



Flexible mobile compounding space for USP <797>/<800>.

Germfree's USP <797> / <800> mobile pharmacies are delivered to your facility in coordination with your construction schedule. These turnkey facilities, integrated into a mobile platform, provide the ideal solution for seamlessly maintaining pharmacy services during your renovation. Germfree's Compounding Pharmacy Rental/Lease Program allows for a smooth transition during all phases of your project. Germfree's mobile pharmacies may also play a critical role in continuing USP <797> / <800> operations during emergencies or after a natural disaster. Our units are equipped with emergency generators for continued operation when regular facility power is otherwise interrupted. Germfree's rental pharmacies are also capable of providing surge capacity for adding compounding resources to your existing operations.

- Available for sale or lease
- Turnkey operational readiness
- Rapidly deployable



Equipment pictured may include custom or optional features

Applications

Germfree's mobile pharmacy is a completely operational mobile pharmacy/cleanroom that meets or exceeds the requirements of USP Chapter <797> Pharmaceutical Compounding-Sterile Preparations and USP <800> Hazardous Drugs-Handling in Healthcare Settings. Our units comply with NIOSH recommendations for pharmacy practices. This allows the facility to be effectively utilized for all USP <797> and USP <800> I.V. compounding requirements.

The pharmacy is tested to meet the guidelines within CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities. The facility is divided into designated work zones. Each zone provides the level of HEPA-filtered air and the equipment required for your current process. Additionally, we strategically place Chemo Hoods, Laminar Flow Workstations, storage and supply areas, gowning benches and staging tables.

■ Hospital compounding pharmacies

■ Radiopharmaceuticals

■ 503b outsourcing facilities



Features

■ Flexibility and adaptability

Our mobile compounding pharmacies are designed by a team of pharmacy experts with flexibility as a guiding principle. With a pre-engineered layout designed for compliance and efficiency, bioGO® mobile compounding pharmacies provide the optimal aseptic compounding space for work with both hazardous and non-hazardous materials as standard. Germfree offers unmatched flexibility in this platform with layouts for USP <797>/USP <800>. This allows a solution tailored to specific pharmacy needs with cost and timeline certainties that are unmatched in the industry.

■ Advanced design and engineering

It is imperative for pharmacies and compounding facilities to have properly integrated engineering controls, which is why Germfree's expertise in this area is a key differentiator. Given that HVAC, pressure schemes, air filtration and containment systems must be precisely configured for the intended use of the facility, Germfree relies on its extensive global experience in engineering and manufacturing mobile cleanrooms and biocontainment laboratories to meet these critical demands to ensure operational readiness on an accelerated timeline. With integrated HVAC, MEP, and Process Support utilities built-in, each facility meets relevant standards determined by the project team for the desired application.

■ Operational readiness

These self-contained units are turnkey with layouts and classifications to meet all process and compliance needs. Germfree's team provides on-site support for a seamless start-up experience with integrated pre-qualification and Factory Acceptance Testing (FAT). This offsite-built, compounding-ready cleanroom product is unique in the market and ensures condensed timeframes for commencing operations.

Key Room Details:

ISO Class 7 Negative Pressure Buffer Room: This Hazardous Drug Preparation area is engineered as an ISO 7 environment. The room is equipped with Class II, Type A2 Biological Safety Cabinets, which are vented to the outside, to protect the product and personnel while preparing hazardous drugs.

ISO Class 7 Positive Pressure Buffer Room: This Sterile I.V. Preparation room is an ISO 7 environment and equipped with Laminar Airflow Workstations to protect the product during aseptic preparations.

ISO Class 7/8 Anterooms: These rooms serve as antechambers and as changing areas for personnel to don their Personal Protective Equipment (PPE), equipped with lockers for storing PPE, a hand washing sink and a gowning bench. These anterooms are maintained at positive pressure relative to the outside. Pressure gauges over doors will display room pressures. There are also alarms to indicate unsafe conditions due to changes in the differential pressures between rooms.



Installations



USP <797>/<800> mobile pharmacy supporting a facility renovation in Arkansas, USA



Accessible compounding pharmacy in operation in North Carolina, USA. (Ramp is not a Germfree solution)



USP <797> hospital pharmacy in operation in Iowa, USA

Architectural features



Trailer pictured above includes customer-specific design elements not found on all trailers.

■ Seamless wall system

Germfree’s seamless interior wall system delivers a monolithic barrier that is robust, durable, easily cleanable, and able to withstand harsh decontamination chemicals and other cleaning agents.

■ Coved floor system

Germfree utilizes a high performance, welded seam vinyl flooring system that is coved at walls and corners for superior cleanability and chemical resistance. Robust by nature, the floor system is designed for heavy use and cleaning.

■ Stainless steel casework

All casework is manufactured with high-grade 304L Stainless Steel with rounded, smoothed edges to prevent snagging of PPE. Casework comes in a variety of designs for various functions. Shelves are removable, and fixed components are engineered for easy cleaning in hard to reach areas.



*Available on select models. Ask your Sales Engineer for more information.



