PRECISION ADVANCE the cell & gene therapy collective™

Advantages of Using POD Cleanroom Technology

PROJECT FARMA
A PRECISION FOR MEDICINE COMPANY

Advantages of Using POD Cleanroom Technology

by **Tony Khoury**, Vice President | **Phillip Massey**, Associate Director | **Anthony Prince**, Consultant

Technological advancements in the biopharmaceutical industry over the last decade have led to medical breakthroughs being approved at an exponential rate. Previously untreatable diseases are now being cured, giving hope to patients and families worldwide. Now more than ever, speed to market and quality is critical in clinical and commercial manufacturing.

With such rapid market growth, demand has increased for flexible alternatives to centralized manufacturing. Having a full-scale GMP facility for each new therapy is implausible yet most facilities are not equipped with the flexibility required to manufacture multiple products. Drug developers and the Contract and Development Manufacturing Organizations (CDMOs) have experienced a significant bottleneck to getting therapies through the clinical and commercial process and ultimately to patients.

In addition, manufacturing technologies continue to evolve, especially for cell and gene therapies, and therefore require innovative manufacturing methods. These factors combined with an urgency to bring the drugs to market as soon as possible, has put pressure on companies and industry experts to find innovative ways to produce drugs.

We have seen our customers employ various approaches to solving these challenges. One approach that we have had first-hand experience with and that has worked well in a number of projects is the use of G-CON's POD technology. Companies like G-CON are now offering flexible, pre-fabricated modular cleanrooms that are built offsite and delivered as a product to the customer site. Project Farma worked with these cleanrooms from their early designs and shared customer feedback as an input to its most recent, complete solution. These prefabricated modular cleanrooms offer several key advantages that are well-known to the industry:

- Flexibility in the process and production
- The ability to scale without interruption
- Reduced product timelines and cost
- Portable platform for easy placement and rapid deployment
- Seamless integration into "gray space" or non-controlled area

As an owner's representative to small and large life science organizations, Project Farma has worked with G-CON on several capital expansions and seen the following additional advantages:

- Consistent Bill of Materials using high quality products and qualified suppliers
- SOP driven production processes
- Fully documented turnover packages and factory acceptance & site acceptance tests
- Controlled manufacturing environments reducing onsite quality and logistics issues

Flexibility and Multi-Product Processing

PODs are easily customizable because they utilize modular equipment, allowing manufacturers the flexibility to re-purpose each POD to their specific needs. Each individual POD acts as a building-block towards the assembly / configuration of a larger POD cluster or group. PODs can be customized down to the individual level to fit the design needs and process requirements of the group. Overall, POD technology can be a solution for every product development stage as it can be used in a single process step or as a total process containment solution. This is key for cell and gene therapy manufacturers as the demand for their therapies will be nonlinear over time. At first, there will be a high demand for the therapy, but the need going forward will level off and may even decrease as the existing population of patients are treated. Utilizing POD technology gives manufacturers the flexibility to re-purpose each POD to a new therapy or process as the demand for their products evolve over time.

Speed to Market and a Cost-Effective Solution

The planning, construction, and qualification of a full-scale GMP facility is costly and can take years to finish. Often, early stage or mid-sized companies are looking for fast and compliant solutions. Taking advantage of POD technology gives these companies the option to invest in phase-appropriate builds with options for expansion by first investing in small-scale upstream/downstream PODs. Once the product is ready for scale up, the initial design can then be duplicated as demand grows, keeping the manufacturing costs stable and predictable throughout production. Deploying prefabricated POD technology significantly cuts down on costs, time to production, and opportunity loss. Furthermore, because PODs are easy to decontaminate and restructure, investing in a POD is investing in an asset that can be repurposed to lease or sell to another manufacturer.

Streamlined Commissioning Processes & Program Integration

POD technology benefits from employing repeatable products, processes, and protocols to save time and money as commissioning efforts become pre-planned, pre-packaged and predictable. G-CON, for example, uses templates and testing schedules to better receive customer commissioning teams for Factory Acceptance Testing. Carefully planned turnover checklists and procedures allow for a seamless transition to Site Acceptance Testing after POD delivery. Consistent management during CQV affords customers a streamlined commissioning package that is always easily incorporated into the overall site validation and readiness strategy. The turnkey nature GCON's package provides smaller companies and facilities the unique opportunity to establish cleanrooms without the need for dedicated SME involvement. "G-CON has focused on ensuring that FAT is comprehensive for every project. This both decreases project timelines, by requiring less onsite testing, as well as catches any possible issues at the factory, where they can be addressed quickly and retested at SAT," stated Tom Ronat, G-CON's Director of Quality.

