Laminar Flow Equipment

Class II Biosafety Cabinets

RABS and Isolators

Cleanroom Pass-Through Boxes

Specialty-Environment Equipment

Mobile cGMP Cleanrooms

Modular cGMP Cleanrooms

### **Biopharma**















# Creating Environments that Serve Life Science Innovation and Advance Global Health

For six decades Germfree has created innovative, cGMP compliant biopharma equipment and facility solutions to serve experts in process development, drug production, and aseptic training applications. Quality, craftsmanship, and superior design have been a staple since Germfree's founding.

From cutting-edge institutions to resource-challenged countries, Germfree established itself as the worldwide partner of choice in advancing global health with solutions that focus on supporting life-saving new therapies.

### Biopharma solutions: Robust, American-Made cleanrooms and equipment

Today, Germfree is a worldwide leader in the design and manufacturing of equipment and facilities for biopharma applications ranging from vaccine research and production to advanced cell and gene therapy processes. Germfree's groundbreaking technologies are built on a legacy of innovation that stretches back to the company's inception in 1962. At Germfree's state-of-the-art manufacturing facility, located in Ormond Beach, FL, USA, all equipment and facilities are built to the highest quality standards and undergo rigorous testing to ensure unmatched product reliability and regulatory compliance.



SIX DECADES OF BIOCONTAINMENT EXPERIENCE



175,000 FT<sup>2</sup> (16,000 M<sup>2</sup>)

OF AIR CONDITIONED

MANUFACTURING SPACE



INSTALLATIONS
ON 6 CONTINENTS



1000s OF COMPLEX EQUIPMENT INSTALLATIONS



100s OF FACILITIES
DELIVERED GLOBALLY











# Providing superior product protection

From complex biopharma cleanroom facilities to biosafety cabinets, Germfree provides complete solutions for superior product safety.

### Laminar flow workstations

Germfree's LAF Series Laminar Flow Hoods are designed for processes which include filling systems for production of non-potent, non-cytotoxic liquid pharmaceutical products dispensed in parenteral vials, syringes, and cartridges. The LAF Series of all-welded stainless steel, vertical clean air benches provide a high degree of localized control for critical aseptic processes and the handling of sterile products.

Germfree manufactures Laminar Flow Hoods for a range of biopharmaceutical processes which require an ISO 5 (EU Grade A) environment for operations such as: Tyvek lid removal, Nest Transport, Filling and Closing and Capping.

HEPA-filtered air continuously bathes the work area removing organisms and particulates 0.3 micron in size with an efficiency of 99.99%. This ensures a smooth and uninterrupted flow of optimal 'First Air' to the process area. Germfree's units are engineered to meet or exceed all advanced specifications for Grade A Laminar Flow Cabinets. Including: ISO 14644-1, US Federal Standard 209E and IES Recommended Practices.

#### **Laminar Flow**

Available in 3', 4', 6', 8' and custom sizes



## Class II biosafety cabinets

Our Class II Biosafety Cabinets provide containment for diverse research and production applications in advanced biopharma laboratories and cleanrooms.

Germfree's biosafety cabinets are fully cleanable and designed for integration into cleanroom environments. With proper use, these BSCs eliminate crosscontamination as well as the release of pathogenic microorganisms or carcinogenic aerosols and drugs to the outside atmosphere. We also specialize in custom integration of process components and equipment.

#### Available options:

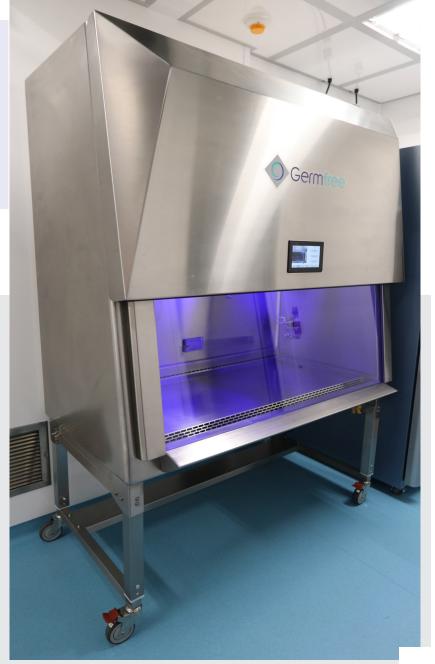
Class II, Type A2 – Approximately 70% of the air from each cycle is recirculated through the supply HEPA filter while the remaining air is discharged from the biosafety cabinet through the exhaust HEPA filter

Class II, Type B2 – 100% of the air entering the cabinet is exhausted out of the building

Germfree produces the most cleanable and robust equipment in the industry.

