BUILDING **FOR LIFE**™

CLEANROOM PODs®

G-CON MANUFACTURING Inc.



TURNKEY SOLUTIONS

SPEED TO MARKET

TRUSTED QUALITY

RELIABLE. FULLY FUNCTIONAL. ON BUDGET. ON TIME.

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At G-CON, our highest aspiration is to ensure that high quality medicinal therapies get to patients as efficiently and as fast as possible. We are passionate about our PODs because we are providing a supply source for needed therapies faster than any other cleanroom providers on the market and with the highest quality. Our team knows that meeting deadlines will save lives.

OUR WHY



Our Vision and Purpose

To save patients' lives by abbreviating the design, build and delivery time of cleanrooms for biopharmaceutical products through our prefabricated and prequalified cleanroom PODs®.

FOCUS

We focus on the patient as this is our ultimate customer. In addition, we focus on excelling in our work and deliverables. We strive to create cost efficient and flexible solutions for the industry so that affordable medicinal drug products of the highest quality can be provided to a global patient base.

INTEGRITY

We believe that integrity of the highest standard is critical in every facet of our business. Our customers trust us with their requirements. We work relentlessly to fulfill those needs while employing the highest ethical and quality standards, always with the patient in mind.

TEAM

We work as a cohesive team, not just within our company, but together with our customers. Their tasks are our tasks. Their goals are our goals. And their success is our success. We recognize that true success can only be achieved as a team, utilizing each member's unique core competences together to achieve the final result – saving patients.

Clonable | **Footprint Compression** | **Scalable**

The POD® Advantage

We have simplified the entire design/build/validate process.

There is a serious global capacity problem facing the world today. Many pharmaceutical companies have lifesaving therapies that they cannot deliver fast enough. G-CON has simplified the entire design/build/validate process via our prefabricated cleanroom line so pharmaceutical companies can focus on what really matters, the patient.

Since 2009, G-CON has led the prefabricated cleanroom industry, fulfilling pharmaceutical and biopharmaceutical needs by embracing new trends. G-CON designs, builds and installs prefabricated cleanroom PODs for a variety of applications; from laboratory environments to personalized medicines and large-scale production platforms.

As the leader in prefabricated turnkey solutions, G-CON PODs represent a significant innovation in pharmaceutical and biopharmaceutical production capabilities. PODs provide the only system that is readily deployable, flexible, prequalified and scalable for any cleanroom need. The added benefit of the prefabricated cleanroom infrastructures is the unsurpassed budget and delivery time reliability, which can only be achieved when such systems are built off-site.



"The POD concept was selected for it "fit" our purpose and the company was a true partner. [We] only have had excellent support [and] the POD concept allowed us to get into conceptual, testing, and development very quickly. The excellent integration of the POD, process equipment and outside facility was the key to success."
- Director, Global Engineering - Global Fortune 500 Pharma Company

PODULAR, NOT MODULAR

PODs fulfill the demands of industry and regulatory authorities where requirements of containment and segregation are important to protect products and the environment. G-CON's PODs provide a prefabricated and prequalified cleanroom infrastructure, guaranteed to be fully functional, with predictable delivery timelines and reliable cost budgets.



No other product or system on the market provides:

- a turnkey approach
- projects in the shortest timeframe
- a finished and functional product that is delivered to the site
- a fully commissioned system with a complete engineering turnover package
- a repurposable asset (with leasing available)
- an asset that can be depreciated like equipment
- trustworthy project predictability

We fulfill the needs of the biopharma industry for cost efficient, flexible processing and facility solution with the most attractive total cost of ownership to enable affordable treatments for every patient.

