



Current Draft USP-797 and USP-800 Compliant Mobile Cleanroom Suite - 48' x 14'

OVERVIEW

Cleanroom Design LLC (“CRD”) will provide our Model CRD-4814 (“Cleanroom”) a turnkey, modular, portable, current draft USP 797, and current draft USP 800-compliant sterile compounding pharmacy.

The Cleanroom can be delivered and deployed on either hard pavement or a concrete pad and is seismically-engineered for installation throughout the continental United States. Details of materials of construction, dimensions, operational performance, and all items and equipment included with the Cleanroom, are described below. The location for Client provided cleaning equipment shall be determined by the client upon Delivery and Acceptance of the Cleanroom. Any required storage racks, carts, shelving, hooks and any other equipment or furnishings that are not specifically mentioned in this exhibit shall be provided by and installed by Client.

MODULAR STRUCTURE

CRD offers a factory-built, over-the-road, weather-tight, modular structure with exterior dimensions of 48’ long by 14’ wide by 14’ overall height to ground. The exterior is clad in weathertight siding with an internal vapor barrier and high-performance thermal insulation. The CRD logo will be displayed on the 30’ lengths.

INTERIOR CLEANROOM SPACES (ILLUSTRATED ON EXHIBIT B)

The interior dimensions are 47’- 3” long by 13’- 3” wide, divided into the following spaces:

1. The 5’ x 13’- 3” mechanical room, B09, room is located at one end, and houses air conditioning, electrical and plumbing system components.
2. The 8’ 4 -1/2” x 13’- 3” hazardous compounding room, A02, is located adjacent to the opposite end of the mechanical room. The room is designed to operate at ISO Class 7 and is fitted out with a pair of seismically-mounted, 100% exhausting, ISO Class 5, 4’ biosafety cabinets. The room operates between -0.01 and -0.03 in. wc. relative to its adjacent gowning room. The biosafety cabinets (PEC) and secondary engineering control (SEC) will each be externally vented as required by USP 800.
3. The 8’ by 5’- 11” hazardous gowning room, A03, connects the hazardous compounding room to the hazardous unpack/storage/workroom, and is designed to operate at ISO Class

7. It is fitted with a hands-free scrub sink with safety shower/eyewash, and is segregated into “dirty” and “clean” zones with a demarcation strip welded into the sheet vinyl flooring. The room operates at a minimum of +0.02 in. wc. relative to the adjacent workroom.
4. The 8’ by 7’- 1” hazardous unpack/storage/workroom, A08, connects the non-hazardous workroom and is designated to be a controlled non-classified space with HEPA filtration. The room will run under negative pressure with greater than 12 air-changes-per-hour relative to the adjacent workroom.
5. The 4’ by 5’ – 11” non-hazardous storage area, A09 is accessed from the workroom. This area is controlled non-classified but does include HEPA filtration.
6. The 4’ by 5’-11” entry airlock, A04, connects the interior workroom to the pharmacy exterior. The space is not ISO classified but is maintained at a minimum of +.02 in. wc. over-pressure relative to the exterior and -.02. in. wc. relative to the workroom to help keep contamination to a minimum when entering from the outside environment.
7. The 8’ by 5’-11” non-hazardous gowning room, A05, connects the non-hazardous compounding room to the workroom and is designed to operate at ISO Class 8. It is also fitted with a hands-free scrub sink with safety shower/eyewash, and is segregated into “dirty” and “clean” zones with a demarcation strip welded into the sheet vinyl flooring. The room operates at a minimum of +0.02 in. wc. relative to the adjacent workroom.
8. The 17’ by 7’-1” pharmacy non-hazardous workroom, A06, and the 4’ by 5’-11” workroom storage area, A09, provides approximately 145 square feet of space for data entry, staging, material transfer, checking, and storage. The room is a controlled non-classified space but does include HEPA filtration, and is fitted with a Trespa epoxy counter. The room operates at a minimum of +0.02 in. wc. relative to the airlock.
9. The 10’ x 12’ non-hazardous compounding room, #07, is designed to operate at ISO Class 7 and is fitted with a pair of seismically-mounted, 5’, ISO Class 5 horizontal laminar flow hoods. The room operates at a minimum of +0.02 in. wc. relative to the adjacent gowning room.

INTERIOR FINISHES

The interior perimeter walls are clad in smooth, gloss-white FRP (fiberglass-reinforced plastic) to provide high-impact, sanitizable surfaces.

The 3” thick modular interior partition walls are surfaced on both sides with FRP over fire-rated gypsum board and insulating foam cores. The 4’ wide wall panels are supported by anodized-aluminum posts with integral raceways for electrical and data cabling. Coved FRP wall angle shall be installed to create a coved transition from wall-to-ceiling and a 6” flash cove on the heat welded sheet vinyl flooring will provide a coved transition from wall-to-floor. Any lips remaining and any 90-degree wall-to-wall transitions shall be sealed with Dow 732 100% silicone caulking.

