

BiochemGARD

Modular Cleanroom Systems

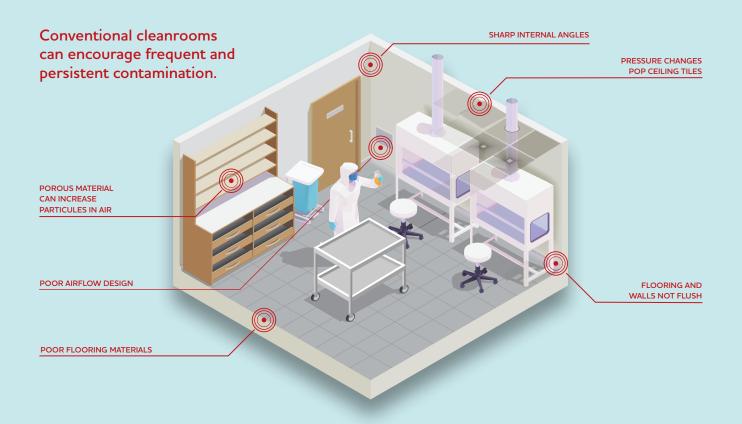
GRIFOLS

Comprehensive Modular Cleanroom Systems, Technology, and Software

As compounding regulations continuously evolve, staying on top of best practices and multiple variables in responsibilities has become increasingly challenging.

We understand protecting patients is your most important responsibility. Trust you can leverage expertise with Grifols **inclusiv** as your full-service partner to provide a turn-key solution for your cleanroom needs now and into the future.

Your Grifols **inclusiv** team uses a comprehensive approach to facility design, engineering controls, environmental monitoring, and equipment installation.





Achieve Cleanroom Confidence

inclusiv modular cleanrooms are designed for safety and compliance in the design, construction, and environmental control of the most stringent sterile compounding settings.

Complies with the recommendations and international regulations on the preparation of sterile products and cleanrooms (GMP, ISO14644, ASHP, OSHA, USP 795, 797 and 800, PIC/S, Quapos).











AND MAINTENANCE



CONTROLLED ENVIRONMENT EXPERTISE



CUSTOMIZABLE





+ DISINFECTANT-READY + DURABLE

+ ANTIMICROBIAL SURFACES

GMP, good manufacturing practice; **ASHP**, American Society of Hospital Pharmacists; **OSHA**. Occupational Safety and Health Administration (Department of Labor); **USP**, United States Pharmacopeia; **PIC/S**, Pharmaceutical Cooperation Scheme; **QuapoS**, Quality Standard for the Oncology Pharmacy Service.

System Components:

Panels

The module is built with 60 mm-thick "sandwich" type panels that can be easily cleaned using antiseptic agents. High density polyurethane rigid foam, which acts as insulation, is injected between two white heat-enameled steel plates. The way in which the panels are joined together allows electric cables to be embedded. The roof is extremely sturdy and strong enough to walk on.

Floors

The PVC coated floor has no seams making it suitable for cleanrooms.

Doors

The doors are flush on both sides and are made of a 60-mm thick sandwiched panel mounted on a rim that is integrated with the wall panels. The main characteristics of the doors are:

- The hinges are recessed into the width of the door
- Handles are fitted on both sides of the doors
- Safety lock with key and optional access control
- Seal on three sides
- Automatic doors are available

Windows

Windows are double glazed and fit flush to the panel. They are made as a monoblock and assembled in the factory.

Light Fittings

The light fittings are air tight and flush to the ceiling; they are specifically designed for use in cleanrooms.

Finishes

All inside corners have a flush, coved finish formed using white PVC or aluminum cornice that is sealed with silicone after fitting.

SCADA systems, supervisory control and data acquisition systems.

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Product availability vary by country.

For more information, visit grifolsinclusiv.com

Air conditioning

Each room has an independent air treatment system, specifically designed in each case to provide the necessary air flow for air renovation, pressure differentials and overall comfort in the installation. Characteristics:

- Three-stage air filtration: F5-F9 and H14 grade terminal filters
- Terminal filtration with H14 grade absolute filters according to the UNE-EN 1822-1:2020 standard
- Supply of independent heat pump for producing optional heat or cold
- Extraction of 100% of the air to the exterior (total exhaust) for the preparation of cytostatic drugs, toxins or for ensuring biosafety
- Air installation in compliance with cleanroom classification D, C, B or A depending on requirements

Control and instrumentation

- Touch-screen control system for monitoring the entire process
- Control of the inward and outward airflow
- Pressure monitoring
- Management of alarms
- Can be connected to existing SCADA systems

Accessories

- Pass-through for materials
- Stainless steel hand basin with soap dispenser
- Hot air hand dryer
- Stainless steel bench for separating areas in staff gowning room
- Stainless steel work table
- Stainless steel cabinet for materials
- See-through membrane voice communicator
- Emergency eye wash
- Automatic door closer
- Automatic door opener
- Automated fumigation system
- Structure with roof for outside installation
- And a wide range of accessories.

ABOUT THE PORTFOLIO

inclusiv[•] is a comprehensive IV compounding portfolio of integrated technology, software, and service solutions designed to support your needs for sterile compounding from the design and building of your sterile compounding environment, to the preparation and verification of your products, through the ongoing management and optimization of your pharmacy operation.



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