OUR COMMITMENT

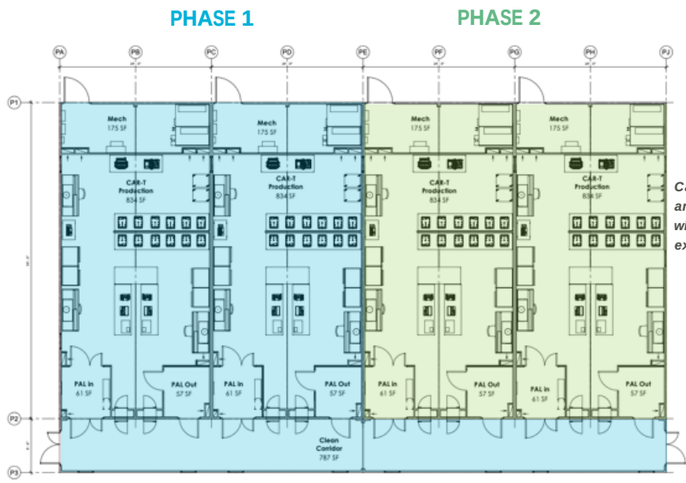


SCALE

SPEED

SAVINGS

Uninterrupted Scalability



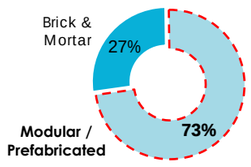
Capacity increase and scalability without interrupting existing processes

We are committed to a 3S approach (speed, scale and savings) to design and manufacture prefabricated cleanroom units timely and efficiently off-site and to introduce these prequalified systems to the customer site quickly without significant resources and on-site interruptions in order to get needed medicines to patients.

PODs allow customers to:

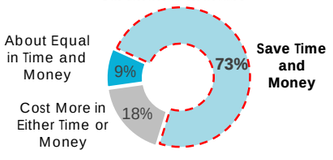
- Ramp-up quickly if drug demand increases
- Ramp-down if the demand diminishes
- Continuously adjust processes based on demand
- Keep current processes running when new units are moved in place for scale up
- Incorporate corridors and unidirectional flow

Which approach would you prefer for your next cleanroom?



Source: Aspen Media, Inc.

Which best describes your view of modular/prefabricated cleanrooms, vs. brick & mortar?



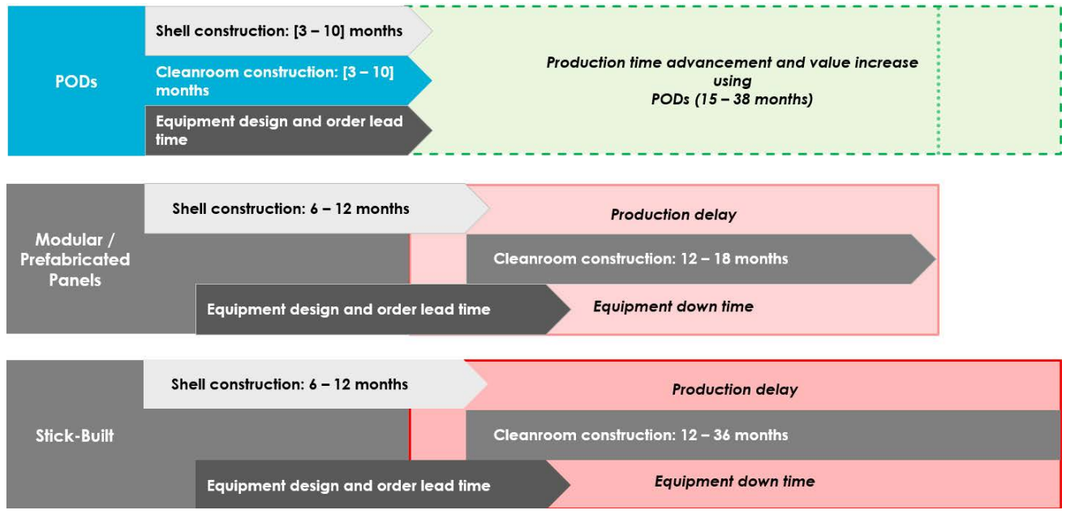
Source: Aspen Media, Inc.