DOORS

Exterior Entry Door

The exterior entry door to the mechanical room and the airlock is powder-coated, insulated steel with wire-glass view window. The door is fully-gasketed and has a deadbolt security lock.

Interior Doors

The interior doors are full-glazed with anodized aluminum frames and integral, solid-rubber gasketing. Manual doors have push-pull hardware and cleanroom-grade hydraulic closers. The sliding gowning room doors and the swing style doors at the compounding room entry have hands-free actuators and a breakaway feature for emergency exit. The powered doors are electrically-interlocked and have red/green LED pass/no pass indicators.

CEILINGS

The ceilings composed of white, powder-coated, sealed Flush-Grid LED 2 x 4 cleanroom-grade light fixtures. The dropped ceiling grid is made of FRP, and ceiling tiles are solid, gloss-white FRP, and are mechanically-attached and sealed with a cleanroom-grade 100% silicone caulking (Dow 732). There is no ceiling in the mechanical room. It is fitted with an overhead LED fixture for proper illumination.

FLOORING

Heat-welded, 6" coved, hospital-grade sheet vinyl flooring is installed in all spaces except the mechanical room. The mechanical room is clad in conventional VCT flooring over the modular substrate.

PASS-THROUGHS

Cart Pass-throughs

The two sterile compounding rooms are fitted with electronically interlocked, transfer cart pass-throughs, measuring 44" wide by 72" high by 24" deep. The pass-throughs are equipped with 18" x 36" x 36" high, three-tier stainless steel carts captive to the ISO Class 7 compounding side to ensure the cart always remains within the sterile space. The pass-throughs also include red light / green light LED interlock indicating lights.

The pass-throughs are manufactured from solid white, heat-welded polypropylene plastic with clear, polycarbonate-glazed doors and Type 316 stainless-steel hardware.

CHAIRS AND GOWNING BENCHES

The Cleanroom includes four (4) cleanroom-grade chairs and two (2) solid white, heat welded polypropylene plastic gowning benches.

REFRIGERATION

The sterile non-hazardous compounding room is fitted with a 26 cubic-foot Helmer Scientific pass-through refrigerator and one (1) single door, 25 cubic-foot Helmer laboratory refrigerator is provided in the hazardous storage/unpack/workroom for hazardous drug storage. Per USP 800, pass-through refrigerators are not to be used in a sterile hazardous compounding room. Both refrigerators are equipped with digital-display control panels and adjustable inner shelving. The refrigerator interior temperatures are logged and alarmed via the PLC control system.

DATA AND COMMUNICATIONS SYSTEMS

The Cleanroom design includes pre-wired data receptacles carried to internal point-of-connection in the mechanical room. The Client's IT personnel will provide a switch upon delivery and make all necessary final connections.

The Cleanroom include room-to-room hands-free (cleanroom side) and console (workroom side) digital intercoms. The hands-free intercoms on the cleanroom side are flush mounted.

LIFE-SAFETY SYSTEMS

The Cleanroom includes internal emergency lighting and exit signs.

The air circulation system is fitted with ionizing smoke detectors, wired to an annunciator panel to be tied into the house system by others. The system will operate in a stand-alone environment but must be tied to the house system for monitoring

INTEGRAL PLUMBING SYSTEMS

Each gowning room is fitted with a stainless-steel, hands-free scrub sink with integral safety shower/eyewash. The Cleanroom requires a connection to cold domestic water via a 3/4" hose or pipe. CRD shall adequately insulate all water pipes located within the Cleanroom envelope in a manner sufficient to prevent freezing. Client is responsible for all utility connection to the Cleanroom and Client shall be responsible for adequately insulating or heat-tracing all water pipes that are outside of the Cleanroom envelope including final connections to the Cleanroom.

The Cleanroom contains an on-board, on-demand water heater.

The CRD Cleanroom requires either direct connection or pumped connection to the building sewer system by others. The scrub sink discharge line is located on the Cleanroom for connection by others. A standard sump station is suitable for pumped discharge, via a vertical-to-horizontal line with a check valve in the vertical run.

HEPA FILTRATION AND AIR CONDITIONING

The airflow in the clean spaces is discharged from ceiling-mounted, terminal HEPA filters with room-side accessible aerosol leak-test challenge ports.

As is stated in the CRD performance criteria, our Cleanrooms are capable of maintaining proper temperature and relative humidity control regardless of the climate.

The mechanical system is designed to provide required ISO classifications with proper air changes to maintain these conditions while in use. The hazardous compounding areas have redundant exhaust fans to provide ventilation for the bio safety cabinets and maintain a pressure differential between the compounding room and gowning room. The mechanical system maintains a single pass for the air in the hazardous compounding and hazardous storage room as required by USP 800. In the unlikely event of an exhaust fan failure the redundant exhaust fan automatically energizes to maintain a safe environment.

Energy recovery coils in the exhaust stream and outside air intake stream are used to precondition the outside air being introduced into the facility. The air being exhausted through the Bio Safety Cabinets can be as cool as 64° when the outside air is over 95°. The energy recover coils can provide 30% of the air conditioning load as precooling and as high as 50% of the energy needed in preheating the outside air reducing the operating costs. The system uses two glycol coils and a small pump to circulate glycol between the exhaust system and outside air intake system providing 100% isolation of the hazardous exhaust and the outside air intake.

