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PORTAFAB PHARMASYSTEM CLEANROOMS

For The Most Demanding S t e r i l e Conditions





PharmaSystem™ For The Most Demanding Sterile Conditions

PharmaSystem modular wall and ceiling systems are the ideal solution for creating cost-effective controlled environments in pharmaceutical and biotechnology facilities.

With FDA requirements becoming more stringent and market demands continuing to rise, manufacturers must find ways to increase product yield and reduce overall construction schedules.

Incorporating a design that includes preengineered modular building systems allows businesses to achieve these goals while maintaining or exceeding the design standards established in current engineering guidelines.

Considering all factors:

- Flexibility
- Relocatability
- Cleanability
- Particle Emission
- Microbial Resistance
- Fungal Resistance
- Corrosion Resistance
- Cost
- Construction Time
- Schedule

PharmaSystem offers an alternative to traditional stick-built construction that helps manufacturers comply with regulatory requirements while reducing construction time and providing the flexibility to expand, rearrange, or relocate in the future.

Simply put, they are the most cost-effective products available for constructing a quality cleanroom envelope.

A Few Customers

Eli Lilly • Pfizer • Bayer • KV Pharmaceutical Cordis • Abbott Laboratories • Monsanto Proctor & Gamble • Prefil • Baxter GlaxoSmithKline • Johnson & Johnson Hoffman & Laroche • Aventis Pharmaceuticals Pall Biomedical • Sigma Chemical West Pharmaceuticals • Washington University



A Total Cleanroom System

PharmaSystem is designed to meet the most stringent guidelines for pharmaceutical and cleanroom construction requiring a high level of aseptic detailing. It is a completely flush panel system with products for partition walls, liner applications, and ceilings.

The pre-engineered wall panels provide a consistent appearance with the flexibility to be modified on an ever-changing jobsite. They can be configured to any layout and are extremely easy to install.

All PharmaSystem components install to form airtight rooms, designed to withstand both negative and positive pressures and feature designed-in redundancy for components to maximize modular benefits.

The need to support mechanical equipment, piping and ceiling systems is critical in cleanrooms, so when an existing facility is unable to offer this criteria, our structures provide the "envelope" without tying into the existing building. These free-standing structures can be designed to any configuration and size requirements.

Turnkey Solutions

PortaFab's commitment to maintaining the highest quality standards extends to the international network of specialized contractors for our cleanroom wall systems.

These contractors must meet the most exacting industry standards of customer service, industry knowledge and expert installation procedures. Their experience in constructing cGMP facilities has made them the preferred source for many leading companies.

Our network of contractors maintain the highest quality control programs to assure compliance with all critical standards. As independent contractors, they choose to work with PortaFab because our PharmaSystem offers the highest quality product available.

With over two decades of cleanroom fabrication experience, PortaFab has earned the reputation as the leader in the design and production of cleanroom systems.



Financial Advantages

Not only does the PharmaSystem have a lower initial cost than conventional construction, but it may be subject to tax incentives and accelerated depreciation. Check with your financial advisors to ensure any eligibility requirements are met in the construction process. These systems also offer tremendous payback when they are reconfigured or moved.

PharmaWall[™] System



Highly Flexible

The PharmaWall System utilizes a patent pending "Z" clip design that integrates with our ½" (12.7 mm) thick panels to be hung off a metal stud framework or an existing wall. The non-progressive system allows for the easy removal of panels.

By connecting to a metal stud framework you no longer have to be limited with the depth of your utility chases. All piping, mechanical and electrical processes can be easily integrated within a 3%", 6", 12" or 18" cavity without having to create a "double" wall out of two free-standing partition walls.

Wall and ceiling panels utilize a surface applied, smooth unplasticized PVC finish which allows panel faces to be chemically welded to one another to create smooth straight line seams. Alternate panel finishes are also available and can be sealed with a caulk joint to create a homogenous finish throughout the cleanroom.

Door frames, windows, and wall-to-floor transitions are also sealed in a similar manner.



