



i.v.TOOLS Misterium

Modular Cleanroom System



GRIFOLS

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The correct preparation and administration of compounded sterile preparations (CSPs) is a complex process that must be conducted by highly skilled professionals in a specialized environment.

Grifols is a global healthcare company with more than 75 years of experience and a record of maintaining the highest quality and safety standards in our own manufacturing processes.

Grifols i.v.TOOLS is our suite of products, technologies, processes, management tools, and services designed to enhance quality, safety, and efficiency and facilitate compliance with guidelines and regulations relevant to the preparation and administration of compounded sterile products.

Grifols provides customized services such as consultation on aspects of compounding, including environmental design and monitoring, operational analysis and workflow, process implementation, and regulatory compliance.

Grifols Misterium® modular cleanroom system offers significant financial and performance advantages over traditional cleanroom solutions.

Misterium is designed to meet the demands of the most stringent medical and aseptic environments. As a result, it is the solution of choice by many biomed, life science, biotech, medical device, nutraceutical, and pharmaceutical facilities.

A Complete Cleanroom Solution

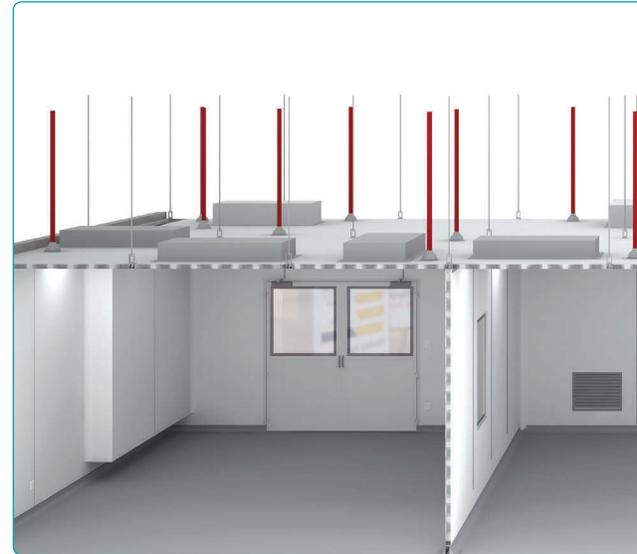
Grifols Misterium offers a complete solution from initial design to the operation of a fully functioning cleanroom.

- 1. CONSULTING**
- 2. CONCEPTUAL AND DETAILED ENGINEERING DESIGN**
- 3. CONSTRUCTION**
- 4. ENVIRONMENTAL MONITORING SYSTEM**
- 5. EQUIPMENT AND AUTOMATION**
- 6. CERTIFICATION AND TRAINING**

Easy Installation & Maintenance

Misterium materials and accessories are suitable for use in positive or negative pressure environments. The system's modular design facilitates efficient installation and can be customized to fit any size space.

- Flush ceiling system with wide hangers allows easy access to mechanical systems without disrupting the cleanroom
- Interior wall panels attach flush to ceiling panel surfaces
- Studless utility and liner wall options
- Aluminum honeycomb panel core
- Antimicrobial uPVC surfaces, coves, and chemically cold-welded seams
- Virtually flush seams for effective sanitation, wash-down, and fumigation
- Multiple flush door, window, and access openings, as well as various hardware options



Controlled Environment

Design and installation of an advanced monitoring system for control of:

- Particle count
- Temperature
- Humidity
- Pressure

Compliance

- Facilitates compliance with relevant state and federal regulations and guidelines for protecting staff, compounded sterile preparation environments, and patient safety
- Certification upon cleanroom completion
- UL and FM approved

System Components



Ceilings

Walkable ceilings for safe and easy access to mechanical systems without disrupting the cleanroom environment:

- 5 foot x 10 foot x 2 inch panels, suspended by turnbuckle/hanger assemblies bolted to the corners of four adjoining panels
- Cutouts for light fixtures and filters can be placed anywhere, oriented in either direction, without necessitating changes to ceiling panel orientations
- Capable of supporting a wide variety of mechanical systems, lighting, sprinklers, HEPA filters, utilities, and small equipment

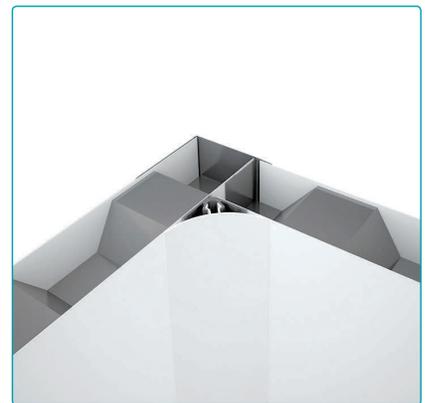


■ Ceilings

Panels

Ceiling and wall panel edges are tightly engaged to adjoining panels with a fixed metal spline. Openings for equipment (lights, filters, etc.) can be located anywhere within the ceiling layout. Cutouts can be made in the factory or in the field by the installer. Prefabricated, powder-coated metal inserts are available to support HEPA filters and lighting fixtures in the prepared cutouts.

Multiple flush door, window, and access options, as well as a wide variety of hardware options, are available.



