A CleanSpace Whitepaper

Modular Cleanrooms

Safeguarding Quality & Patient Health in Compounding Pharmacies

CleanSpace™

cleanspaceus.com

Building Compounding Pharmacies: The Road to Operational Readiness

We enable pharmacy owners and pharmacists to perform their vital duties as pharmacists effectively and adapt and grow their practices in response to evolving healthcare needs and regulations.

This holistic approach ensures our clients are well-prepared to deliver exceptional care with every prescription they compound and without worry of an FDA 483 warning from a non compliant cleanroom.

Building a compounding pharmacy represents not just a business opportunity but a commitment to meeting the particular health needs of individual patients. You are at the forefront of bridging a vital gap in patient care, offering tailored medication solutions where mass-produced pharmaceuticals cannot. This endeavor, however, demands specialized equipment and expertise that not only meets standards for sterility requirements but also is optimized for day to day operations. Your decision to build a compounding pharmacy places you at the heart of personalized healthcare, poised to impact patient well-being significantly.

Throughout the construction process, we actively involve our clients, imparting knowledge on the critical aspects of their compounding pharmacy spaces, such as design considerations, material selections, and technological integrations that enhance usability, cleanability, and durability. This hands-on learning ensures they understand how each element contributes to a safe and efficient work environment. Secondly, we provide ongoing guidance on maintaining and scaling their operations within these spaces.

At **Cleanspace**, we offer more than just cleanrooms; we provide complete solutions tailored to your compounding pharmacy's unique needs. From design and construction to commissioning and beyond, we're your trusted partner on the road to operational readiness.

The Role of Cleanrooms in Pharmaceutical Sterility

Compounding pharmacies are unique in their requirements. Mass-produced medications often fall short of meeting the specific needs of patients, which is where compounding pharmacies shine. And to create these customized medications, you need an equally exceptional cleanroom.

Cleanrooms, environments specifically engineered to maintain extremely low levels of particulates, such as dust, airborne microbes, and aerosol particles, are necessary for compounding operations because contamination can lead to compromised drug quality, endangering patient health and exposing the operator to legal penalties.

Cleanrooms are equipped with specialized High-Efficiency Particulate Air (HEPA) filtration systems to meet strict purity standards. Additionally, their design and operation must adhere to stringent protocols for staff entry and exit, clothing, and behavior within the room to preserve the sterile environment essential for safe compounding practices.

We design, manufacture, and build our cleanrooms. Compliance doesn't stop with the walls, ceilings, and air changes. People and processes are a major contributor to maintaining compliance. CleanSpace defines process protocols that enhance the day to day operation of your facility to ensure safe manufacturing of pharmaceutical products.

In recognizing the paramount importance of product safety and integrity, our development pathway offers a comprehensive solution tailored to these critical needs. Every aspect of our cleanrooms creates an environment where medications are compounded with the utmost confidence.

Regulatory Standards

We provide, produce, and develop a well-thought-out manufacturing process that meets compliance guidelines for USP and ensures that the process works and works well.

The US Pharmacopeia (USP) governs the compounding of sterile preparations and the handling of hazardous drugs in healthcare settings. The two most relevant USP chapters for compounding operations are USP 797 and USP 800:

USP 797

Guidelines for the process, testing, and verification necessary to ensure the sterility and correct handling of Compounded Sterile Preparations (CSP). It covers environmental monitoring, personnel training, storage, and beyond-use dating.

USP 800

Protections for personnel and the environment when handling Hazardous Drugs (HD), medications identified by the National Institute for Occupational Safety and Health (NIOSH) as posing a risk of harm to healthcare workers and others who may be exposed to them due to their toxicity, carcinogenicity, teratogenicity, or other harmful properties.

Our cleanrooms are designed to meet and exceed **USP 797** and **USP 800** standards, making compliance a seamless part of your operation. We've got you covered every step of the way.