Radius Coving

A durable wall system with broad design flexibility, PharmaWall modular walls are constructed to meet cGMP standards for pharmaceutical and biomedical cleanroom design. The completely modular system is designed to comply with the most stringent guidelines for sterile conditions.

Radius covings create fully flush corner transitions and seamless wall-to-ceiling and wall-to-floor connections. Monolithic wall and ceiling joints are bonded together and all electrical receptacles and windows are constructed to provide a totally flush surface.

By providing aseptic detail at all corners, the PharmaWall system allows for total "cleanability." All wall-to-wall and wall-toceiling junctions are trimmed with an extruded coving that features a large 3" radius. The 2-piece cove connects into an extruded clip that can be mounted to either wall or ceiling surfaces.

Recessed panel base features an extruded aluminum track to accept both epoxy floor coves or VCT floor coving, producing a sealed, radius transition between the floor and wall.

Process Integration

Piping penetrations and enclosures can be easily created by incorporating the PharmaWall System with different metal studs creating any cavity depth required for process or electrical services. Openings for the integration of service panels, utility chase boxes, pass-thrus and fire extinguisher boxes can be easily accommodated.

Z-Clip

"Z" clip integrates with ¹/₂" thick panels to be hung off metal stud frameworks or existing walls. Panels can be easily removed without disturbing adjacent panels.



Wall System

A fully integrated aseptic envelope system provides smooth, cleanable surfaces to meet and maintain requirements of FDA validation and cGMP applications.





PharmaSystem[™] Cleanroom

a. Partition Wall

1/2" thick uPVC coated panels finished to one or both sides of metal framework producing easy to clean surfaces.

b. Raised Air Wall

Eliminates the need for a return air grille and provides a more cleanable detail, reducing the number of crevices in room.

c. Low Wall Returns

Utilizes a return air grille allowing the cleanroom floor system to be coved flush against the low wall return plenum.

d. Liner Wall

Provides ability to skin existing concrete, block or sheet rock walls.

e. Cavity Walls

Electrical, mechanical and process piping can be integrated within cavity chases by using metal stud framework.

f. Wall Protection

Stainless steel guard rails in high traffic areas.

g. Integrated Stainless Steel Fittings

Electrical and mechanical between panels.

h. Sliding Door

High strength 2" thick molded seamless lightweight fiberglass panel for easy cleaning.

i. Swing Doors

Sealed non-absorptive panels with lightweight poured polyurethane foam for exceptional strength and dimensional stability.

j. Windows

Glazing provides a flush, ledge-free surface.

k. Panelized Ceiling

Flush cleanroom ceiling providing walk-on capabilities for maintenance access.



I. T-Grid Systems

Wire or rod supported T-grid systems with a variety of tiles to meet cGMP requirements.

m. Aseptic Cove Detailing

Rounded snap-in cove allows easy to clean ceiling and corner transitions.

n. Radius Floor Coving

Radius floor track with offset panel receiver provides flush transition between floor to wall finishes.

o. Integrated Openings

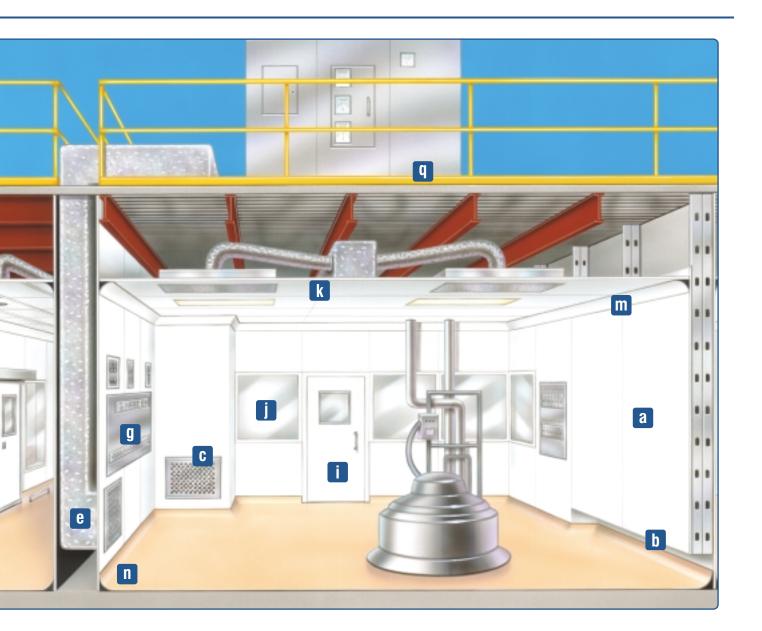
Flush openings for integration of service panels, utility chase boxes, fire extinguisher boxes.

