

## PROJECT MANAGEMENT VALUES DRIVEN IN PHARMA INDUSTRY

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### CASE STUDY

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#### ABSTRACT

In the pharmaceutical industry, project management is key to addressing the unique regulatory, compliance and quality related needs of the industry. As the process of drug development and the critical issue of time to market can capitalize on project management techniques to effectively apply scheduling, risk management, and comprehensive quality assurance and control to the process of bringing a drug to market in a cost-effective but safe way.

“JUST DO IT” is the approach that XYZ Generic Company was using before this project arrives.

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#### PREFACE

Dr. Desai, Senior Vice President of Project Management was taking a sip of tea, while sitting in his cabin. And he was thinking about his journey in XYZ Generic Company from Jan, 2011 to Jul-2013. For wrapping of NCE-1 project XXX tablet submission within due date and for successfully establishing PM Dept. of India operation - he had got a lot of appreciation. Even though in terms of timeline he managed to make the submission happened in right time, but he was thoughtful whether this product will be approved in time, whether it's going to match the expectation of Reviewer of OGD (FDA) and how he will architect his journey for several other products, which are in pipeline.

In flashback, a lot of memorable happenings were running through his mind. This is because; this project was a nightmare for him. His thoughts were constantly dragging towards existing pharmaceutical project management process, deficiencies what he had observed and some of the facts i.e. how the relevantly strategic thinking worked for managing this crucial project, and last but not least key lessons learned from this project.

#### BACKGROUND

The XYZ Generic Company is a pharmaceutical corporation; the company is the largest producer of generic drugs in USA. The company produces more than 200 generic pharmaceuticals in approximately 4000 dosages, exporting to over 115 countries around the globe. Over the years the XYZ Generic Company continued to prosper and built up a loyal staff and work force.

For the past several years, pharmaceutical companies have been consistently facing the challenges due to patents expiring, challenges from regulatory authority, and changes in how patients access medicine to name few. To counter attack the stated challenge and sustain in business for profitability, now mainly XYZ Generic Company is focusing on effective Project Management by understanding the relevance of strategic thinking to Project Management. Since, it's the only way to sustain in challenging pharma environment. To illustrate the importance of Project Management, here is the case of XYZ Generic Company for a product called XXX tablet which basically gives an insight on current pharmaceutical project management process,

deficiencies in conventional project management, the relevance of strategic thinking to project management, defining the key issues, summary of key lessons learned.

### The Opportunity

In Dec 2009, it was found that XXX tablet, the market has witnessed FTF opportunity. So, VP RA finalizes its filing strategy as NCE-1. Only two patents listed 08, Sep12 (prod patent) & 13, Jul 21. Till 08, May, 2009 – there is no current generic competitor. And lunch scenario is promising since if product is going to be successfully approved by FDA, company is going to shared Exclusive with Innovators. Forecast for this molecule is 18 Mn\$, which is based on consideration the market share expectation of 15-20%

### The challenges

#### *Uniqueness and specific Challenges in case of Pharmaceutical Industry:*

Like other industries, Pharma industry has also “stress points”— since, those points are most crucial. The stress points are schedule, cost, and quality. Specifically in the pharmaceutical industry, a tougher time is during drug development. In recent years, the market is facing cut-through competition, and the political, regulatory, social and economic pressures have become acute. Also, each year recall of drug product is taking place. So, the most point in the pharmaceutical industry is to maintain quality. Poor quality can be a matter of life and death. Being the leader in bringing a product to market is tough, since the path of drug development is always uncertain. Because of the risks involved in the pharmaceutical industry, utmost care needs to be taken in terms of quality control measures. Quality and time to market—must be well cooked through careful process for reducing the associated risks. For detail regarding development process in Pharma generic industry, please refer Appendix 1.

#### *The spot light on specific challenges pertaining to this project:*

- Early launch with 34 months approval timeline.

- Filing date Constraint; its need to be submitted on or before 10-Jul-2013.
- Limit the number of changes that can be introduced via an Amendment.
- No major changes midcycle to enable us to accomplish first cycle approval.
- Need to be right the first time in terms of submission.