Compounding pharmacies handle a diverse range of products, which are classified into four categories:

1. Hazardous Sterile
2. Non-hazardous Sterile
3. Hazardous Non-sterile
4. Non-hazardous Non-sterile

Each category has its handling, storage, and preparation guidelines, as outlined in USP 797 and USP 800. The distinction between these categories determines the appropriate compounding practices and environmental controls required to ensure safety and compliance.

However, it's important to note that the regulatory landscape for compounding pharmacies is highly dynamic due to the marketplace's unceasing drive to enhance patient safety, ensure medication efficacy, and adapt to new healthcare challenges and technological advancements.

Realized Value

Guidelines provide essential baselines for safety and compliance, but the approach goes beyond these fundamentals. Proper optimization requires a deeper understanding of context and operational goals. Our value is rooted in designing facilities that maximize usability, maximize output, and minimize long-term costs. By transcending the essential requirements and integrating nuanced insights into our design process, we ensure our clients achieve peak productivity, performance, and sustainable success in their compounding pharmacy operations.

Compounding Categories

Our dedication to designing for flexibility ensures that your facility is primed for future scalability and adaptability, allowing it to evolve seamlessly with your business. We build state-of-the-art cleanrooms fully equipped to handle prospective changes.

Hazardous Drug-specific Regulations

Containment Segregated Compounding Area (C-SEC)

A C-SEC is necessary for non-sterile HD compounding and must be a negative pressure environment that is distinct and separate from other pharmacy areas. Physical barriers and airlock systems maintain the necessary pressure differentials. This layout facilitates easy cleaning and decontamination processes, with surfaces and finishes selected for durability and resistance to HD compounds.

HD Storage

Hazardous drugs must be stored in a designated area that is clearly marked and separate from non-hazardous drugs. Shelving and storage units should be constructed of materials that are easy to clean and resistant to corrosion, with a design that prevents dust accumulation and facilitates the containment of spills.

Sterile HD Compounding

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ISO Class 7

In addition to the USP, the International Organization for Standardization (ISO) promulgates its own, independent, and globally recognized standards for cleanroom cleanliness (ISO 14644-1) based on the number of particles of specific sizes present in a cubic meter of air. ISO Class 7 permits a maximum of 352,000 particles/m^3 of size 0.5 µm or larger.

Compounding Cleanroom Design and Layout Considerations

We take immense pride in our 40 years of experience, and our commitment to quality remains unwavering. Our approach includes stringent cost, schedule, and scope controls, which are essential for transitioning your project from design to full-scale manufacturing. We deliver on budget and within the shortest possible timeframe, enabling your operations to scale efficiently and effectively.

Designing a compounding pharmacy demands precision and a deep understanding of pharma processes, regulatory requirements, and the usability of your facility. Every aspect of the design must adhere to the strict standards set forth by the USP, which includes careful planning of the layout, materials used, and integration of technology and equipment. This design supports the safe and efficient preparation of compounded medications, ensuring sterility and minimizing the risk of contamination or error.

FUTURE PROOFING: With modular design at the core, we build our cleanrooms are built to adapt to the evolving needs of our clients and regulators. Whether you're expanding your services or adapting to new regulations, our scalable solutions ensure you can do it efficiently and cost-effectively.

Adjacency and Workflow

A well-designed compounding pharmacy layout ensures a logical and efficient workflow by strategically placing the anteroom for smooth transition in and out of the cleanroom. The layout directs a seamless progression from receiving raw materials to storing, compounding, and dispensing medications, with intuitive space arrangement to reduce travel distance and obstacles in the process. Minimizing personnel and material movement in the cleanroom reduces particle disturbances and contamination risks, and proper equipment placement facilitates easy access and error reduction. Ergonomically designed workstations also minimize the risk of errors due to fatigue or discomfort.

