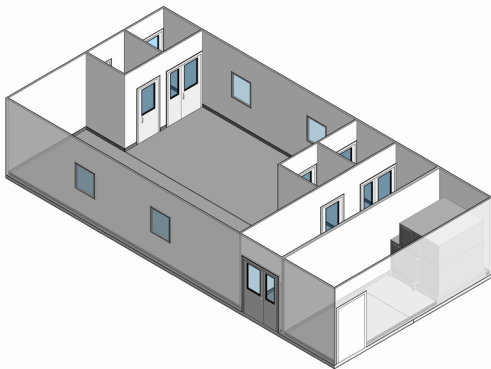


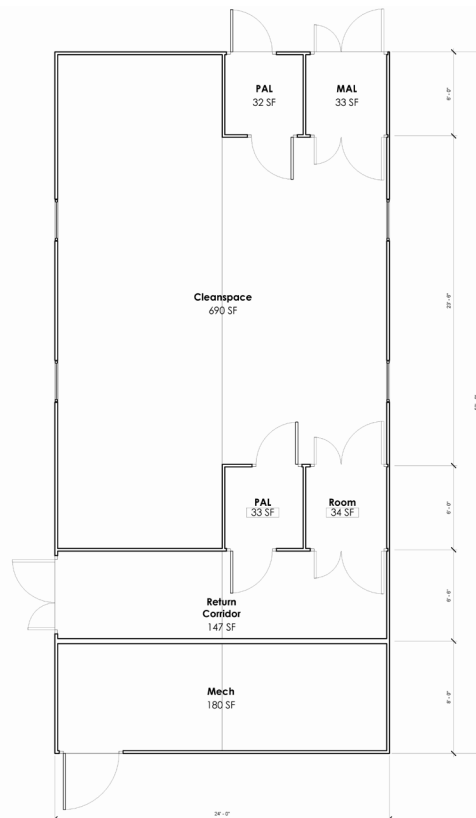
BUILDING FOR LIFE

Standard Cleanroom POD Catalogue

Making Cleanrooms
a Product



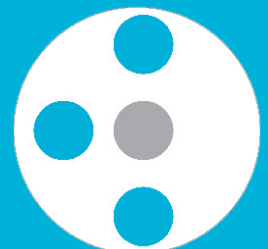
2 ISO VIEW



1 GENERAL ARRANGEMENT PLAN
3/8" = 1'-0"

The Prince, Castlecomer, Co. Kilkenny, Ireland, R95 X8ER | +353 (0) 56 449 1491

www.gconbio.com | sales@gconbio.com





The New World of Therapies Requires New Thinking In Facility Design & Construction

The Needs

Past processing infrastructures typically handled large volume processes, that required large footprint, product dedicated facilities. New therapeutic developments required rapid build-up of capacities that traditional construction could not accommodate. Cell/gene therapies and higher expression rates in existing biologics, created the need for small footprint, flexible process intensified facilities.

Specific requirements for these facilities include:

- rapid and reliable delivery time and project budgets
- scaling out without interrupting existing processes
- standardizing process, cleanroom and facility designs for faster delivery
- repurposability and mobility of the cleanrooms

The Traditional Approach

These needs typically cannot be met by traditional facility approaches. Every traditional project is treated as a new infrastructure and with that design and build phases are lengthy and unreliable. Project schedules are often 12 months or longer as the hourly compensation models employed by designers and contractors do not incentivize a swift process. Additionally, the budgets are often exceeded due to a variety of unaccounted costs.

The G-CON Approach

G-CON's innovative prefabricated cleanroom platform is ideal for meeting these needs. PODs are rapidly deployable turnkey cleanroom infrastructures built off-site. Every POD quote is all inclusive; from engineering design through qualification with highly reliable pricing and delivery schedules. The units are delivered fully functional and prequalified after a well defined Acceptance Testing Strategy is performed.



Turnkey Solutions



Speed to Market



Ease of Scalability

The Paradigm Shift

The FDA's 21st Century Initiative declared the need for "A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight." The industry at large has embraced this approach as well, seeking such flexible facilities for their production needs.

These requirements are met by innovative, podular, prefabricated designs, which also allow for rapid supply of capacity demands. POD based facilities can be erected within 6 to 8 months, and can also be scaled up or down for changes in demands. At G-CON, we believe timelines need to be reduced further, without sacrificing quality, as delivery speed saves patients lives !

Our Vision

G-CON has developed a large portfolio of cleanroom PODs for various applications in order to supply the optimal cleanroom design to the end-user. The key elements that are critical to cleanroom infrastructures - high quality, CGMP compliant designs, delivery speed and predictable costs are inherent to every G-CON POD design. In order to maximize efficiencies related to delivery speed and cost reduction, G-CON provides a two-pronged approach to serve our clients in an even more optimal way. This includes introducing for our clients - Standard POD designs and full turnkey POD-based facility solutions.