The facility design also reduces cross contamination. Outside air intakes are on the opposite end of the facility as the exhaust. Exhaust stacks are above the roof line and the intake is in the lower wall on the opposite end.

The cooling system consists of multiple air cooled condensing units. Two systems are used to condition the outside air provided to the unit. The two units reduce the energy necessary to maintain the desired 64°-68° air at less than 60% RH. To achieve the humidity at this temperature the air must be cooled near 50°. This air is too cool for occupant comfort, so it must be “reheated” to 64°. The heat that was removed by the air cooled condensing units is used to warm this air up near the desired temperature. The compressor heat that would normally just be exhausted through the air conditioner is diverted by a valve to a coil in the air handling unit. This bypass valve can adjust to over 6,000 positions to provide very little reheat to recovering almost all the heat removed from the outside air. The final temperature adjustment is achieved with a SCR controlled electric heater. This heater is used to temper the outside air in the winter to 64-68° for the compounding rooms. The SCR controlled electric heater also provide very precise temperature control, so the occupants have the same temperature conditions from winter to summer.

The workroom and unpacking / storage room have an additional duct heater to allow the temperature to be adjusted warmer for the staff that is not fully gowned.

An electric humidifier is used to provide humidity to the outside air when it is too dry. The SCR controlled unit can generate from 0 to 50 pounds of humidity per hour.

The air is also filtered three times before it is introduced into the space. An outside air prefilter, rated at MERV 7, removes dust and pollens from the airside air. An intermediate filter, rated at MERV 13, removes very small particles suspended in the air stream and HEPA filter/diffuser assemblies provide the ISO rated environment.

Additional systems are provided to allow operation of the air condition systems at low ambient conditions. The cooling compressors can operate below freezing but should not be needed below 50°. This capability ensures that heat is available for hot gas reheat of the supply air minimizing the need to purchase electric to reheat. Refrigeration receivers are used to store refrigerant needed to reheat in the summer when reheat requirements will be reduced.

All the systems are constructed with components available for HVAC / Refrigeration distributors throughout the country. The glycol used is propylene glycol 40% solution to reduce environmental impact over automotive type ethylene glycol. This glycol also available through distributors throughout the country and 5 gallons are provided to “top off” the system if ever needed.

CONTROL SYSTEM

The Cleanroom will be controlled and monitored by a PLC (process-loop controller)-based system.

The system will provide electronic temperature, pressure, and relative humidity monitoring, control, and alarming in all zones.

The system will control, monitor and alarm the process exhaust fan control.

The system will provide refrigerator temperature monitoring and alarms for the refrigerator included with the Cleanroom.

The system will have a 15” diagonal touch-screen display for password-protected access.

The system will provide continuous data logging and trending, as well as external alarms to selected smartphones via text messaging as well as email. Two-way communication will allow CRD personnel to trouble-shoot operations remotely.

The installation will include digital-display manometer gauge/ transmitters that will deliver the signals to the control panel for temperature, relative humidity and temperatures.

Alarms are sent via text and email messaging to CRD offices and selected personnel of end user.

The Cleanroom control panel will include 6-months trial of contract Remote Monitoring software and 2-way password-protected access from any computer, including real-time data logging to cloud storage, and real-time text and email alarming for out of range values. The recurring cost for this package after the trial period is \$3,000.00 per year billed in increments of \$750.00 per quarter. If the end user wishes to continue services at the end of the 6-month trial period, a contract will be presented at that time.

PROCESS EXHAUST SYSTEM

Per current draft USP-800 regulations, Primary Engineering Controls (PEC's) and Secondary Engineering Controls (SEC's) for sterile hazardous compounding must be externally-vented via redundant exhaust fans.

CRD furnishes an integral exhaust system, capable of supporting two (2) @ 4', 100% exhausting BSCs, along with a corresponding makeup air conditioning system. The features of the CRD exhaust system design include:

1. twin, redundant, high-static axial fans, with variable-speed controls, on the exterior of the cleanroom or on the top of the 's building; The location is determined after the onsite engineering visit.
2. horizontal, stainless-steel duct connection to the BSC outlet, with bubble-tight damper, for low interior profile;
3. common stainless-steel fan intake manifold with barometric dampers to isolate the inactive fan;
4. automatic alarm and fan change-over in case of fan failure;
5. 10' stainless-steel, rain-proof discharge chimney with spring-loaded guy-wires for installation following deployment.
6. The 10' high chimney positions the discharge approximately 24' above ground of the Cleanroom. If the exhaust fans must be mounted on the Client's building roof, the 10' chimney positions the discharge approximately 12' above the rooftop. The exhaust fan must be at least 25' away from the nearest air return regardless of whether it is mounted on the Cleanroom or the building rooftop.

OPERATIONS AND MAINTENANCE MANUAL

CRD will provide a detailed operations and maintenance manual with the Cleanroom.