Pressurization and Airflow Control

We customize the airflow to suit your specific needs. Whether it's laminar or turbulent airflow, we've got it covered. With our expertise, you can be confident that your compounding pharmacy will have the perfect balance of pressurization and airflow, creating the ideal conditions for precision and purity.

Maintaining proper room pressurization prevents cross-contamination between different areas. In non-HD compounding pharmacies, USP 797 requires positive pressure environments to keep contaminants out. For HD workflows, USP 800 requires negative pressure to contain hazardous particles.

In either case, the design must include an airflow control system that maintains the correct directional flow of air, from clean to less clean areas, and a layout which avoids obstructing laminar airflow (airflow in parallel layers, with minimal mixing between the layers). In turbulent airflow, the air currents mix and create a chaotic pattern. Equipment blocking airflow can create turbulence, leading to potential contamination. There should be enough space around the equipment for proper air circulation.

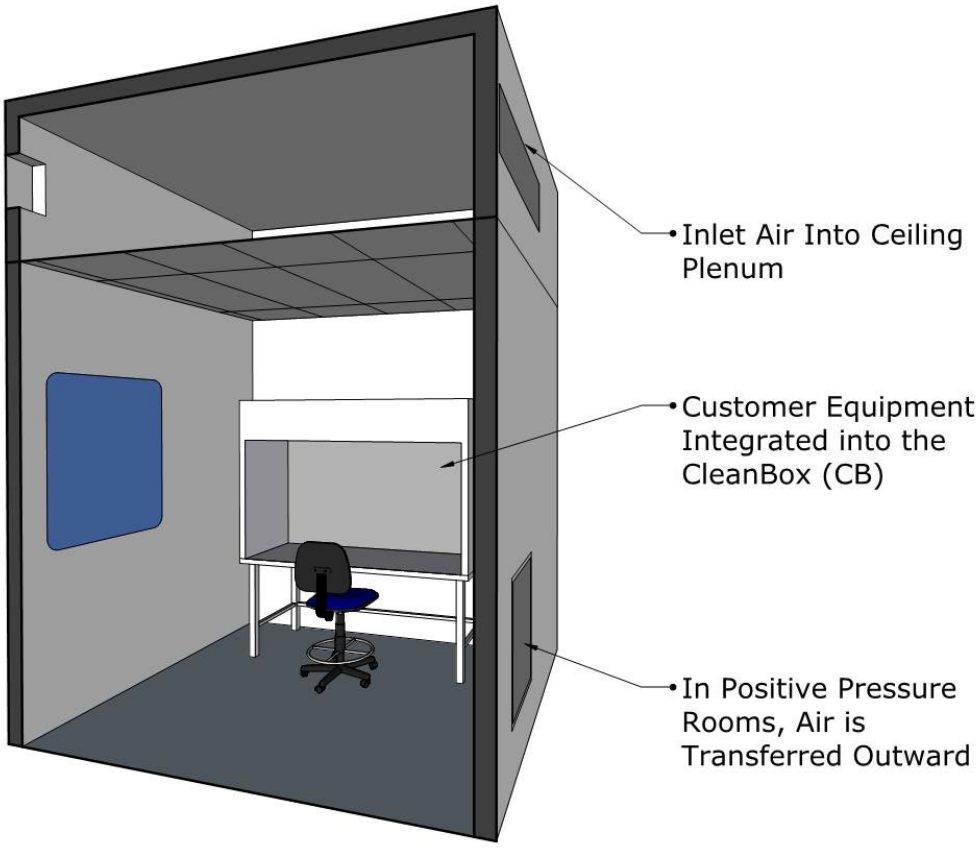
HVAC Systems: Heating, ventilation, and air conditioning (HVAC) precisely regulate temperature, humidity, and air purity in a cleanroom. Special attention is given to the selection and placement of HEPA filters to ensure the removal of airborne particles. The system must be robust enough to maintain consistent environmental conditions, essential for both the stability of compounded medications and the comfort of personnel.