G-CON has developed a portfolio of six standard cleanroom PODs. These PODs are fully designed, allowing them to be mass-produced. Delivery time is as little as 3 months with the future goal of being able to maintain an inventory of ready to deliver PODs. Mass production of standard PODs will also lower costs. We believe cleanroom infrastructures have to become an off-the-shelf piece of equipment.

Turnkey platform facility solutions are available and are in progress. The shell building is a pre-engineered free-span building that is much more economical and flexible than traditional approaches.

Redeploying proven designs reduce design, construction, and validation costs and gets therapies to patients faster.

Innovative



The Creativity
You Want



Eliminating the Complexity, Redesign & Hours of Cleanroom Construction Projects

Many manufacturing processes do not differ within their specified application. Often the processes have very similar unit operations and the main variant is the scale and mass balances. However, even when such processes have been designed for many years and a vast knowledge base exists, new projects of the same application tend to be redesigned. Instead of using a template or even standard approach, hundreds of manhours are utilized to start from a blank slate. In doing so, efficiency, costs and time-to-run all suffer.

We understand that time is of essence. The vast majority of our projects are schedule driven. We are better able to meet our clients' deadlines by not waiting for permits, procuring from well-known suppliers, and having a process-driven design, build and commissioning process. All of this process is controlled by our ISO-9001 Quality Management System and executed by a highly experienced team.

Traditional Design & Built → ranges from 18 – 34 months



Standard Pre-designed/Prefabricated → ranges from 3– 5 months

We believe we can further reduce the timelines, eliminating or reducing the design and procurement blocks, when utilizing productized, predesigned cleanroom units.



Standardization is Key

We understand that planning a manufacturing site has many challenges. Quality, capacity, timing and budget all are paramount. Project management, bringing it all together, is a complex process. Why not have the cleanroom infrastructure part being taken care by us ? The cleanroom POD approach eases these burdens, speeds up the process and provides a turnkey delivered solution.

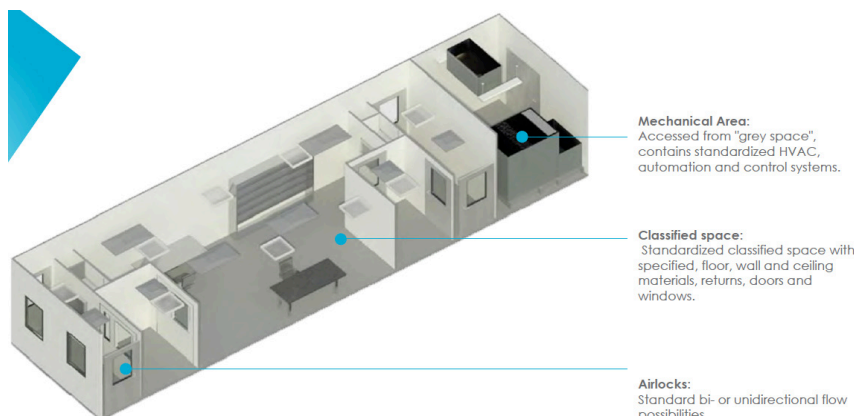
To further ease the burdens, we have developed a new standard POD product range, which offers “off-the shelf” designs that can be manufactured and delivered in 3 months or less for a set list price. These units are fully functional with all necessary components included to run a cleanroom, including automation and fire suppression. Such standard PODs can be ordered like a piece of equipment by their own inventory number. Lengthy BOM and URS reviews and generation are not necessary as these are included with the product. The client simply reviews the size and flow pattern to ensure alignment with their process needs.

Ultimately, when standardization sets in, G-CON's vision is to mass produce the standard POD product range to be able to built to stock and have the cleanroom system ready for you to be delivered immediately. Instead of waiting for a cleanroom structure being build on-site in 6 months, these off-site built cleanroom units can be delivered in 3 months now and even faster in future.

Our standard portfolio includes six PODs; three different dimensions of two different material and personnel flows. These units have an ISO7 classification, a common background for a multitude of applications.

Standard PODs can certainly be configured, but such will increase the delivery time and cost.