p. Loadbearing Integration

Structural members can be designed within cavity walls to support load-bearing envelope structures.

q. Free-Standing Plenum Caps

Envelope structures create a free-standing structure capable of supporting AHU's, utilities and personnel.



Wall Panel Surfaces Available For PharmaWall and PharmaCeiling*

Surfaces	Joint Type	Benefits
uPVC-coated galvannealed sheet steel	Chemical weld	Scratch resistance, chemical resistance, anti-bacterial
Painted steel	Caulk joint	Impact resistance, custom colors
Stainless steel	Caulk joint	High corrosion resistance, durable, low maintenance
Painted aluminum	Caulk joint	Non-corrosive, lightweight
Fiberglass reinforced plastic – gel coat	Chemical weld	Scratch resistance, impact resistance, lightweight

*Other surfaces available upon request.



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PharmaWall[™] System

Superior Panel Performance

PharmaWall System has been designed to create a smooth, monolithic and easy to clean finish. It features radius corners and non-shedding, non-porous surfaces.

Typical construction involves aluminum honeycomb cores and skins that are nonhygroscopic and corrosion resistant. The surfaces withstand repeated cleaning and sanitization with various chemicals and are resistant to sustaining microbial and fungal growth.

All components are designed to allow for the easy removal of any sources of extrinsic contamination while architectural finishes comply with design guidelines for room classification, usage, and product manufacturing.

By offering 3%", 6", 12" or 18" deep cavities, the wall system can be used in conjunction with unlimited mechanical, electrical and process applications. Panels can also be configured to a variety of room heights.

Fire Ratings

PharmaWall panels are Class Anoncombustible in accordance with ASTM E84. By lining a fire-rated wall with PharmaWall, room owners can benefit from the monolithic finish of the cleanroom wall system while meeting building codes for fire ratings.

Utility Integration

Process service panels are easily integrated into the PharmaWall system in a recessed manner that minimizes ledges and joints. The panels can be designed to allow maintenance access and provide for future piping expansion.

The modular design of PharmaWall allows cleanroom designers and contractors the ability to make field modifications during the installation process. This flexibility provides for a number of potential design cost savings.

Integrated System

Door systems are available with smooth, easy to clean surfaces that are non-shedding, nonporous, and resistant to sustaining microbial growth. Doors are available in a number of finishes including FRP, PVC faced, glass, aluminum, painted and stainless with swing, sliding or roll-up operation.

Windows are mounted into the wall system to provide a completely flush surface without ledges or joints. Insulated glass units are also available. To minimize any air flow disruption, windows can also be integrated into return air walls.

Low wall returns are easily created by installing return air grilles into the plenum style design or raised air walls can be used to eliminate difficult to clean return air grilles and reduce the number of crevices in the room.



Head Track

Two-piece snap in system provides a smooth, rounded and easy-to-clean cove for ceiling-towall and wall-to-wall transitions. Three way welded corner assemblies are available for inside ceiling corner and wall intersections.



Window

Various glazing options provide panel width windows to achieve a flush, ledge-free finish. Double flush glazing is easily incorporated into all wall thicknesses.



Floor Track

Recessed base to accept radius floor coving, producing a flush transition between the floor and wall.



PharmaSystem[™] Ceilings

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PortaFab cleanrooms, pharmaceutical and containment rooms can be installed with either T-Grid systems or walkable panelized ceiling structures. Radius coving is available with all ceiling systems to produce a cleanable junction at wall-to-ceiling connections.