### **Class II Biosafety Cabinets**

Available in 2', 3', 4', and 6' models



### **RABS** and Isolators

Germfree's Biopharma products meet a wide variety of cGMP process development and aseptic production applications. Our RABS and isolators are engineered and constructed to meet or exceed the current US and EU Good Manufacturing Practices, ISPE Baseline Guides®, ISO 14644, Biological Safety Levels (BSL), and other relevant standards.

#### **Isolators**

Isolators are a core component to the pharmaceutical industry, critical for a range of processes. These gastight enclosures provide a complete barrier to ensure aseptic conditions and containment. Germfree manufactures advanced cGMP-compliant isolators to protect sterile products, personnel, and the working environment. Germfree's Aseptic Isolators can be customized to meet the rigorous demands of your specific application.



### **RABS**



### **Restricted Access Barrier System**

Many pharmaceutical applications require localized Restricted Access Barrier Systems (RABS) within the cleanroom. Germfree's purpose-built RABS units maintain the integrity of sterile materials, containers, vials and surfaces that may come into contact with the product during normal operations. This is accomplished by providing physical separation between personnel and product. RABS can provide many flexible options for aseptic processing when a Pharmaceutical Isolator is not required.

# Pass-through airlocks

Germfree has leveraged our decades of facility design experience to develop a pass-through airlock that is uniquely engineered to meet the demands of a modern cleanroom. All stainless steel construction with coved interior and exterior corners and a pharmaceutical grade finish make these pass-through boxes the most cleanable and robust on the market.

When materials are placed within the pass-through a HEPA-purge cycle is initiated, which rapidly exhausts and filters the interior air until it has reached ISO Class 7. Interlocks assure that both doors cannot be opened simultaneously and that the receiving side door remains locked until the HEPA-purge is complete. These units are available in a variety of sizes and are designed to fit seamlessly into your new or existing cleanroom facility.





# Specialty-environment equipment

Germfree leverages decades of equipment and facility design experience to offer custom solutions for most applications.

Our expert engineering team will work with you to create the perfect custom equipment for your application. As a single source provider, all aspects of your project will be managed by Germfree and manufactured in a controlled environment. A dedicated project manager will serve as a singular point of contact for the duration of the project.

Germfree has the tools and expertise needed to deliver a solution fit for your needs. While projects can be drawn from the ground up, cGMP compliant projects can also be based on standard equipment or facility platforms.

Proudly engineered and manufactured in Florida, USA for six decades.





## Mobile cGMP cleanroom trailers



### Accelerate project timelines while receiving a solution that will last.

Germfree bioGO® Mobile Cleanrooms are available in standard and custom configurations to meet immediate needs for cGMP process development, cell and gene therapy, and aseptic training. Each facility is engineered and constructed to meet or exceed the current US and EU Good Manufacturing Practices, ISPE Baseline Guides®, ISO 14644, Biological Safety Levels (BSL), and other relevant standards. Our sophisticated trailer and vehicle-based units deliver critical cleanroom capacity throughout the world. With a deployable rental fleet available, our mobile facilities are available on accelerated timelines and are provided with full integration of equipment, utilities, and services for temporary or long term needs.

#### Key aspects:

n Available for Lease or Sale n Standard and Custom Configurations n Proven Engineering and Fabrication

#### Features:

Seamless Arcoplast walls

Ample equipment space

Durable cleanroom flooring

## Modular cGMP cleanrooms



### Extensive experience in modular facility design and construction.

Germfree's bioGO® single or multimodule Cleanrooms are available in standard and custom configurations to meet a wide variety of cGMP development and manufacturing applications such as Cell and Gene Therapy, Viral Vectors and Vaccine Development. These facilities are structural modules that can be configured in multi-level layouts with optional placement of the MEP/HVAC on top, inside or adjacent to the facility. Germfree's modular facilities can be installed as a freestanding outdoor building or within a shell building (boxin-box). Each facility is engineered and constructed to meet or exceed the current US and EU Good Manufacturing Practices, ISPE Baseline Guides®, ISO 14644, Biological Safety Levels (BSL), and other relevant standards. Germfree provides an integrated solution across project management, production, and quality to accelerate project timelines while receiving a process-ready solution.

#### Features & options:

Proven solution — operational in an expedited timeline

Manufactured in our controlled environment to control cost and risk

Architectural facades to match your existing facility











### Germfree

4 Sunshine Blvd. Ormond Beach, Florida USA +1 386-265-4300

### **Germfree Europe**

Swords Business Campus Swords, Co. Dublin K67 D8H0 Ireland +353 (0) 1 894 8800