Reliable



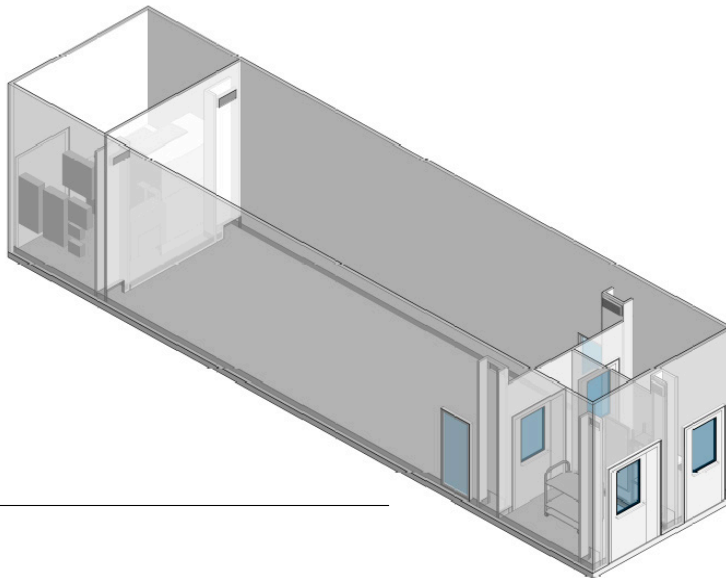
**The Track Record
You Can Rely On**

Standard POD Layouts

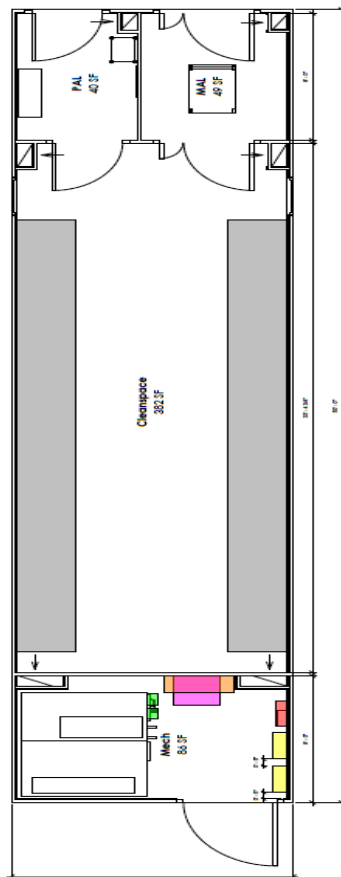


12' x 50' x 13.5' POD - Bidirectional

3.5 x 15.5 x 4 m POD - Bidirectional



PERSPECTIVE VIEW 2



Order number:

POD-BD-1250

Product Description

Standard 12' wide bidirectional POD structure, fully designed as a piece of equipment ready to order.

Applications

- Inoculation suite
- Isolator filling area
- Research
- Laboratory space

Personnel/Material Flow

Bidirectional

Cleanroom Classification

Grade C/ISO 7

Wall Materials

UPVC panels

Ceiling Materials

UPVC panels

Floor Materials

Nora floor system

Lighting

LEDspan

Doors

Aluminum powder coated

Automation

Siemens PLC, LVL 4 Stand Alone

Fire Protection

LVL 3 Wet Sprinkler System

Delivery Time (Standard Design)

3 Months

What is included:

- Air handling and HVAC system
- Automation
- Engineering
- Project Management
- Fire suppression system
- Factory Acceptance Test
- Site transfer
- Site Acceptance Test/Commissioning
- Qualification documentation

Dimensions:

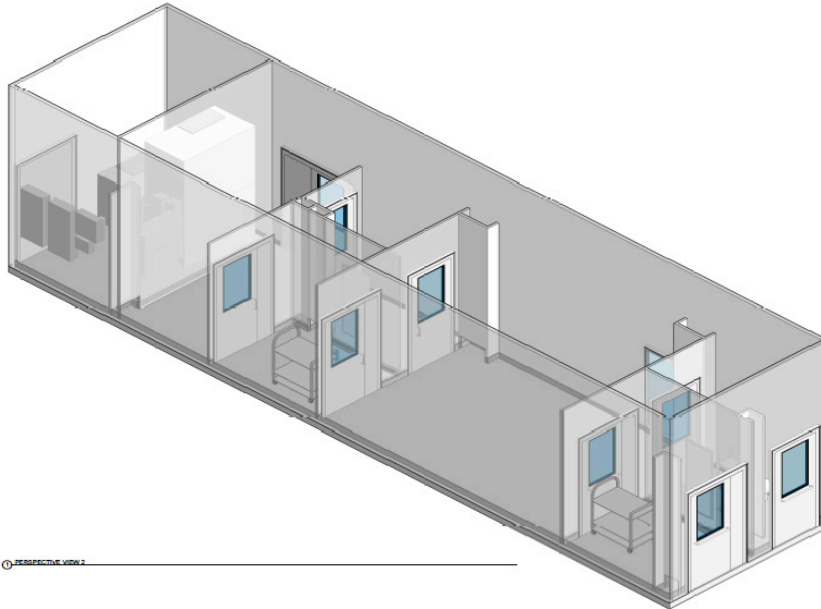
External
W: 12' 3.5 m L: 50' 15.5 m H: 13.5' 4 m