PharmaCeiling[™] Panelized System

The PharmaCeiling panelized system is designed as a flush ceiling system which provides end users and owners with the ability to access the area above the cleanroom for mechanical services or walk-on capabilities for maintenance access when applicable. The PharmaCeiling System is a 2" thick composite panel using a steel skin on both sides of an aluminum honeycomb core. Ceiling panels utilize a smooth unplasticized PVC finish which allows panels to be chemically welded to one another forming tight, straight-line bonds between adjoining panels and beams. Additional finishes are also available.

The unique design of the ceiling allows the additional benefit of incorporating flush lighting, filters and other ceiling mounted equipment.

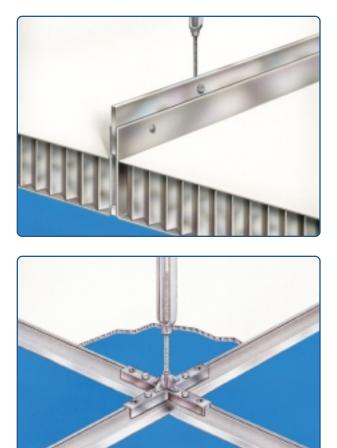
The PharmaCeiling System is supported at intermediate points with threaded rod to the existing building structure minimizing the need for catwalks above the cleanroom areas. The PharmaCeiling System can be supported from our free-standing "envelope" structures in applications where the existing building cannot support the design.

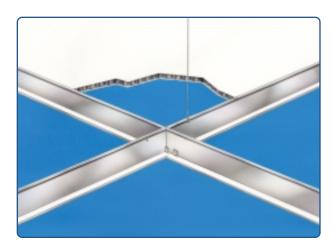
2" Gasket Grid

The 2" Gasket Ceiling Grid System combines flexibility with simplicity to meet the ever-changing needs of the technology industries. The system offers the complete versatility of nonprogressive construction required in most cleanrooms. It is a functional stick-built system that provides a 2" wide structural grid system with aluminum extrusions and zinc die castings to receive standard filter modules, light fixtures and blank ceiling tiles. Truly an engineered system for ease of installation, the system can be used in 2' x 2', 2' x 4', 4' x 4' and custom layouts.

1½" Gasket Grid

The $1\frac{1}{2}$ " Gasket Grid Ceiling System is the perfect solutions for diverse applications including pharmaceutical, microelectronics, aerospace, food processing, and hospital industries. The gasketed grid is designed with a $1\frac{1}{2}$ " face tee to support HEPA filter systems and light fixtures. Installation is simplified with a clip assembly requiring no special tools for the attachment of grid components. Choose from a wide selection of module sizes such as 2' x 2', 2' x 4', or 4' x 4'. Available in painted white and clear anodized finishes.







Specifications

PharmaSystem

PharmaSystem is designed to add the same protection, strength and reliability to a new or existing cleanroom, ensuring performance geared to the expectations for which the cleanroom is being installed. The wall panels shall install within a framework providing a smooth, flush wall finish on both sides. PharmaSystem is designed for use in cleanroom environments where maximum performance, strength and reliability are required.

The PharmaWall and PharmaCeiling Systems are designed for easy removal of wall or ceiling panels without disturbing adjacent panels or ceiling (nonprogressive) minimizing contamination possibilities to the cleanroom environment.

Basic Uses

System designed to comply with federal standard 209E. Typical applications for the PharmaSystem modular system include:

- · Development centers
- · Pilot and scale up plants
- · Clinical trials and quality control buildings
- Bulk and intermediate manufacturing plants
- Finishing and packaging plants
- Distribution centers
- Laboratories: BSL 2 and BSL 3
- Cleanrooms
- Animal facilities and vivariums

Cleanroom Wall Support System

Hanging Components: All "Z" strips shall be 6063-T5 aluminum extrusions with 201R1 anodized clear finish. The support "Z" strip will be secured horizontally to framework in a minimum of two continuous rows. Supporting "Z" strip will be fastened to framework at least every 24" o.c. Fasteners shall be supplied by installing contractor. Receiving "Z" strip shall be factory installed in a minimum of two rows for the width of the wall panel. The wall panel shall hang onto the framework and match up the "Z" strips to support the panels on the framework.

