The Importance of Reduced and Predictable Project Timelines

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Introduction

Reducing project schedules and completing facility projects on time has never been more important to our industry than it is today. It is critical that drug manufacturers have the capability of and capacity for producing therapies and treatments that are needed by patients around the world. With the spotlight on the new cell and gene therapies that are being launched and their effectiveness for curing life-threatening diseases, the importance of well-controlled project timelines using prefabricated modular facility solutions continues to grow.

The Impact of Lengthy Project Timelines

Historically, most drug manufacturers have followed a traditional facility construction approach with lengthy project timelines, high onsite complexity, and risk. Very few of the facilities built using this approach were completed on time to their planned schedule, and it was not uncommon for a new facility project to take up to 5 years from start to finish. Because of the duration of project schedules and the unpredictability of traditional on-site construction, drug manufacturers have had to make large capital investments in new facilities long before they required the capacity for their drug products. This has posed significant financial risk to the companies with the following potential outcomes:

Risk	Outcome
A facility built for a drug product that failed in clinical trials and/or did not get regulatory approval	No ROI on capital investment
A facility delayed in start-up that could not commercially manufacture a new drug product upon regulatory approval	Lost revenues
A facility which was undersized and not capable of meeting the market demand for a drug product	Full ROI on capital investment not achieved or delayed
A facility which was oversized and underutilized for producing a drug product that did not achieve the expected market acceptance	Lost revenues

These financial risks can be reduced significantly if project timelines can be reduced with a higher level of certainty that they will be completed on schedule.

The Problem with the Traditional Design and Construction Approach

There are many reasons for lengthy schedules and why they get delayed during the design, construction, and commissioning phases of a traditional project. Because most facilities in our industry have been stick-built, each one has been a unique or custom design based on the manufacturers' requirements, but also on the A&E firm's experience, design preferences, and desire to differentiate their work. This non-standardized approach requires a significant upfront engineering design effort with multiple stage gates for design reviews and approvals before moving to the next phase.

Traditional stick-built facilities require sequential construction phases where the building shell is first erected, followed by building core and utilities, and finally the critical cleanroom and process infrastructure. This requires the continual planning, coordination, and interaction of multiple sub-contractors and services at the construction site. Due to the complexity, there is often a domino effect of construction delays if tasks are not started or completed on time due to permitting issues, material availability, labor shortages, or weather

The Benefits of the Prefabricated Modular Approach

PODs represent an innovative prefabricated modular cleanroom solution that can be effective in avoiding the extended project schedules, delays, and many other issues experienced with traditional construction. The off-site fabrication of the PODs allows for parallel construction activities of both the cleanroom infrastructure and shell building/core which provides a more compressed project timeline. In addition, the PODs are fabricated in a well-controlled factory environment by an experienced labor force. Therefore, the risk of schedule delays as well as the number of on-site contractors, staging areas, safety issues, and overall project liability can be significantly reduced.

The end result is a shorter and more predictable project timeline that can help drug manufacturers produce the required capacity when they need it. The prefabricated approach also mitigates manufacturers' financial risks by allowing them to delay their capital investment until months before the capacity is required or until the product is further along in the clinical trial process and with a higher probability for regulatory approval. The prefabricated modular approach can help companies prevent the potential loss of millions of dollars in revenue as well as prevent the wasting of millions of dollars in capital to build a facility that cannot be used as planned.

About the Author:

Dennis Powers is the Sr. Vice President Product and Strategy for G-CON and has over 25 years of experience working in the biopharmaceutical industry on both the manufacturing and supplier sides of the business. He has held positions in various technical and management functions including engineering, operations, project management, and validation. Through his career, Dennis has worked closely with numerous companies in the biopharmaceutical industry to provide process, equipment, and facility solutions to meet their specific needs. He is an active member of ISPE and PDA.

Dennis received his B.S. in Mechanical Engineering at the University of Delaware and his M.S. in Management from NYU Polytechnic University.

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