Reliable Speed

With most traditional projects being treated as new infrastructure, the design and build phases are lengthy and unreliable. Project schedules are often 12 months or longer and hourly compensation models employed by designers and contractors do not incentivize an efficient process. With modular panel and stick-built cleanroom designs, construction of the cleanroom is the rate-limiting step due to lay-down area and worker density limitations, and generally spans 12 - 36 months.

Podular, prefabricated designs, however, allow for rapid supply of capacity demands. POD based facilities can be erected in as little as 6 months. While PODs are being built, the host facility can be built or renovated, and the process equipment can be ordered and produced.

At G-CON, we believe timelines need to be reduced further, without sacrificing quality, as delivery speed saves patients' lives.



Source: LEK Consulting and G-CON Management.

COST SAVINGS

G-CON's off-site construction creates manufacturing control of productivity, time, logistics and safety. Customers using PODs immediately realize financial benefits when they save operational costs spent on energy and do not experience business interruptions. While competitor cleanrooms are simply an empty facility, GCON's price point includes all necessary cleanroom components, such as automation controls and fire suppression equipment.

01 **Predictable Timelines**

02 **High and flexible productivity levels**

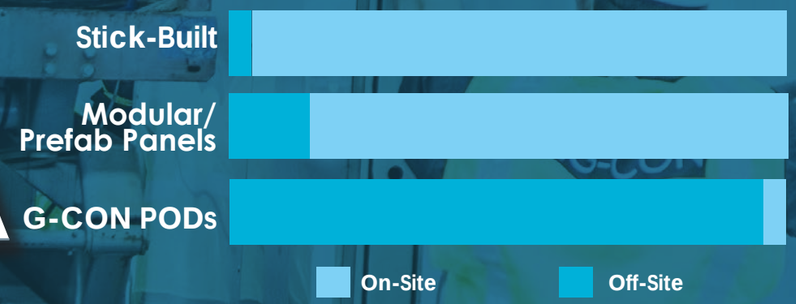
03 **Known materials and cost items**

04 **Elimination of interruptions (e.g., weather)**

05 **Ability to move assets where they are required**

	BUILD ON-SITE	BUILD OFF-SITE
No interruption at production site	✗	✓
No need for construction insurance	✗	✓
Minimal permitting	✗	✓
No logistics issues	✗	✓
No time lost for safety training on-site	✗	✓
No area needed for storage	✗	✓

WORK LOCATION BREAKDOWN COMPARISON



OUR SOLUTIONS

We create flexible solutions for multiple applications.

G-CON offers a wide variety of prefabricated cleanroom solutions ranging from standard PODs to project specific PODs. All configurations are mobile and configurable.



Standard POD®

Recommended for: Cell therapy, laboratory purposes and aseptic filling

- Three standard POD sizes, each with bidirectional and unidirectional flow options
- Fully designed and available in three months
- Readily available upon request

mobilePOD®

Recommended for: Compounding and filling and various lab applications

- Mobile POD trailer for urgent care needs in different locations
- Can be CNC or classified space
- Fully outfitted with furniture
- Configurable for different tests

megaPOD®

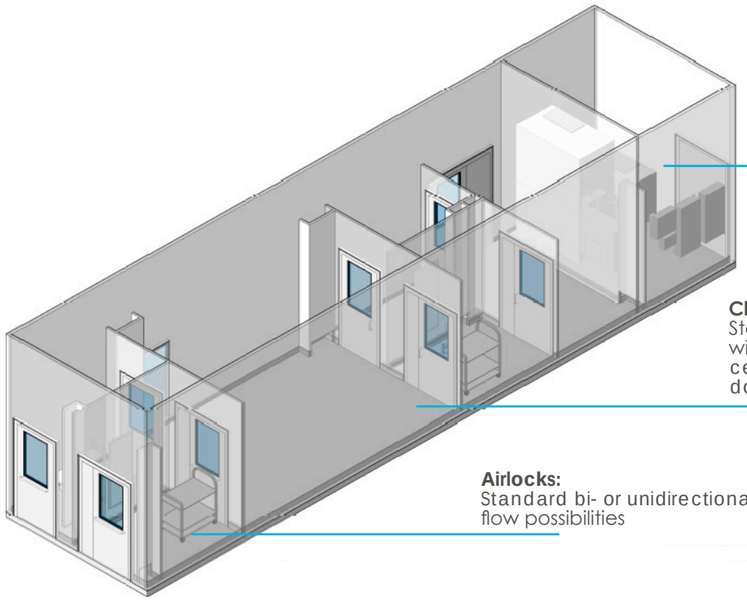
Recommended for: Large scale SU bioreactors, oral solid dosage, large volume solution prep and filling isolator/ RAB systems

