“Futureproofing” Cleanroom Facilities

Dennis Powers
Senior Vice President, Product & Strategy

Background

Legacy facilities in the biopharmaceutical industries were traditionally purpose built for large scale processes with little to no inherent flexibility for scaling or bringing in new products and process capabilities. And because many were oversized, they ended up being underutilized and did not realize their forecasted potential or provide a timely return on investment. Today, there is a growing demand for manufacturing facilities that have the flexibility to accommodate multiple products that are produced at smaller volumes, while having the capability to scale operations with minimal impact to ongoing operations. New facility designs, therefore, need to be “futureproofed” to allow for a more rapid response to changes in market demands and manufacturing network needs.

When “futureproofing” a facility design, a first step is to evaluate the processes and utilities. Following that, the cleanrooms that provide the critical controlled environments required for manufacturing should also be considered. The cleanrooms must have inherent flexibility to accommodate future process changes, scale out for capacity increases, and to reconfigure areas for the addition of new products. Over the past decade, there have been significant advances in prefabricated and modular cleanroom infrastructure solutions that offer significant advantages over traditional construction, and these infrastructures can now be designed and built with the flexibility and agility to support a biomanufacturers evolving demands.

The “Box-In-Box” Approach

The ”Box-in-Box” facility approach where Modular (2D)or PODular (3D) cleanrooms are installed within a conditioned shell structure is gaining popularity, and when sized appropriately, can accommodate for future expansion or scale out of additional cleanroom footprint. This is done by installing new cleanrooms into the available unused inactive space or converting warehouse space to manufacturing space, in either case with minimal impact to the existing operation. And if a prefabricated off-site approach is utilized (e.g.,. turnkey PODs), the onsite construction time can be minimized to just weeks for the installation, assembly, and connection of the prefabricated units. Because the PODs are independent and self-supporting (does not require structural integration with the shell building) the approach also provides the flexibility to redeploy or relocate the cleanrooms in the future if needed.

Modular cleanroom solutions are typically provided as pre-engineered systems or kits of architectural components including wall panels, ceiling systems, doors, accessories, etc. that are delivered and assembled at the facility site by an experienced installer. The wall and ceiling panels can be provided with different external architectural finishes (ex. uPVC, PET, SS) and core materials (ex. Aluminum honeycomb, mineral wool) depending on the application. These panel systems can be integrated within a prefabricated POD cleanroom or installed as a standalone cleanroom system within the shell building (assuming it is capable of structurally supporting the modular panel ceiling system).

With proper planning and design, modular panel systems, can provide the flexibility to reconfigure existing cleanroom spaces in the future through the addition/removal of airlocks, relocation of walls to expand spaces or connect to adjacent areas, even when installed in prefabricated systems. And while there are various suppliers of modular architectural components that use similar materials of construction, there can be significant differences in their design, quality, ease of installation, and options for MEP (Mechanical, Electrical, Plumbing) integration, all which can have an impact on "futureproofing." Integrated utility chases, electrical raceways that can be routed vertically or horizontally, and reconfigurable process panels, are just some examples of features available from the leading suppliers, that should be considered and are critical for providing maximum flexibility to ensure that the facilities built today will meet the demands of tomorrow.

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.