

## **PROJECT MANAGEMENT IN PHARMACEUTICAL INDUSTRY**

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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.

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.

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.