Scaling Without Interruption

POD technology helps to solve the industry's growing bottleneck by providing alternatives to outsourcing product production without having to build new facilities. Companies now have the flexibility to create faster and predictable product scheduling without limiting themselves to CDMO's production capacity and scheduling. Rather than constructing and qualifying their own facility, manufacturers can now lease humidity and temperature controlled warehouses to house their manufacturing PODs.

The ability to customize and prefabricate PODs allows for quick construction and installation of the facility without the opportunity loss that typically occurs between approval and production. The offsite assembly of PODs allows for parallel-path, independent completion before transport and installation. Each POD is designed with its own failsafe HVAC system that requires few connections to the host facility, because typical HVAC mezzanines are not required, a large portion of the facility design process can be removed. The PODs integrate seamlessly with facility utilities. As the PODs are a sub-system within the warehouse environment, facility planners are afforded additional flexibility when determining site location. This flexibility translates to a broader selection for acquisition or easier construction process as applicable.

POD technology's inherent flexibility affords small to midsize companies in late phase clinical trials the opportunity to scale processes in reduced time and for a fraction of the cost. When expanding, additional pods can be added to existing structures to meet increasing demand and deliver life-changing therapies to patients in need.

Project Farma and Modular Cleanrooms

Project Farma, as owner's representative, evaluates, audits and selects equipment and modular cleanroom providers. We provide program management, vendor selection, equipment selection and procurement, validation, engineering, reliability and maintenance to operational readiness and facility turnover.

As an owner's representative, PF evaluates and recommends sites that suitable for a modular solution. We analyze and select architectural and construction management firms that are best suited to upgrade the site selected so that its facility and utilities can service the cGMP manufacturing operations including the POD technology.

In parallel, we collaborate with the POD team to integrate the GMP equipment into the modular cleanroom while igniting a Part 11 compliant building automation system to integrate all the GMP data and controls. Project Farma's validation program development, strategy and execution utilize quality by design principles and a risk-based ASTM E2500 approach. We own the complete GMP document lifecycle from the user requirement specifications (URS) through process performance qualification (PPQ).

When procuring a modular cleanroom, Project Farma provides a URS along with commercial procurement specifications, collaborates with the POD team and leverages Project Farma's playbooks to provide an efficient and quality compliant integration and validation strategy. PF also ignites the reliability and maintenance engineering program and SOPs to train staff as part of operational readiness and facility startup.

About Project Farma

Project Farma is a patient-focused consulting firm providing business strategy, project management, validation, engineering consulting services with a proven track record in cell and gene therapy. We partner with cell and gene therapy organizations in addition to healthcare, pharmaceutical, bio-pharmaceutical companies to support finding ground-breaking treatments and solutions. Our cell and gene therapy clients include early stage startups, established advanced therapy companies, medical institutions and CMOs/CROs. We are committed to helping advance cutting-edge medicines by leveraging our deep knowledge and broad experience in cell and gene therapy to meet any new challenges.

Contributing Authors

Tony Khoury
Vice President

Phillip Massey
Associate Director

Anthony Prince
Consultant

PRECISION
ADVANCE the cell & gene therapy collective™

PRECISION for medicine | PROJECT FARMA | PRECISION value & health

Precision ADVANCE, a collection of interconnected services and complementary teams, uniquely focuses on the complexities of clinical, regulatory, manufacturing, and commercial needs to successfully bring cell or gene therapies to market.

Connect with one of our experts. Contact us at **precisionadvance@precisionmedicinegrp.com.**
To learn more about Precision ADVANCE, visit **precisionmedicinegrp.com/advance.**

PROJECT FARMA
A PRECISION FOR MEDICINE COMPANY

2 Bethesda Metro Center, Suite 850
Bethesda, MD 20814
projectfarma.com