Internal
H: 9' H: 2.75 m

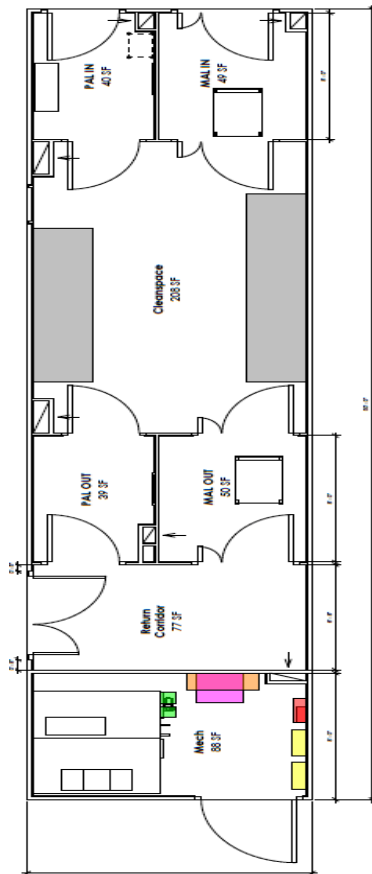
Cleanroom area: 382 sq. ft. 35.3 sq.m

12' x 50' x 13.5' POD - Unidirectional

3.5 x 15.5 x 4 m POD - Unidirectional



PERSPECTIVE VIEW 1



Order number:

POD-UD-1250

Product Description

Standard 12' wide unidirectional POD structure, fully designed as a piece of equipment ready to order.

Applications

- Inoculation suite
- Isolator filling area
- Small scale cell therapy

Personnel/Material Flow

Unidirectional

Cleanroom Classification

Grade C/ISO 7

Wall Materials

UPVC panels

Ceiling Materials

UPVC panels

Floor Materials

Nora floor system

Lighting

LEDspan or as specified

Doors

Aluminum powder coated

Automation

Siemens PLC, LVL 4 Stand Alone

Fire Protection

LVL 3 Wet Sprinkler System

Delivery Time (Standard Design)

3 Months

What is included:

- Air handling and HVAC system
- Automation
- Engineering
- Project Management
- Fire suppression system
- Factory Acceptance Test
- Site transfer
- Site Acceptance Test/Commissioning
- Qualification documentation

Dimensions:

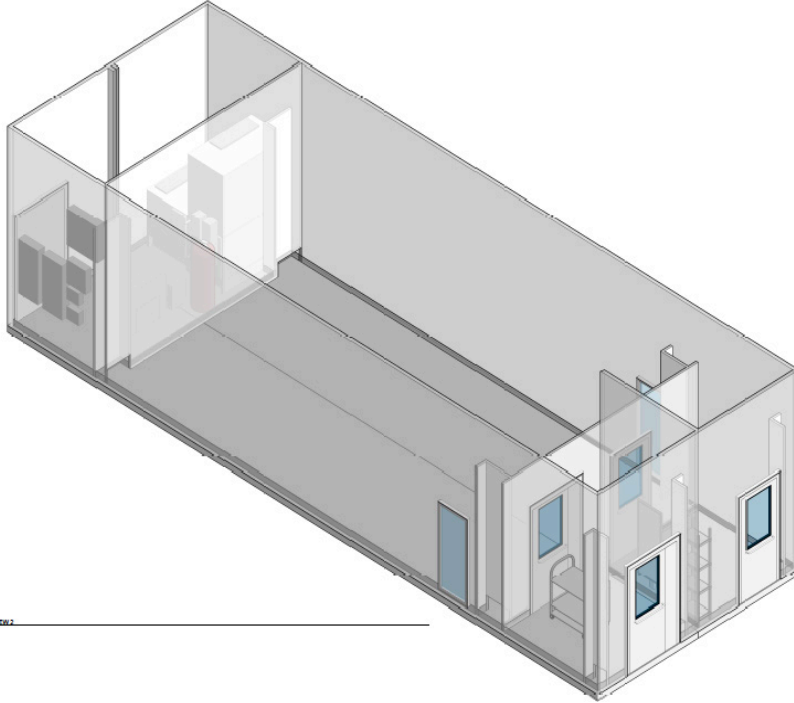
External
W: 12' 3.5 m L: 50' 15.5 m H: 13.5' 4 m

