The Benefits of Applying Project Management in the Pharmaceutical Industry
TABLE OF CONTENTS

Abstract 1
About the Author 1
Project Management in the Pharmaceutical Industry 2
Specific Challenges in the Pharmaceutical Industry 3
The Benefits of Applying Project Management in the Pharmaceutical Industry 4
The MSMPP Curriculum and its Relevance to Project Management in the Pharmaceutical Industry 5
Abstract

Project management is a discipline that can be applied to all industries and works very effectively in the pharmaceutical industry where major shifts in recent years have significantly impacted the way in which a pharmaceutical company brings a product to market.

In the pharmaceutical industry, project management is the key to addressing the unique regulatory, compliance and quality related needs of the industry. The process of clinical research and drug development, coupled with 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-efficient way.

ABOUT THE AUTHOR

Leanne Bateman, MA, PMP, CSM, is the Academic Program Chair of Management of Projects and Programs at Brandeis University, Division of Graduate Professional Studies (GPS). She also is a faculty member, and the Principal Consultant with Beacon Strategy Group, a Boston-based management firm specializing in project management services. Leanne has 18+ years of experience across the areas of health care, biotech, information technology, high-tech manufacturing, human resources, construction, senior housing, government, and higher education. She is a member of the Project Management Institute, a certified Project Management Professional (PMP), and a certified Scrum Master (CSM).
Project management is a discipline that can be applied to all industries, regardless of the product or service they are designed to deliver. Beyond its basic application across various industries, project management has tremendous value when effectively implemented to significantly increase the success of the product or service being delivered.

The pharmaceutical industry has encountered major shifts in recent years, both within the industry and in its external environment. Some of the factors responsible for this shift include the rising cost of healthcare due to an aging population, the increase in rigorous regulatory requirements, and company mergers within the industry. These factors have led to an increased need for restructuring, cost reduction, and culture change projects.¹

In the pharmaceutical industry, project management is the key to addressing the unique regulatory, compliance and quality related needs of the industry. 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.

Every industry has different “stress points”—those points that are most critical to the specific product or service being delivered. The most typical stress points are schedule, cost, and quality. Depending on the industry, one (sometimes more) of these stress points directly affects that industry’s profit, thereby making that point absolutely critical to the success of the product, and the company delivering it. It becomes, therefore, a priority in the set of processes involved in producing the product.

Specifically in the pharmaceutical industry, there has never been a tougher time to be involved in drug development. In recent years, the market has become much more competitive, and the political, regulatory, social and economic pressures have become much more intense. Also, each year at least one drug company experiences a recall of one of their drugs, lawsuits from their customers or lawsuits from their competitors.

The most important stress point in the pharmaceutical industry is quality. Poor quality in this industry can literally be a matter of life and death, in its worse cases. Being the first to bring a product to market is also critical, though the course of drug development is unpredictable. Because of the risks involved in the pharmaceutical industry, due diligence is of the utmost importance in terms of quality control measures. So these competing priorities—quality and time to market—must be well managed through careful process in order to reduce the risks inherent in this industry.

Another current challenge for pharmaceutical companies is the pressure they are under to increase their productivity, as the number of new products reaching the market has been on the decline over the past few years. This productivity decline has led many to believe that the industry is in need of a new and better approach in its management of clinical research, drug development, and product delivery.

The two key challenges in the pharmaceutical industry are quality and schedule, both of which are directly addressed by the tools and techniques used in project management.
The Benefits of Applying Project Management in the Pharmaceutical Industry

Over the past decade in particular, there has been a significant increase in the use of project management in the pharmaceutical industry. 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 the tumultuous ride from phase III clinical trials, filing a new drug application, negotiating with and obtaining FDA approval, working with the Division of Drug Marketing, Advertising, and Communications (DDMAC), and navigating the many options and choices through the early years of a product’s launch and commercialization.

Coordinating the various processes from one phase to another, meeting timelines and dealing with complex regulations is often challenging during the drug development process. Project managers are able to assign the appropriate amount of time and resources to each phase of the development, thereby ensuring that work can progress forward in a logical but controlled way. They simultaneously manage the potential and realized risks while also focusing on the quality of the process and product at each stage of development. By managing the process in a well planned and controlled manner, the Project Manager can also assure that all tasks are completed correctly the first time so no rework has to be performed, which will delay the project and its time to market.

Finally, more and more pharmaceutical companies that have been unable to add full-time project management staff have turned to outsourcing to meet their project management needs. Key pharmaceutical decision makers clearly recognize the impact that project management has on their companies’ bottom lines, so despite a tough economy and competing resources, they have increasingly found ways to bring in project management consultants to facilitate their projects. The use of project management in the pharmaceutical industry—whether as inhouse or outsourced expertise—has proven invaluable to help these companies manage their competing priorities of quality and schedule.

The MSMPP Curriculum and its Relevance to Project Management in the Pharmaceutical Industry

There are seven core courses and three electives required to complete the Master of Science in Management of Projects and Programs (MSMPP) at Brandeis University. The core courses are:

- Foundations of Project Management
- Professional Communications
- Advanced Scheduling and Control
- Organizational Leadership and Decision Making
- Risk Management in Projects and Programs
- Negotiating and Conflict Resolution
- Program Management: Theory and Practice

These courses are directly applicable to managing projects in the pharmaceutical industry. There is also an elective course specific to the pharmaceutical industry entitled “Special Topics in Project Management: Clinical Trial Project Management”.

Consider the important points specific to the pharmaceutical industry discussed earlier. Each of these points directly corresponds to one or more of the MSMPP core or elective courses:

**Project Manager Leadership**
- Professional Communications
- Organizational Leadership and Decision Making
- Negotiating and Conflict Resolution

**Project Management Methodology: Tools and Techniques**
- Foundations of Project Management
- Program Management: Theory and Practice
- Special Topics in Project Management: Clinical Trial Project Management

**Risk Management**
- Advanced Scheduling and Control
- Risk Management in Projects and Programs
- Negotiating and Conflict Resolution

The Management of Projects and Programs curriculum at Brandeis University, therefore, is highly relevant to anyone interested in a project management career within the pharmaceutical industry.

For information about the program, please visit the program website.
Master of Science in Management of Projects and Programs

In summary, the MSMPP seeks to advance project and program management professionals in the field by providing a robust curriculum that balances the hard and soft skills essential of project and program managers. The curriculum is aligned but not tied to PMI Standards, allowing the master’s program to retain its applied focus and while recognizing the relevance of the professional standards.

1.877.960.2037 | info@brandeisonline.com | projectmgmt.brandeis.edu