The framing system shall be coordinated with building structure to perform under vertical and lateral design loads and seismic requirements.

All metal framing to support wall system shall be a 3%" deep cold formed metal stud framework with a galvanized finish in accordance with SSMA and NAAMM.

Radius coving at ceiling and corner transitions shall be extruded with an extruded aluminum receiver clip with 201R1 anodized clear finish.

Wall panels are mounted above an extruded aluminum radius floor track with 201R1 anodized clear finish. Radius floor track allows a recess for various flooring materials to be coved and finished flush with the face of the cleanroom wall panel.

Materials and connections shall be manufacturer's standard, capable of supporting design forces. Provision shall be made for movement of surrounding structure in design of separations and joints.

Materials:

Metal Framing: Aluminum 6063-T5 alloy. *Fittings:* ASTM-A36 or ASTM-A635.

Finish for Aluminum Extrusions: 201R1 anodized, clear finish.

Cleanroom Wall Panel – General

uPVC Steel-Aluminum Honeycomb: Panels shall have a face sheet of 22-gauge smooth sheet steel with an unplasticized polyvinylchloride (uPVC) finish and a back sheet of galvannealed steel. Sheets shall be laminated to both sides of an aluminum honeycomb core.

Panel Thickness: 0.50" (12mm)

Colors: As selected by the owner from manufacturer's standard panel colors.

Doors

Swing Doors: Doors shall be heavy duty molded fiberglass reinforced polyester shell (size to be determined) x $1^3/4^{"}$ insulated with polyurethane foam. Door shall be seamless with 20-gauge stainless steel capping. Door hardware requirements to be determined by customer. Door frames shall be extruded aluminum and include $1^{1}/_2$ pair of $4^{1}/_2^{"}$ x $4^{1}/_2^{"}$ mortised hinges and strike plate.

Door Glazing: 1/4" (6mm) clear tempered glass as specified.

Sliding Doors: Unitized high strength 2" thick molded seamless lightweight fiberglass panel for easy cleaning. Stainless steel (20 gauge) edge capping for added strength and protection. Manual with automatic closer and "holdopen" feature. Panels open and close in unison.

Door Glazing: 1/4" (6mm) clear tempered glass as specified.

Windows

Window Frame: All glazing to be flush-mounted in an extruded aluminum frame. Window panels to be sealed in place with caulk.

Glazing: 1/4" (6mm) clear tempered glass as specified.

Side Wall Returns

Return Air Grilles: Extruded aluminum return grille with border on all four sides. Size to be determined by application.

Floor Mounted Bumper Rails

Bumper rails are formed using precision tooling to maintain uniform diameters. Bumper rails are fixed to the floor using stainless steel mounting spigots and shall be permanently fixed to the floor slab. Bumper rails can be easily removed from the spigot for cleaning.

Tube size: 2" diameter *Finish:* 316 stainless alloy

Cleanroom Panelized Ceiling

uPVC Steel-Aluminum Honeycomb: Panels shall have a face sheet of 22-gauge smooth sheet steel with an unplasticized polyvinylchloride (uPVC) finish and a back sheet of galvannealed steel. Sheets shall be laminated to both sides of an aluminum honeycomb core.

Panel Thickness: 2" (50mm)

Colors: As selected by the owner from manufacturer's standard panel colors.

Materials.

Metal Framing: Aluminum 6063-T5 alloy. Rod: LH/RH 9" long ¼"-20 x 1¼" hex head bolt threaded zinc plated steel rod. Turnbuckle: 4" LH/RH zinc plated turnbuckle spaced at 48" centers or as required.

Plenum Structure

Roof Deck: Deck shall be 22-gauge ribbed steel "B"-deck, 11/2" deep, painted primer gray and cut to length.

Structural Steel: Steel "I" beams and columns shall be A36 structural steel. The plenum structure shall be designed for maintenance and equipment loads and include both live and dead loads.

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