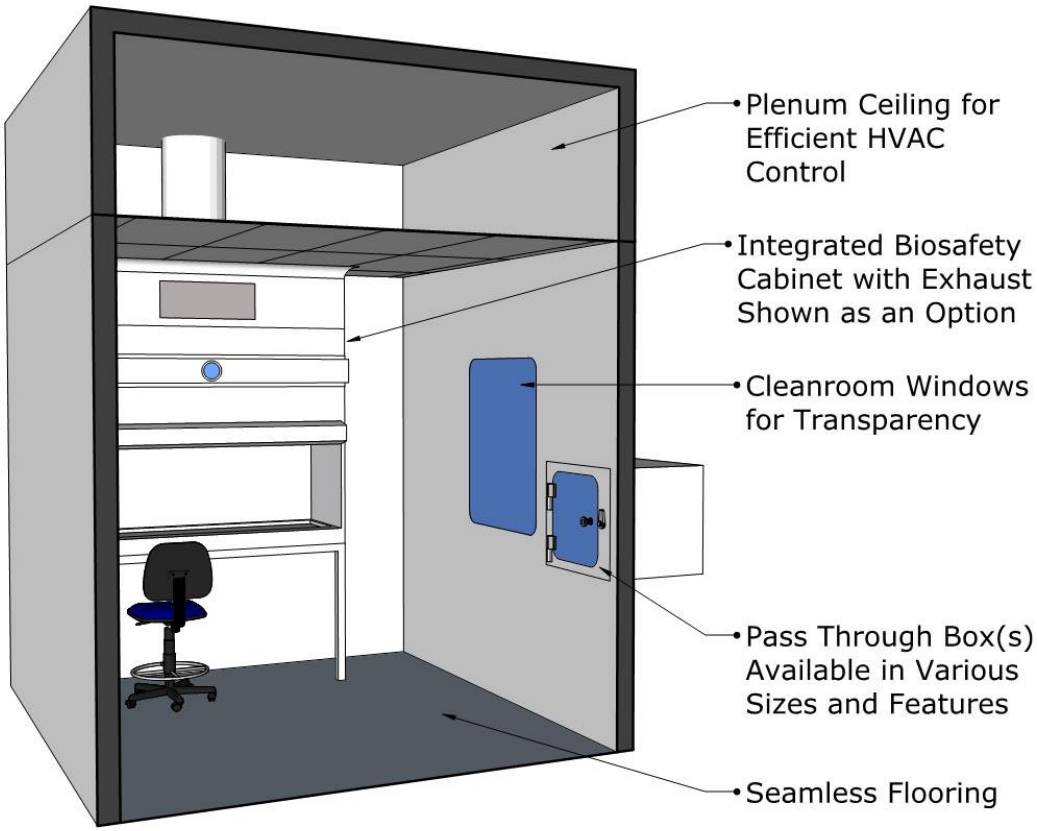
Negative Pressure: In compounding pharmacies dealing with hazardous drugs, which require a negative pressure environment that directs air into the room from cleaner adjacent areas (per USP 800), the pressure gradient prevents cross-contamination. This system depends on careful calibration of the HVAC system to maintain the required pressure differential consistently.

Exterior Exhaust: The removal of contaminated air from a cleanroom is managed by an exterior exhaust system designed to prevent recirculation. The routing of ductwork requires planning to ensure compliance with local building codes.

Fresh Air Intake: In alignment with the requirement for negative pressure environments, compounding pharmacies also incorporate a 100% fresh air intake system. This system helps maintain the necessary air changes per hour (ACH) (e.g. at least 12 ACH for USP 800). The fresh air intake is carefully managed to ensure proper air balance and prevent undue strain on the HVAC system, especially in maintaining temperature and humidity levels.

Why settle for costly stick frame construction when you can maximize your budget runway with modular cleanrooms? We offer flexibility, scalability, and efficiency that traditional construction can't match. Get the most out of your investment.


