving analysis time, saving in number of stability studies, etc. The API, excipients and packaging material costs were also reviewed periodically and appropriate source change was implemented through regulatory submissions. Since the project manager is the central repository for issues and hurdles that arise in different projects and witness to the measures taken to resolve them, he/she can help to avoid re-work.

Time is a critical resource for a project manager and timelines are vital to every project. There is fairly large chance that a project will exceed budgets if the project manager is unable to meet the project schedule. Time taken by researchers is added in the project manger's activities timeline and ultimate delivery period is chalked out. These timelines should take into account minor slippages due to any genuine reason as the researchers need time to discover a new research molecule. The success of a project manager depends on completion of a project in the stipulated time.

Another key requirement for a successful project is good communication. Communication breakdown can seriously impact the overall functioning of a project. Ineffective communication within departments leads to increase in timelines in project completion, in dissatisfaction, wastage of resources. These all may lead to attrition, as the employees start losing faith and interest in the employers. Every project has more than one stakeholder, where all the stakeholders are interdependent. Through frequent discussions with various stakeholders, a project manager can soon shortlist the constraints involved, resolve them and show the way forward, in such a way that the next stakeholder does not suffer much damage. Usually, communication gaps are known to occur when clear cut responsibilities are not assigned and any changes/delays/updations are not communicated to the stakeholders. If there are improper communication channels, the impact is readily seen on the scheduled timelines.

A project manager spends approximately 90 percent of his/her time communicating with various other stakeholders. He/She therefore needs to plan, structure and control his/her communications. Efficient communication is one of

the strong tools of a project. The project manager must give his/her team members enough information (e.g. bar chart, network diagram, project management plan, risks) so that they can manage their own work efficiently. The project manager has to find out the issues from every department, get commitments and get the work done from people who do not report to him. Many a time he/she may have to ask for commitments from people higher up in organisational hierarchy, but he/she has to question and confront them. This requires lot of communication and interpersonal skills. Only then can the project manager become effective and efficacious. Project managers are thus required to have influential communication abilities across hierarchies. They need to communicate regularly with the project team, as well as with any vendor, the customer and their own company's upper management. Effective and frequent communication is very important and critical to ensure that the project is moving in the right direction and this ensures that any potential problems can be identified early. This leads to improved project performance and enhanced customer satisfaction.

Communication by the project manager needs to be on one hand effective and convincing from the top to the bench level; and at the same time he/she needs to use discretion while sharing information to safeguard company's commercial and IP interests. Right information and right amount of information should be available to the right person so that a right decision can be taken. Frequent communication with the project team is always critical and a helpful tool to influence greatly success of any project. It is even more important when working with a virtual or remote team. Web-based communication tools can help in such cases. Communication acts like glue that holds a project team together.

The project manager should hold regular team meetings and status reviews to communicate progress and to provide a forum for team discussion and airing of views. Participation in team meetings should be encouraged, and certain team members should be required to report on the status of their activities. Project documents such as plans and budgets should be updated and circulated to the team regularly. The project manager should encourage open and frank discussion among the team members, both formally and informally. This in turn will increase the transparency and will create trust in the employees, thus, helping in retaining them.

Project Management: A facilitator in drug development

Some of the most common problems encountered during the course of drug development processes are related to planning, delays in development, unforeseen activities, cost overruns, and losses resulting from high turnover. The industry is growing constantly, particularly when it comes to researching and developing new products. And to top it, in recent years, the cost of developing a new drug has increased significantly along with greater competition.

Currently many softwares are available for project management but almost no or very few schools teach the soft skills required for this job function. Pharma Industry at large has not realised the importance of this function and in many pharma companies the project manager organisation structure itself is not mature enough. It is many times viewed as a function related to software and informatics and therefore IT professionals are recruited or sometimes people with pure management background are taken on board. Sometimes it takes the form of line management. But to be really very effective a Project Management team should comprise of committed people with technical background having sufficient experience in a related field, who can understand and appreciate the market and IP dynamics and also have an understanding of regulatory matters, first carry out process mapping and identify loopholes and weak links and then start with corrections in the process.

In short, Project Management should be a bottom to top process rather than top to bottom. The function should be independent and enabled. It should be sufficiently supported by the top

management. Only then can Project Management function effectively.

At times, our belief that the pharma industry is unique, has prevented it from learning from other industries. In such a scenario, the probability of re-addressing a problem that is already solved by other industry goes up. Unfortunately the industry tends to view projects as standardised and as relatively uniform, which in reality are not. But with the discovery and development process becoming more sophisticated, there will be need for better project planning, quality assurance and control processes within and between functions. The pharma industry should be open to learning from other industries to better manage their projects.

It is critical to spend more time in planning rather than managing the project. Some plans fail because the work breakdown into tasks does not match with how people work. Work breakdown assumes discrete units of work that someone will spend a fixed amount of time on a task before moving to the next task. Hence, including the team in preparing the work breakdown structure will ensure successful project coordination. While one individual may find a task within his/her skill set, another person may struggle. It matters which person does which task. Therefore, delegation as per skills/experience/ability to complete within the time period required should be adopted.

Assessment of project risks is also important. If it is considered that a pharma project is likely to have a high control risk, then monitoring progress should be carried out more frequently. Reporting and feedback on performance relative to the original objectives is also important to make improvement in future projects.

To sum up, project managers in the pharma industry today are at a thrilling juncture, charged with executing some of the most ambitious growth plans in a sector which has managed to more or less beat the slowdown. They should be able to apply experience from other industries, as well as the past experiences from pharma industry, to ongoing projects in order to solve problems in a practical manner.

CONCLUSION

The pharmaceutical industry is booming and the race for manufacturers to bring new products to market faster is closer than ever before. As business continues to grow, defying an economy that is otherwise struggling to stay afloat, pharmaceutical companies everywhere are scrambling for new ways to develop their products faster, within budget, and according to quality standards. Recently, more and more pharmaceutical companies have begun to focus their attention on one of the most simple, cost-effective ways to improve their processes and speed product development (particularly the clinical trial phase) and that is project management. According to a recent study by the Center for Business Practices (CBP), 45 percent of organizations surveyed have implemented centers of excellence for project managers and project management. Companies who implemented project management improvement initiatives spent an average of $676,000 per year on them, for an approximate ROI of 28 percent. Project management is particularly helpful for providing structure and focus through its efficiency in bringing new products faster to market, providing tumultuous ride from phase III clinical trials, filing a new drug application and obtaining regulatory approval, working with the Division of Drug Marketing, Advertising, and Communications (DDMAC) and navigating many options and choices through the early years of a product's launch and commercialization.

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