Internal
H: 9' H: 2.75 m

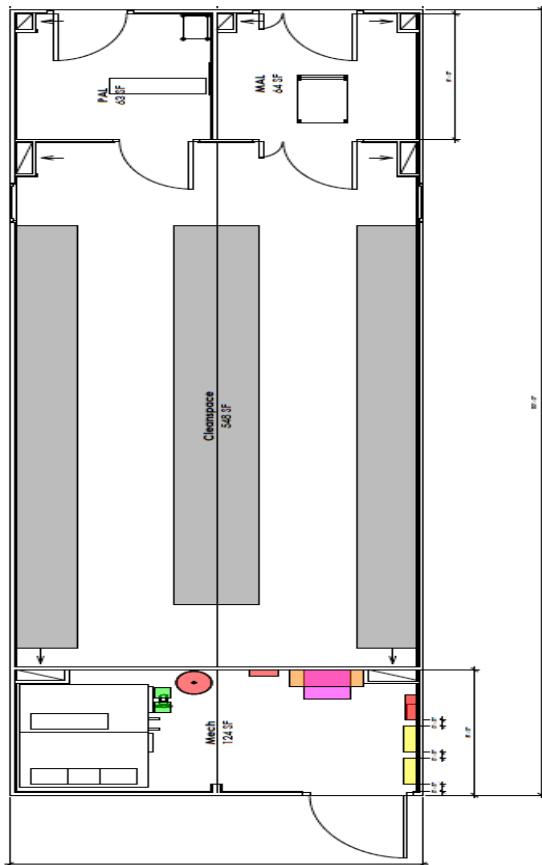
Cleanroom area: 208 sq. ft. 19.3 sq.m

17' x 50' x 13.5' POD - Bidirectional

5 x 15.5 x 4 m POD - Bidirectional



PERSPECTIVE VIEW 2



Order number:

POD-BD-1750

Product Description

Standard 17' wide unidirectional POD structure, fully designed as a piece of equipment ready to order.

Applications

- Gene therapy
- Isolator filling area
- Individual unit operations
- Research & Development

Personnel/Material Flow

Bidirectional

Cleanroom Classification

Grade C/ISO 7

Wall Materials

UPVC panels

Ceiling Materials

UPVC panels

Floor Materials

Nora floor system

Lighting

LEDspan or as specified

Doors

Aluminum powder coated

Automation

Siemens PLC, LVL 4 Stand Alone

Fire Protection

LVL 3 Wet Sprinkler System

Delivery Time (Standard Design)

3 Months

What is included:

- Air handling and HVAC system
- Automation
- Engineering
- Project Management
- Fire suppression system
- Factory Acceptance Test
- Site transfer
- Site Acceptance Test/Commissioning
- Qualification documentation

Dimensions:

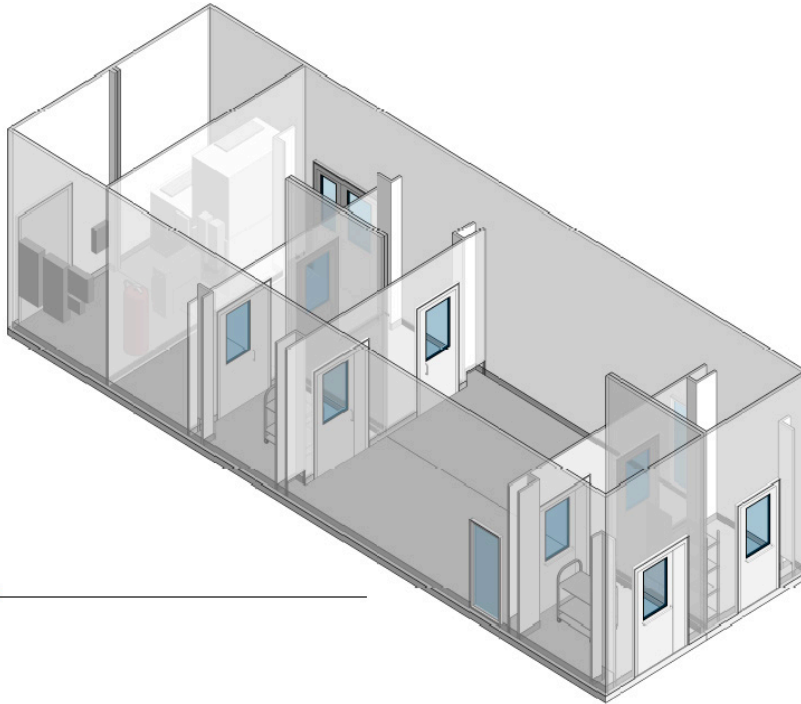
External
W: 17' 5 m L: 50' 15.5 m H: 13.5' 4 m