Electrical, Controls and Data Acquisition

Germfree's bioGO® USP Trailer Suites come with an 8 camera system, and data receptacles in the process suite, central data cabinet with wires terminated to patch panel. The door interlocks are SOP-driven, with a wave to open (soft interlock) process.

The Building Management System (BMS) comes with a reliable controls panel, one HMI with max 3 levels of user access, ~20% extra OI for expansion, remote access (requires client IT interface), includes all sensors for control monitoring, audible and visual alarm in each space.

Architectural

The bioGO® Mobile Pharmacy comes with powder coated doors, and drop ceilings with Arcoplast panels. With interchangeable equipment and furniture, these facilities bring advanced capabilities when existing infrastructure is insufficient or unavailable.



Equipment

Germfree's facilities are provided with the primary compounding equipment and furniture necessary for pharmacy operations. Cleanroom-grade HEPA-Purge Pass-Through Chambers are utilized to safely transfer materials. All-stainless steel furniture and casework is installed throughout the pharmacy to provide storage and work space. Additionally, Germfree manufactures a complete line of pharmacy equipment, including Class II, Type A2 Biological Safety Cabinets, which can be integrated into any facility.



HVAC

The HVAC system is designed to maintain conditions within the cleanroom accounting for temperature, humidity, room differential pressure and cleanroom particulate concentration. The following room conditions are the basis for design:

- Room Temperature: 68 Deg. F ± 2 deg. F
- Room Humidity: +/- 60% R.H.
- Air Changes PAL ISO-7: approximately 24 minimum per hour
- Air Changes Production ISO-7: approximately 45 minimum per hour

Typical electrical utilities provided:

- 300amp, 208V 3 phase
- 110 Duplex Outlets
- 208/220 Single Phase Outlets
- UPS power can be supplied to outlets throughout trailer
- 3-phase Critical Power Outlet

GENERAL OPTIONS

Logo Packages

■ Optional

Basic Custom Logo - Customer-supplied vector logo for placement on both trailer sides

■ Optional

Full Logo Trailer Wrap - Customer-supplied vector branding for full vinyl wrap around exterior of trailer
Customer can supply concept art for design (additional fees apply)



Testing & Quality Control

Germfree's bioGO® Quality Process is designed to evaluate performance as well as fit and finish of every system on our mobile platform. Evaluation and testing is conducted on all components and aspects of the facility.

Germfree's Quality Team ensures all products leaving our facility are ready for turnkey use. All systems are thoroughly vetted commissioning ready.

Germfree's commitment is to provide a complete, stand-alone facility that is process ready and installed with complete confidence onsite.

Installation

Prior to delivery of the bioGO® Mobile Pharmacy, Germfree will work with you to determine what site work needs to be completed before installation can occur.

Pre-installation Consultation includes:

- Overall Location of the unit and the surroundings
- Power Supply
- Data cables and integration
- Fresh/waste water connections
- Negative pressure buffer room exhaust assessment
- Location grade assessment
- Accessibility



Documentation

Each mobile pharmacy is delivered with a full set of as-built drawings and a factory acceptance test summary. Additional documentation, if necessary, can be requested from your project manager.

Commissioning and Qualification (C&Q)

The commissioning and qualification verification process will confirm and document that the facility, system, or equipment is installed and meets user requirements and design specifications. Commissioning and qualification process will be detailed in a Commissioning and Qualification Plan (CQMP) following a risk based approach.

Good Documentation Practice shall be followed throughout the project.

Quality Control

Our bioGO® Mobile Pharmacies undergo intensive QC checks throughout the build process. Pre-qualification and Factory Acceptance Testing (FAT) are conducted prior to leaving Germfree's manufacturing facility.

Project Management

A dedicated Project Manager will oversee all aspects of your cleanroom purchase from order through delivery. In doing so, it is possible to guarantee a seamless transition into your bioGO® Mobile Pharmacy.

Quality Statement

Quality Policy

Germfree will consistently provide products and services that meet or exceed the requirements and expectations of our customers. We will actively pursue ever improving quality through programs that enable each employee to do their job right the first time and every time.

Accountability

We will deliver our products on time, as promised, and of the highest quality.

Ownership

We will strive to exceed expectations at every level and we will work to make sure that each customer is satisfied with the service that they receive.

Longevity

All of our products are constructed from the highest quality materials and are designed to operate reliably for decades. We stand behind our work and take pride in our superior craftsmanship.



Standard Layouts

USP <797>/<800> - Sterile/Hazardous Combination Cleanroom

Designed for maximization of compounding space and workflow and dual purpose under USP <797> and USP <800>, this layout includes both ISO Class 7 Negative Pressure space as well as ISO Class 7 Positive Pressure space (with integrated pass-through for material handling). ISO Class 7/8 Anterooms adjoin each compounding space with bench demarcation and access to pass-through and Pharmacy Command Center.



Three Distinct Work Zones

Germfree's Mobile Compounding Pharmacies are designed with the user in mind, see the key below:

Diagram Key

- 1 ISO Class 7 Negative Pressure Buffer Room
- 2 ISO Class 7 Anteroom
- 3 Pharmacy Command Center - CNC Space
- 4 ISO Class 8 Anteroom
- 5 ISO Class 7 Positive Pressure Buffer Room