This specific case is dealing-how faced hurdles are directly addressed by the tools and techniques used in project management.

### The Project Concept

“JUST DO IT” is the approach that XYZ Generic Company was using before this project arrives.

The importance to complete submission in time with flying of colors need to be communicated across all levels in the organization. Since, there is no room for failure and delay, Managing Director; Site head along with other Sr. management team decide to drive this project by dint of Project Management team here in India with the guidance of GPM team of head office. Thus, it is imperative that the said project needs to be carried out efficiently and successfully as failure is not an option. The sheer complexities of managing a large scale project can be overwhelming. Now question is that how to make a start. Whether newly PM Dept. of XYZ Generic Company will operate for multi-project in multi-product environments or only consider XXX tablet Project. So, the company finally introduced its new Senior Vice President of Project Management Dr. Desai (M. PHARM, Ph.D., PGDBM). The new Sr. VP is methodical and strategic in his decisions in that he holds no qualms in executing the “early kill” process on any project that shows signs of possible failure.

After Dr. Desai joined, he formed the small team for PM. As per the instruction of higher management, PM dept. starts operating for multi-project in multi-product environments. Since Dept. is new, employees working in other functional departments are not cooperating and the proper flow of information was not taking place. As a result, the newly hired executives in PM dept. face the challenge of determining which projects, each potentially having strong

value proposition and being championed by different business units in an intensely competitive market should be well-invested and which should receive early termination.

### Project Team and Organization

So, Dr. Desai after talking to Sr. management team has decided to change organogram and mode of operation of PM. Initially, as a trial it has been decided XXX project is going to be handled as per the new proposal. Latter on by analysing this case portfolio for PM dept. will be enhanced. So, here first and foremost goal is to form a team who are committed to a common purpose, performance goals, and approach for which they hold themselves mutually accountable. Sr. VP thought for a matrix structure. Project team can be divided in two parts- core team and support team. Core team members are from different functions of an organization such as QA, F&D, RA, QC, AO who have significant authority & responsibility in the organization and have specialist/technical Support teams are group of team who are having generalist/business skills. In a project management team, every member have specific job. He was having the vision to manage the project efficiently; and every member must have specific responsibility & proper authority to perform his/her job. In stead of Weak/Functional Matrix, he thought of implementing Strong/Project Matrix. Where he was in the impression that project manager is primarily responsible for the project. Functional managers provide technical expertise and assign resources as needed. But, it was not running fine due course of time. So, for setting the base he made his mind to move from Strong/Project Matrix to Balanced/Functional Matrix. By this, project manager is assigned to oversee the project and power is shared equally between the project manager and the functional managers. It brings the best aspects for this kind of startup projectized organizations. He tried to have a close look, such that 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.

### Planning

Sr. VP - PM's quest is to make the regulatory submission of XXX tablet on time and to get approval at the earliest. He has taken a start up on one of the challenging project. Since, it's having timeline constrain new chemical entity-1 (NCE -1 filling). Several conflicting circumstances and competing interests threaten completion of the project and Sr. VP Project instructed all team members to keep watchful eye on the progress and to take firm stand on timeline. With this in mind, project management team carefully developed time metrics, which is depicted below:

**Table 1: Time Metrics**

Steps	Projected Timeline
Initiation	10-May-2011
ED API Available	16-Sep-2012
API Sub Available	23-Oct-2012
Stable Formulation	12-Mar-2013
Stability Start	22-Mar-2013
Stability Submission	05-Jul-2013
Bio Report	06-Jul-2013
Submission	10-Jul-2013

### A journey of project from Start-up to submission:

Dr. Mahesh called a meeting for all team members of Project Management. He started the discussion pertaining to API source by seeing all the quotations. Since, API sources of China are cheap; everybody is interested to go for API vendor from China. So, it was decided also to go for Chinese vendor. After QA's inspection it was found that the said source is not reliable and their plant facility is not cGMP approved. But due course of time, he has realized that to procure API from outside of India, form 10 needs to be processed to DCGI. And for approval it's need approximately 1 month time.