Inlet Air Into Ceiling Plenum
Customer Equipment Integrated into the CleanBox (CB)
In Positive Pressure Rooms, Air is Transferred Outward


Plenum Ceiling for Efficient HVAC Control
Integrated Biosafety Cabinet with Exhaust Shown as an Option
Cleanroom Windows for Transparency
Pass Through Box(s) Available in Various Sizes and Features
Seamless Flooring

Minimizing Cross-Contamination

Whether it's complying with ever-evolving regulations or steering clear of construction errors, we know the challenges you face, and we are here to ensure that your project proceeds without a hitch, saving you time, money, and headaches.

To further reduce the risk of cross-contamination, compounding cleanrooms feature controlled door swings, pass-through cabinets, and filtration systems. Another key consideration is the placement and robustness of access controls. Secure and controlled

Clean and Dirty Separation

A clear demarcation of clean and dirty areas within the anteroom is achieved through physical barriers and distinct color-coded or marked areas on the floor. The separation helps in maintaining a disciplined flow of materials and personnel, reducing the risk of contamination of clean areas by used materials. Cross-contamination risks are further reduced by clearly separating areas for different stages of compounding (e.g. weighing, mixing, filling).

Visual Acuity and Communication

Good design facilitates communication and visual contact between pharmacists and technicians. This can be achieved through the use of physical windows and, where necessary, camera systems. These features help in maintaining a high level of workflow efficiency and safety, allowing for easy monitoring and communication without compromising the sterile environment.

> When people build compounding pharmacies out of stick frame materials, it's a composite construction with cost overruns. With a modular cleanroom, you build flexibility and scalability and maximize your budget runway.

Finishes Based on Space Classification

The selection of finishes (like wall coverings, flooring, and ceiling materials) is determined by the classification of each space within the compounding pharmacy, but general requirements include:

Durable finishes that withstand rigorous use

Non-porous surfaces to prevent contamination

Non-off-gassing materials ensuring cleaner air quality

Easy-to-clean surfaces for maintaining sterility

Non-off shedding features, even if the wall is damaged

Different areas, such as unrestricted, semi-restricted, and restricted zones, require different treatments to facilitate cleaning and maintain the necessary environmental conditions.

Modularity and Scalability

> At Cleanspace, we are not just builders. We are business partners who realize the importance of educating our clients about their investments. We enable our compounding pharmacy clients to achieve operational readiness and scalability, ensuring you can produce safe and efficacious products in a facility that not only complies with regulations but also provides a profound understanding of their cleanroom's functionality.

Each compounding pharmacy has unique needs and challenges. Whether you are building a new facility from the ground up, or retrofitting an existing space, the project will depend on tailored designs that fit their operational goals, budget constraints, and compliance framework. And, because requirements inevitably change as regulations evolve and as a facility grows, flexibility and scalability also need to be considered from the earliest planning stages.

A design philosophy that incorporates modularity allows for easy adaptation and expansion. Modular design elements can be reconfigured or upgraded with minimal disruption to ongoing operations, which future-proofs the facility with a cost-effective solution for expanding their services or adapting to new regulations.

Achieving Compliance and Innovation Efficiently

Understanding the regulatory framework and industry best practices associated with compounding pharmacies is only the start of a journey towards delivering a turnkey cleanroom solution. Real world expertise and practical know-how translate conceptual blueprints into fully operational, compliant, and efficient workspaces — from initial design to final construction and beyond.

We understand that sterility is non-negotiable in pharmaceutical compounding. Our modular cleanrooms are engineered to ensure that your medications remain pure and free from contaminants, safeguarding patient health and compliance with regulatory standards.

> “Cleanspace has a holistic vision when building Compound Pharmacies. Beyond design, construction, commissioning, and fabrication of panels, we see the vision of the owner’s requirements and help them move down that road to full-scale production capabilities.