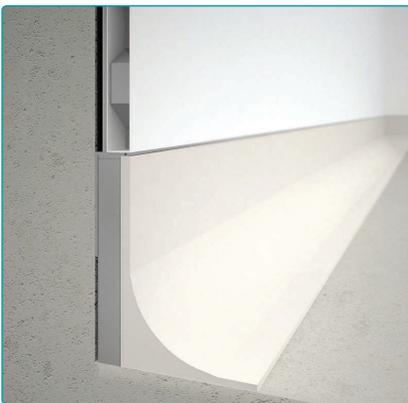
Panels ■

System Components

Floors

Heat-welded sheet vinyl floor coverings are bonded to the subfloor in accordance with manufacturers' specifications. PVC coving is used at wall, floor, and ceiling junctions within the cleanroom. Adjustable studless wall floor track consists of a two-part aluminum extrusion assembly.

- Lower portion attaches to the floor and accepts the upper portion, which is raised and leveled to desired height
- Adjustment range is 3 1/2 - 5 1/2 inches
- Floor tracks facilitate a floor cove installation flush with the wall panel



■ Floors

Doors

Doors are flush on both sides and are made of a 2 1/3 inch thick sandwiched panel mounted on a rim that is integrated with the wall panels.

Windows

Flush double-glazed windows for doors and studless walls consist of two panes of 1/4 inch tempered glass, bonded and sealed to an aluminum frame filled with desiccant to reduce moisture.

- Same thickness as door/wall, providing a flush installation
- Replaceable in nonprogressive systems
- Adjustable via leveling bolts
- Sealed with silicone caulk

Light fittings

Light fittings, specifically designed for cleanroom applications, are airtight and flush to the ceiling.

Applications

Hospital Pharmacy, Intravenous Mixtures

Tissue Banks

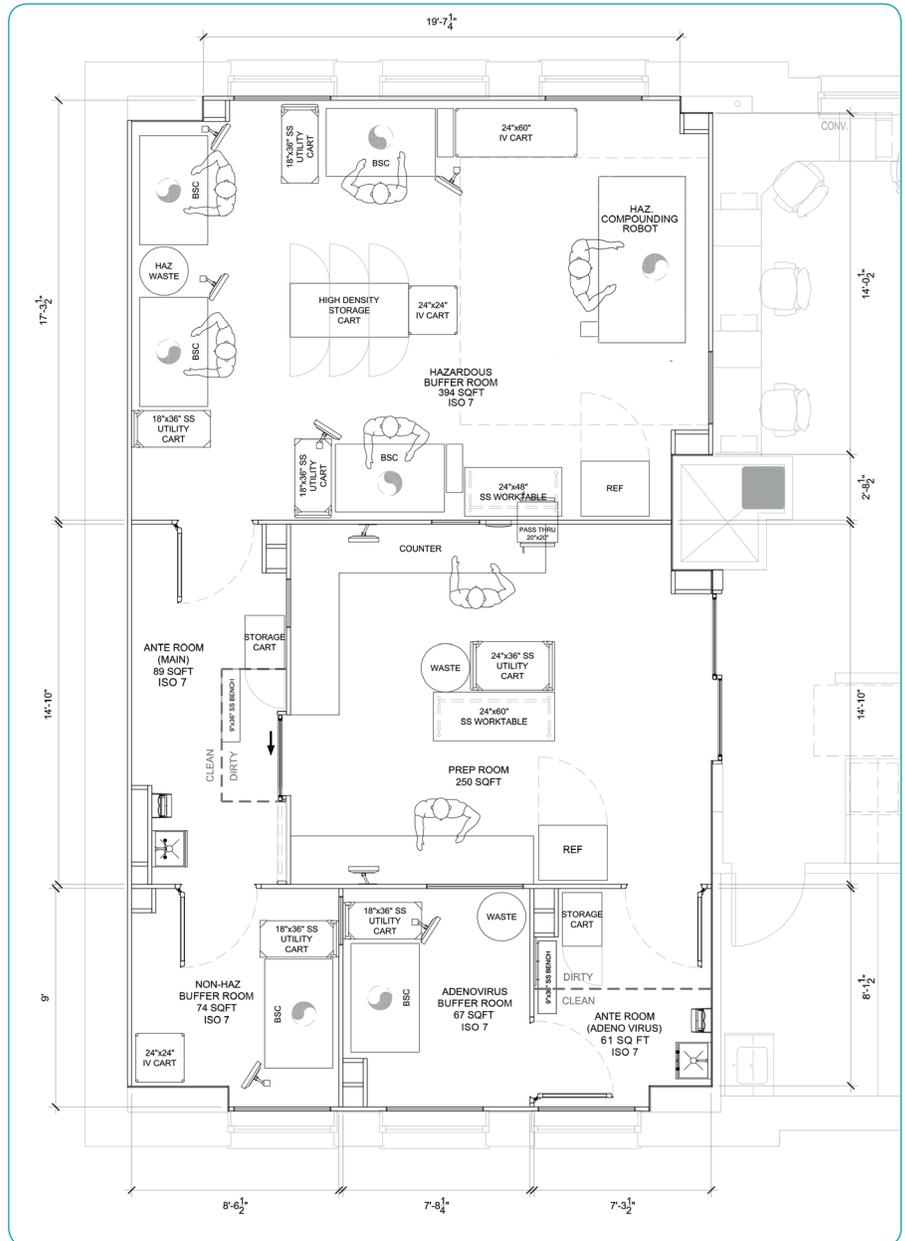
Blood Banks

Gene & Cell Therapies

Microbiological & Sterility Control

Microbiological Containment Laboratories

Misterium Reverse: Infection control setting that creates and monitors negative pressure conditions for specific patients to prevent transmission of infectious agents in healthcare settings.



i.v.TOOLS

ENVIRONMENT

Grifols' sterile manufacturing
expertise applied to the
compounding pharmacy

GRIFOLS

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