Unless and until API cannot be sourced Product development cannot be started. So to address this issue Dr. Mahesh has finalized the API source from Hyderabad. Even though API cost went up, he preferred to go with Indian source for availability of API in time. To control this cost issue in latter days, he discussed with VP - RA to find a way for PAS submission for

alternate API source, so that during commercialization cost issue can be resolved.

Since, this project demands a great deal of collaboration and teamwork. Dr. Mahesh and PM team always interact internal stakeholders as well as external stakeholders with one another and work closely with external stakeholders that include the CROs, Regulatory authorities, Excipients vendors and API vendors. He also prioritizes on cooperation of everyone as any conflicts will put a strain on the overall effort of the entire team. He realized that to form a successful and productive workforce, matching the right people with the right job according to skill and experience is not enough. That's why he has taken a strain to create common collective vision, which extends from top management through all management levels and technical leads. And in each case he tries to pass on this vision to all involved members and stakeholders in such a way that assures them of the value of their contributions. This finally not only reinforces ownership of their tasks and responsibilities, but it will also generate enthusiasm, passion, and proactive attitudes that impact performance and productivity significantly.

Always, he stayed connected with functional departments. He insisted R&D and AO to work vigorously to develop desired product followed with specification, methods for analysis and validations. In the meanwhile, he was constantly following up with USA agent for getting Reference listed drug (RLD) sample. Finally with intense follow up R&D and Analytical Operation (AO) team able come up with stable formulation by 20-February-2013 which is around 15 days before scheduled time. So immediately, he took a call to do an early start for stability charging. As per guideline, minimum requirement is 3 months stability data prior to submission. (1-3)

He along with team also careful evaluated finance aspect to determine whether or not we can actually afford to complete the project without losing money. Based on the budget information at hand, when required they have went for spending more (API sourcing), while in case clinical trials, they manage to reduce budget. Completing a projects "on time and on

budget" are the foundations of full productivity and efficiency for success.

As, this project is having time constraint it was planned to do the bio study in QPS (USA). Because, getting Bio NOC is less time consuming. Nonetheless, bio study in case of USA is ten times costlier than conducting bio study in India. However, in India getting Bio NOC is time consuming i.e. 2 months. But in this case, XYZ Generic Company has got stable formulation before scheduled time. So, Dr. Mahesh wished to change CRO services from QPS to Clinigene (India origin). In this way he thought of cutting cost. Detail pertaining to bio activity is depicted below:

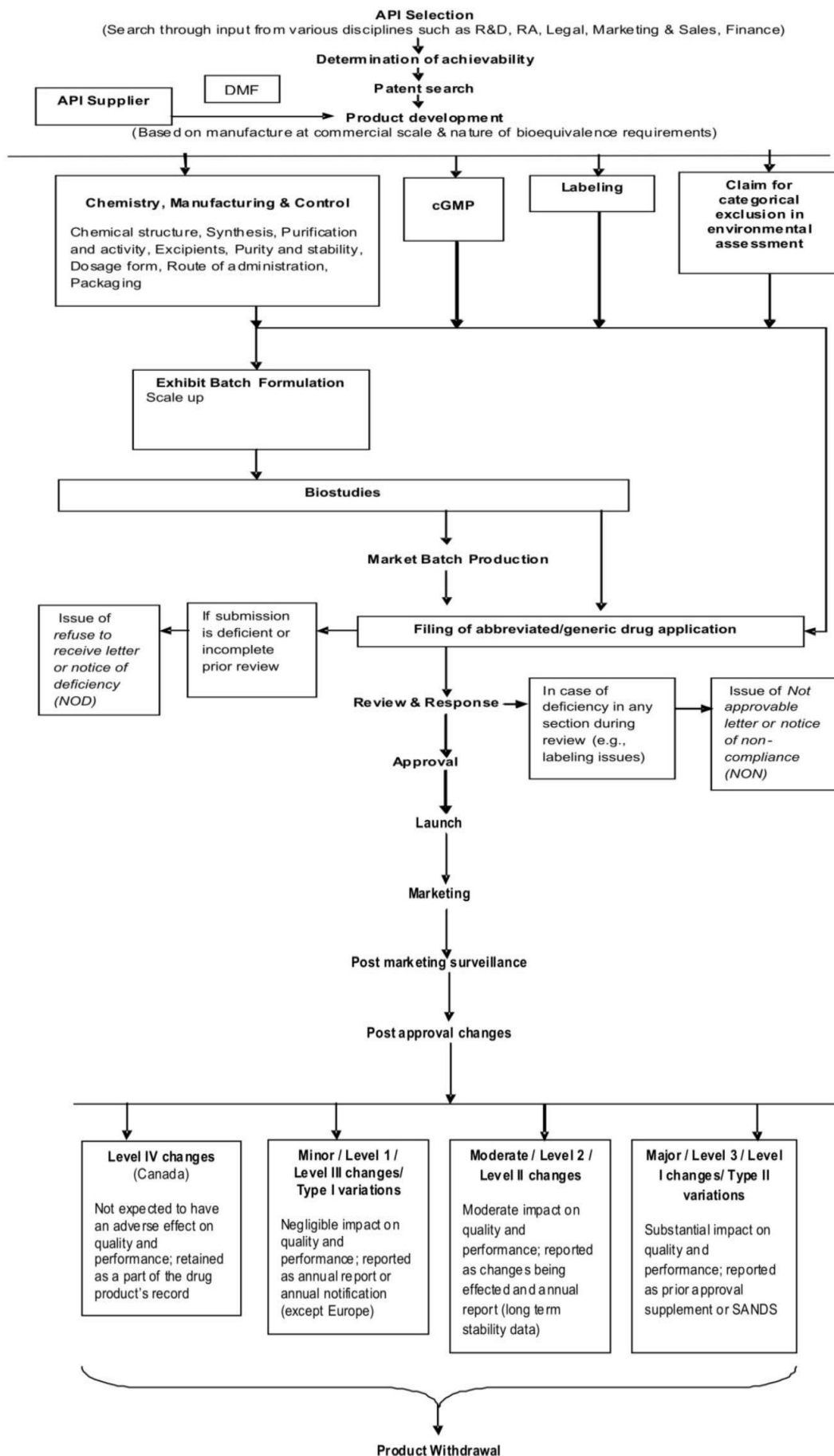
- 02 Mar 13: At Clinigene CRO, clinical trial started.
- Fast: P-I: 10 Apr 13/ P-II: 17Apr 13; 100% preliminary results by 2 May, 13;
- Draft report by 31 May 13
- Fed: Group 1: P-I: 11 Apr 13 / P-II: 18 Apr 13; 100% preliminary results by 3May 13; Draft report by 3 Jun 13
- 13 May, 13: Fast and Fed study passes. RTS expected by 28Jun13.
- 08 Jul, 13: RTS submitted on 06Jul, 13.

In the meantime, he tried his best to ensure that RA should get all requisite data & documents and sufficient time for compilation. Finally it got submitted as per planned timeline.

### Post Project Appraisal

Coordinating the various processes from one phase to another, meeting timelines and dealing with complex regulations is obviously challenging during the drug development process. By understanding this, senior management team understands the importance of Project management. After PM team involvement, the appropriate amount of time and resources to each phase of the development has been assigned. As a result, thereby it was ensured that work can progress forward in a logical but controlled way. Simultaneously, Project was managed nicely by understanding the potential and realized risks while also focusing on the quality of the process and product at each stage of development.

**Development of generic products**



## Figure 1: Development of generic products

By managing the process in a well-planned and controlled manner, the Project Manager also assured that all tasks are completed correctly the first time so that no rework has performed, which deprive to delay the project and it's time to market. So, from this case it is evident that the use of project management in the pharmaceutical industry has proven invaluable to help these companies manage their competing priorities of quality and schedule.

## CONCLUSION

So, in the pharmaceutical industry, project management is key to addressing the unique regulatory, compliance and quality related needs of the industry, is not it? As the process of drug development and the critical issue of time to market can capitalize on project management techniques to effectively apply scheduling, risk management, and comprehensive quality assurance and control to the process of bringing a drug to market in a cost-effective but safe way.

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## CONFLICTS OF INTEREST

The author declares that there are no conflicts of interest.

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