- High bay POD units oversized equipment needs
- Ballroom configurations are available
- Different utilities can be implemented

POD® Systems

Recommended for: Any medicinal drug or medical device application (up-stream/downstream processing, formulation, filling, packaging, gene/viral vector therapies)

- Project based processing cleanroom clusters for a variety of applications such as mAbs, cell and gene therapies, vaccines, etc.
- Larger scale areas and infrastructures
- Ballroom or unit operation structure designs



Mechanical Area:
Accessed from “grey space”. Contains standardized HVAC, automation and control systems.

Classified/Processing Space
Standardized classified space with specified floor, wall and ceiling materials, returns, doors and windows

Airlocks:
Standard bi- or unidirectional flow possibilities

G-CON has eliminated the complexities of cleanroom construction projects.

STANDARDIZATION IS KEY

The G-CON Standard POD®: A ready-to-go cGMP suite delivered in 3 months

Available Dimensions:

12’W x 50’L x 13.5’H

17’W x 50’L x 13.5’H

24’W x 50’L x 13.5’H

Material and Personnel Flow Options

Unidirectional

Bidirectional

Standard parts, standard construction procedures, standard quality checks and commissioning, and no additional engineering

A standard product that is repeatable with a verifiable process and easily mass produced

Known parts, known methods and known testing, designed by experts who have spent years designing and building PODs

OUR ADVANCEMENTS

Readily Deployable Integrated Solutions and Cleanroom Infrastructures

“[This is] innovation that reduces the significant size and cost of cell and gene therapy manufacturing facilities to enable scalable capacity, distributed manufacturing and marks another step toward enabling our partners to bring their life saving treatments to patients at scale.”

-Co-founder & CSO International CGT Manufacturing Technology Company

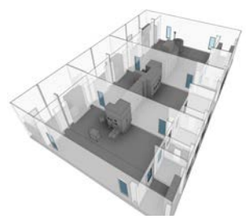


Cell Therapy

Capacity scaling without interruption for the manufacturing of therapies to treat rare diseases.

- Robust containment and controls
- Rapid and reliable delivery time and budgeted costs
- Scale up and scale out without interrupting existing processes
- Possibility to move the infrastructure if production is decentralized

Easy Scalability



Aseptic Filling

Fully integrated solutions for aseptic fill finish.

- Small footprint
- Robust cleanroom environment around a fully integrated fill system
- Prefabricated and pre-qualified with ability to drop-ship wherever the fill capacity is required.
- Easily scalable fill capacity without interruption of existing processes

Full Integration



Mobile Testing LabPODs

A mobilePOD fully fit-out with Avantor’s VWR® equipment, casework and furniture.

- Fast-track delivery of diagnostic and analytical lab capability where and when it’s needed
- Fully integrated turnkey lab solution
- At site testing in a contained environment
- Ideal for COVID-19 diagnostic testing
- Elimination of lengthy turnaround times

Fast Turnaround

OUR QUALITY



Experience you can trust.

We test every functional component of PODs prior to delivery with a Factory Acceptance Test (FAT) and after delivery with a Site Acceptance Test (SAT). With dedicated and in-house Quality and Commissioning Departments, we can also provide and execute a complete IQ/OQ package that meets the FDA and EU requirements for commissioning and qualification for every POD we build.

