

Grifols is recognized as a world leader in the health care community. Committed to delivering innovative and cost effective solutions for hospitals and pharmacies, Grifols provides state of the art modular clean room systems under the Misterium™ name.

The Misterium System is ideal for industry, hospitals, pharmacies and research activities that require clean environmental conditions. Whether it is compounding sterile IV preparations, handling cell cultures, gene therapy or oncology, there is a Misterium solution.

We are a leader in providing complete clean room solutions for pharmacies and hospital operations. Grifols has designed and constructed more than 1.2 million square feet of clean rooms worldwide and managed more than 150 modular clean room installations at hospitals.

Grifols' Unique System - A Complete Solution

Grifols is committed to giving you the support and tools to create, operate and maintain your clean room. Our "complete solution" is a total clean room service that includes the design and installation of high quality clean rooms that meet all applicable regulations and guidelines. Grifols' staff will assist you during each step of the process from initial design considerations to the operation of a fully functioning clean room.

Grifols unique position in health care services provides unparalleled support for the design, installation and operation of clean rooms.

Our "Complete Solution" includes:

Clean Room Expertise

We share our expertise in pharmacy and hospital clean rooms to help you make more informed choices in your selection of the room's layout, size, options and functionality. Our goal is to deliver the most effective solution for our customers.



The Grifols' approach provides the most efficient design and installation. We help our customers navigate the clean room process, including design, equipment selection and installation. We strive to find the best quality products for the long term effectiveness of your clean room and be within your budget.

Our staff is also available for ongoing guidance and assistance. Grifols' engineers and staff can handle project details, including permits, equipment selection and installation and meeting validation and certification requirements.

Workflow Analysis

Grifols identifies the optimal design and solution to meet your proposed clean room's work flow requirements. We perform a functional analysis of all activities, procedures and location of resources within the pharmacy environment. We review the flow of people and materials to assure that the clean room design optimizes efficiency and usefulness, minimizes contaminants and meets regulatory standards.



Installation and Project Management

An on-site project manager assures that the installation is completed in a timely and efficient way. A Misterium clean room system can be assembled and installed faster than conventional construction. This reduces costs and lessens disruption to your facility's operations and productivity.



With our engineering expertise in electrical systems and HVAC design, installation and products, we strive to meet your operational needs and ensure your clean room will be in compliance with applicable regulations and standards.

Certification

Certification is an important final step demonstrating that a clean room functions correctly and meets operational requirements. We assist in obtaining initial certification and ongoing, on-site independent certification by a CETA (Controlled Environment Testing Association) approved third party entity that certifies the clean room in accordance with the requirements set forth in the ISO 14644-1 standard. This certification becomes part of the formal clean room documentation. Grifols will not invoice its final bill until the Misterium clean room has been fully certified.

Training and Standard Operating Procedures

As part of our complete solution, Grifols provides training to assist staff in the use and maintenance of the clean room. Training can be customized and programs may include technical systems overview, clean room documentation, maintenance and required sanitization practices. We can also provide additional training on USP <797> requirements, proper garbing techniques and standard operating procedures.

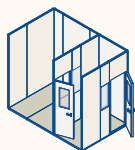


Grifols can assist in reviewing work flow in the new clean room and work with you to ensure the safety of your clean room staff.

Misterium and its Modular System

Why Modular?

The advantages of modular clean room construction over conventional make modular the first choice in quality clean room construction.



Modular construction is flexible, convenient and allows faster construction with a better result than other types of clean rooms. Misterium's modular panels are among the most efficient and economical. Our flush seam wall construction allows for easy maintenance, which means savings in the amount of personnel time and costs to maintain a high quality environment.

Key Benefits of Misterium's modular system:

Flexible Design

All Misterium rooms are designed to accommodate your operational requirements, schedule and budget as well as be in compliance with USP <797> for sterile compounding and/or cGMP. Our rooms can be designed and installed to meet any classification, with

differential air pressures, temperature and relative humidity control, and dedicated heating and air conditioning.

If the demands on your clean room change, the Misterium system can be reconfigured and components may be reused and reinstalled. Rooms can be redesigned and revised using interchangeable panels and fixtures in order to meet future needs.

High Quality

Misterium uses one of the highest quality modular panels available and is currently being used in pharmaceutical manufacturing (c-GMP) facilities worldwide. Our clean rooms are durable with easy to clean components and a long usable life.

The modular panels are fire resistant and have an antimicrobial uPVC finish. Walls have a smooth surface that is scratch resistant and delivers superior corrosion resistance compared to painted wall systems. All air handling and electrical materials and equipment will meet or exceed the applicable installation standards.

Efficient Installation

The speed of installation is a major advantage of Misterium's modular system. Misterium materials are prepared before delivery. Our clean rooms can often be installed, depending on the size, within two to four weeks with minimal disruption to your facility's operations. Every stage of design and installation is carefully monitored. This means a well managed and a predictable construction schedule.

Ease of Maintenance

Misterium's design and quality construction is a key to its easy maintenance and keeping the room clean. Rooms have fully flush windows, doors and walls as well as solid walls, floor and ceiling. All inside corners have a flush, coved finish, that are sealed with silicon after fitting. The floor is seamless and coved where it meets the walls. Surfaces that may collect dust are minimized. All joints are caulked to prevent particle induction or loss of room pressure.

Optional Features

Our clean rooms can be customized to include supplemental features such as sliding doors, pass throughs, gowning areas, and automatic hand washer and hand dryer systems, as well as specialized furniture and equipment.



For the Complete Clean Room Solution –

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Grifols' staff is available to discuss clean room design, answer your clean room questions and help find the best solution for your facility. A Misterium clean room specialist can help ensure the success of your project.

Additional Information

A companion document, Grifols' primer on clean rooms, provides an overview of clean rooms design and operation. This overview discusses clean room air flow and operation, regulatory standards, hazardous drug preparation, maintenance, cleaning and disinfection requirements.

Grifols' construction of the clean room on our project was a great success.

Their commitment to quality and communication provided a worry-free management experience.

– Austin Schultz, LEED®AP, AC, Project Engineer
Turner Construction project for AmerisourceBergen

GRIFOLS

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misterium
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