Internal
H: 9' H: 2.75 m

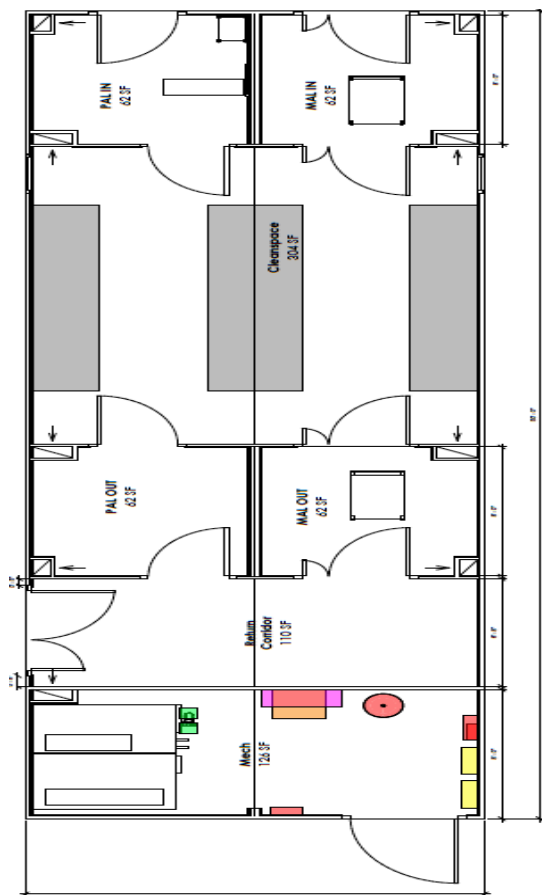
Cleanroom area: 548 sq. ft. 51 sq.m

17' x 50' x 13.5' POD - Unidirectional

5 x 15.5 x 4 m POD - Unidirectional



OUT VIEW 2



Order number:

POD-UD-1750

Product Description

Standard 17' wide unidirectional POD structure, fully designed as a piece of equipment ready to order.

Applications

- Inoculation suite
- Isolator filling area
- Small scale cell therapy

Personnel/Material Flow

Unidirectional

Cleanroom Classification

Grade C/ISO 7

Wall Materials

UPVC panels

Ceiling Materials

UPVC panels

Floor Materials

Nora floor system

Lighting

LEDspan or as specified

Doors

Aluminum powder coated

Automation

Siemens PLC, LVL 4 Stand Alone

Fire Protection

LVL 3 Wet Sprinkler System

Delivery Time (Standard Design)

3 Months

What is included:

- Air handling and HVAC system
- Automation
- Engineering
- Project Management
- Fire suppression system
- Factory Acceptance Test
- Site transfer
- Site Acceptance Test/Commissioning
- Qualification documentation

Dimensions:

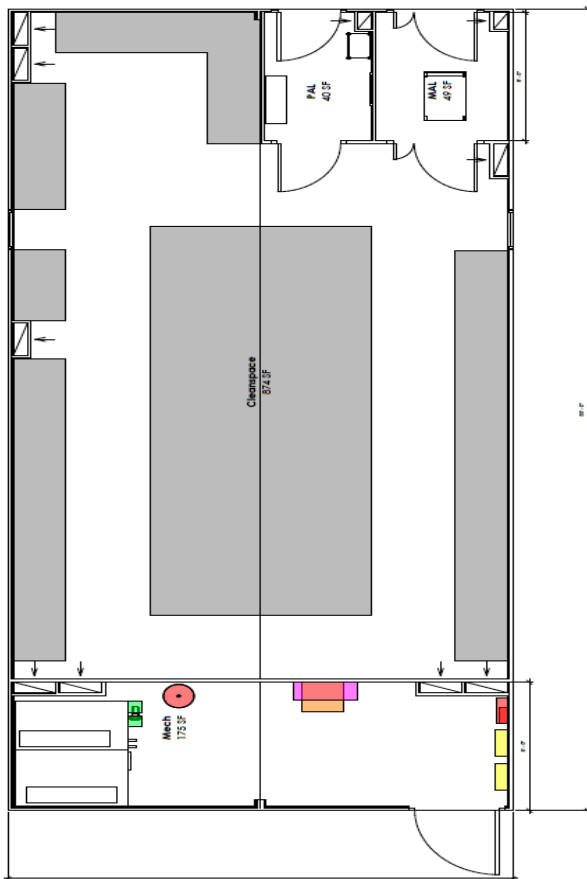
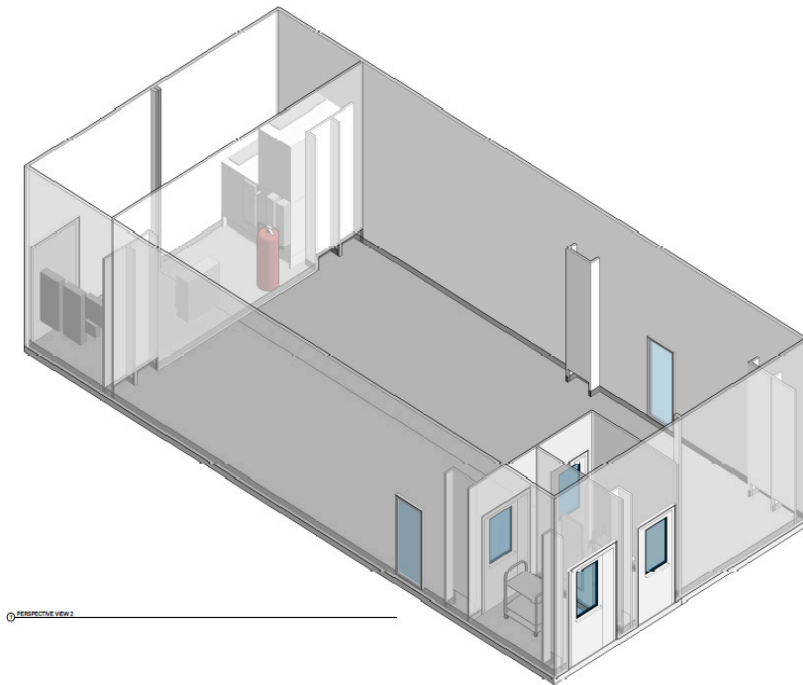
External
W: 17' 5 m L: 50' 15.5 m H: 13.5' 4 m

Internal
H: 9' H: 2.75 m

Cleanroom area: 304 sq. ft. 28.2 sq.m

24' x 50' x 13.5' POD - Bidirectional

7 x 15.5 x 4 m POD - Bidirectional



Order number:

POD-BD-2450

Product Description

Standard 24' wide unidirectional POD structure, fully designed as a piece of equipment ready to order.

Applications

- Inoculation suite
- Isolator filling area
- Small scale cell therapy

Personnel/Material Flow

Bi-directional

Cleanroom Classification

Grade C/ISO 7

Wall Materials

UPVC panels

Ceiling Materials

UPVC panels

Floor Materials

Nora floor system

Lighting

LEDspan or as specified

Doors

Aluminum powder coated

Automation

Siemens PLC, LVL 4 Stand Alone

Fire Protection

LVL 3 Wet Sprinkler System

Delivery Time (Standard Design)

3 Months

What is included:

- Air handling and HVAC system
- Automation
- Engineering
- Project Management
- Fire suppression system
- Factory Acceptance Test
- Site transfer
- Site Acceptance Test/Commissioning
- Qualification documentation

Dimensions:

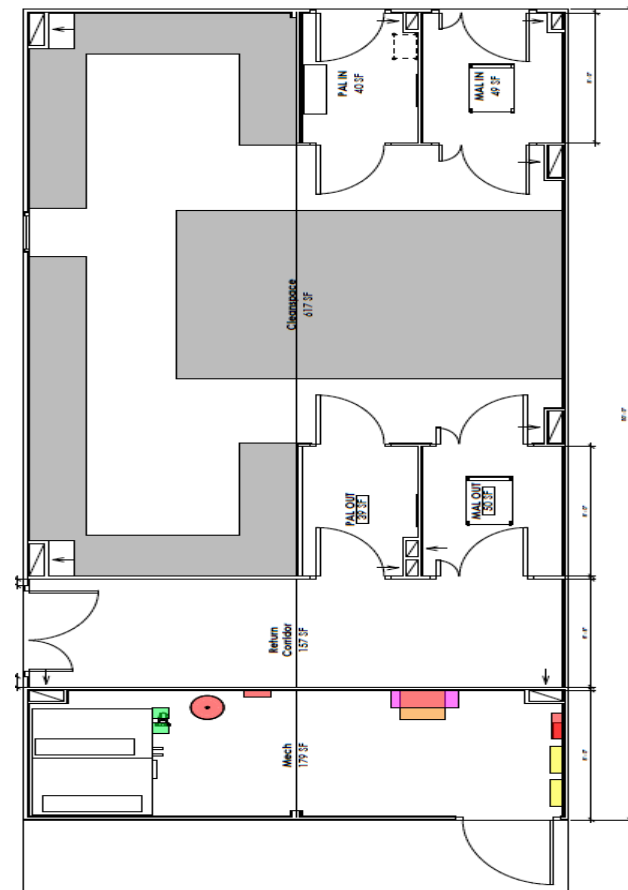
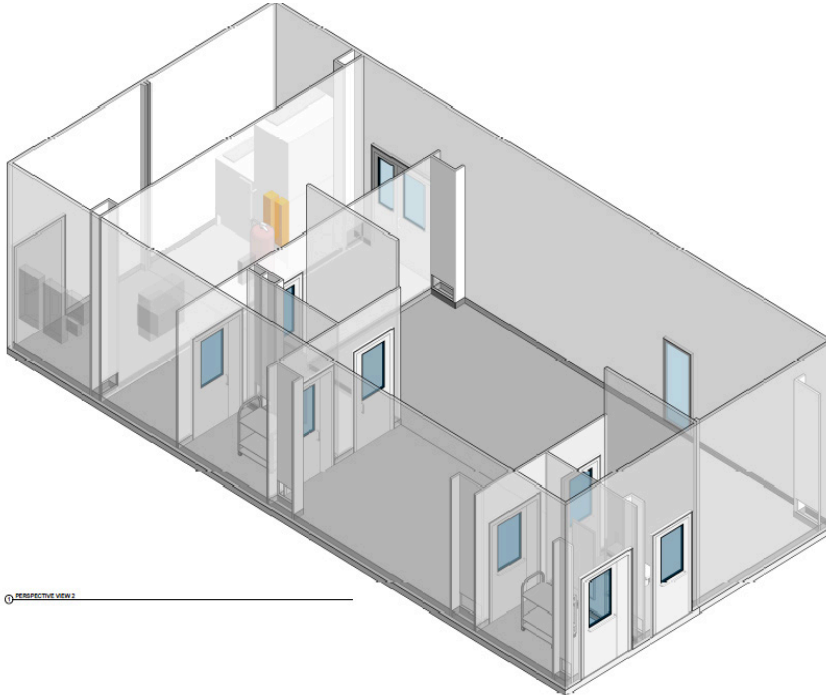
External
W: 24' 7 m L: 50' 15.5 m H: 13.5' 4 m

Internal
H: 9' H: 2.75 m

Cleanroom area: 874 sq. ft. 81.2 sq.m

24' x 50' x 13.5' POD - Unidirectional

7 x 15.5 x 4 m POD - Unidirectional



Order number:

POD-UD-2450

Product Description

Standard 24' wide unidirectional POD structure, fully designed as a piece of equipment ready to order.

Applications

- Inoculation suite
- Isolator filling area
- Small scale cell therapy

Personnel/Material Flow

Uni-directional

Cleanroom Classification

Grade C/ISO 7

Wall Materials

UPVC panels

Ceiling Materials

UPVC panels

Floor Materials

Nora floor system

Lighting

LEDspan or as specified

Doors

Aluminum powder coated

Automation

Siemens PLC, LVL 4 Stand Alone

Fire Protection

LVL 3 Wet Sprinkler System

Delivery Time (Standard Design)

3 Months

What is included:

- Air handling and HVAC system
- Automation
- Engineering
- Project Management
- Fire suppression system
- Factory Acceptance Test
- Site transfer
- Site Acceptance Test/Commissioning
- Qualification documentation

Dimensions:

External
W: 24' 7 m L: 50' 15.5 m H: 13.5' 4 m

Internal
H: 9' H: 2.75 m

Cleanroom area: 617 sq. ft. 57.3 sq.m

Fast. Flexible. Scalable.



G-CON Qualifications

The G-CON Manufacturing team has an in-depth knowledge of the biopharmaceutical industry. Most team members have been part of the industry for many decades, understanding the manufacturing processes, cleanroom infrastructure needs, utility requirements and facility designs. The G-CON team understands the regulatory requirements and necessary quality attributes. Many team members are active working group members in a variety of review boards and task forces. cGMP is not just an acronym for us, but a compliance topic we take very seriously.

We are **BUILDING FOR LIFE**.

Contact the G-CON sales team at sales@gconbio.com to learn more about our new standard POD portfolio.



Trusted Experience.

- Design, fabrication and installation of PODs for the following applications:
 - Autologous CAR-T Cell Therapies
 - Allogeneic Gene Therapies
 - Viral Vector Manufacturing (Lentivirus and AAV)
 - Stem Cell Therapies
 - Monoclonal antibody processing
 - Aseptic filling
 - Vaccine manufacturing
 - Oral solid dosage forms (continuous)
 - Biosafety level containment
- Clinical and Commercial Scale Facilities
- Client base ranging from start-ups to 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