Quality Assurance

- A robust ISO 9001 Quality Management System
- Regular review of all business functions that impact POD quality
- Regular grading and review of our vendors

Quality Control

- We execute QC checklists throughout POD build, from superstructure fabrication through site installation
- We inspect and document all incoming critical Quality Components (cGMP impact)

Commissioning and Qualification

- We provide a fully leverageable (FAT/SAT) package
- We use an ASTM E 2500 approach, meeting regulatory guidance for drug manufacturing
- Result: Delivery of a cleanroom facility that is fully cGMP tested and compliant

ISO 45001 www.intlcert.com

ISO 9001 www.intlcert.com

OHSAS 18001 www.intlcert.com

ADDITIONAL SERVICES



G-CON Building Services

G-CON Building Services provides host facility project management solutions to pharmaceutical and biopharmaceutical clients to simplify customer cleanroom projects and provide project completion in a more timely and cost-efficient manner.



Cleanroom Facility HVAC Services

G-CON provides full-service HVAC Test and Air Balance (TAB) testing for its cleanroom PODs and also for the shell facility housing the PODs. When both scopes are completed in a coordinated fashion, budgetary surprises resulting from hiring multiple contractors are eliminated, saving time and money during this critical final step.



Automation & Environmental Management

We provide a robust automation system within our PODs, which includes a multifunction Building Management System (BMS). The BMS controls the environment of the POD to ensure customer process conditions are met. Amongst other features, the POD BMS can operate door controls, room pressure, as well as communicate with the host facility BMS through several communication protocols. G-CON also offers a 21 CFR Part 11 compliant Environmental Management System (EMS). Our EMS stores data from the POD for temperature, pressure and humidity and allows the user to retrieve that data in a way that is not corruptible.

Collaboration Partners

Process Technology

PALL · L7 INFORMATICS · vanrx · LifeAire Systems · Oribiotech · MilliporeSigma · avantor · cytiva

Facility Products & Services

ips · ASGARD CLEANROOM SOLUTIONS · BUTLER · LEDspan · SPAN CONSTRUCTION & ENGINEERING, INC. · vai · VALSOURCE

BUILDING FOR LIFE ™

G-CON MANUFACTURING Inc.

Fast. Flexible. Scalable.



G-CON Qualifications

G-CON's name is synonymous with fulfilling the needs of the biopharma industry for cost efficient, flexible processing and facility solutions. G-CON's founders developed the POD technology to address a critical need for autonomous cleanroom systems to manufacture personalized cancer vaccines, leading to developments for laboratory purposes and aseptic filling, for example. Over the past ten years, the G-CON team has continued building this expertise supporting the industry's demand for more rapidly deployable cleanroom facilities for clinical and commercial supply.

Please contact the G-CON sales team at sales@gconbio.com to learn more about how we can support your laboratory needs.



Trusted Experience.

- Design, fabrication and installation of PODs for various applications, including but not limited to:
  - Cell Therapy
  - Gene/Viral Vector Therapies
  - Aseptic Filling
  - Various Lab Applications
- Clinical and Commercial Scale Facilities
- Client base ranging from start-ups to top global Fortune 500 pharma companies

Proven Capabilities.

- Accelerated design and delivery using a standardized design and execution approach
- Autonomous design with integrated HVAC, electrical, utility and control systems allowing for:
  - Pre-qualification testing at factory
  - Rapid installation, start-up and site qualification testing
  - Independent operation
  - Inherent containment and segregation by design
  - Scaling and expansion with minimal impact to operations
- A flexible and mobile manufacturing asset that can be:
  - Installed in new or existing facilities
  - Re-deployed to other locations
  - Re-purposed for different processes or application
  - Purchased or leased

Fully Qualified.

- Robust ISO 9001 Certified Facilities and Quality System
- cGMP Clinical and Commercial Scale Facilities
- Vertically integrated manufacturing operations
- Global project delivery
- Pre-engineered design, fabrication, and testing standards
- In-house Engineering, Project Management, Automation, Quality and Commissioning

TURNKEY

SPEED TO MARKET

SCALABILITY

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