

SALIENT CHARACTERISTICS/PRICING SCHEDULE

“Brand Name or Equal”

EQUIPMENT REQUIREMENT: Manufacture: Odulair Model: HD2-NHD1 - USP 800 Mobile Trailer Facility.

Company is to design and build a 53' semi-trailer with one large ante room, one hazardous buffer room and one non-hazardous buffer room that meets USP 800 and USP 797 code compliance.

Drawings will be provided with the below salient characteristics. The Drawings/Semi-trailer will comply with the features listed below and the attached drawing:

Salient Characteristics

USP 800 Hazardous Drug & USP 797 Non-Hazardous Drug Pharmaceutical Compounding Pharmacy Trailer

ROOMS & AREAS

- Ante Room ISO 7
- Sterile Hazardous Drug Buffer Room ISO 7
- Sterile Non-Hazardous Drug Buffer Room ISO 7
- Sterile Hazardous Drug Storage Area
- Self-Supporting Modular Design inclusive of walls, roof / ceiling, flooring, lighting, electrical & filtering equipment
- Modular clean room must fit within our trailer or within your designated space
- Modular Clean Room seismic integrity provisions where necessary
- Finishes - Non-porous and cleanable surfaces, ceilings, walls, and floors subject to wet cleaning

ANTE ROOM

- 2 Scrub sinks with eye wash station positioned at least 3' from the Sterile HD Buffer Room door
- Clean Personal Protective Equipment (PPE) Storage Bin
- Soiled PPE Waste Bin
- Staff Changing Bench
- Environmental Services Closet

STERILE HAZARDOUS DRUG BUFFER ROOM Equipment

- 2 ISO 5 Class II Type B2 Biological Safety Cabinets (BSC) with 100% Outside Air Supply and Exhaust - 3ft each
- Interlocking HEPA filtered Pass-Thru Chamber from Ante Room
- Stainless Steel Workstation
- RFID Refrigerator for inventory control
- Soiled PPE Waste Bin
- Storage Cabinet for sterile hazardous drugs

STERILE NON-HAZARDOUS DRUG BUFFER ROOM Equipment

- ISO 5 Horizontal Laminar Airflow Workbench (LAFW) - 4ft
- Interlocking HEPA Filtered Pass-Thru Chamber from Ante Room
- Stainless Steel Workstation
- USP 797 Compliant Refrigerator
- Soiled PPE Waste Bin
- Non-Hazardous Drug Storage Cabinet

MECHANICAL ROOM

- Back-up Generator With Automatic Transfer Switch
- Water Storage Tanks (Fresh & Gray)
- Data Connection Package - Interior Video Intercom System

UTILITY REQUIREMENTS

- Electrical: 208V 3-Phase 200 Amps
- Water: 1" Potable Water Line
- Sewer: 4" Standard Sewer Line

WHEELCHAIR RAMP

- ADA Compliant
- Aluminum ramp with guardrails, landing, and stairs
- Width: 4'
- Installation on site

ENVIRONMENTAL CONTROLS

- All Facility & Engineering Controls Compliant with new USP 800 and USP 797
- Physically separated Ante Room and Sterile Hazardous Drug Buffer Room and Sterile Non Hazardous Drug Buffer Room
- C-PEC Containment Primary Environmental Control: (BSC or LAFW) LControls)
 - ISO 5 Biological Safety Cabinet (BSC) located in the Sterile HD Buffer Room
 - ISO 5 LAFW located in Sterile Nonhazardous Buffer Room
- C-SEC Containment Secondary Environmental Controls (Room Controls)
 - ISO 7 Ante Room Environmental Controls:
 - Positive pressure
 - Minimum of 30 Air Exchanges Per Hour (ACPH) compliant with USP 800
 - High Efficiency Particulate Air (HEPA) filtered supply air
 - 24/7 Real-time Environmental Room Monitor providing:
 - ❖ Temperature
 - ❖ Humidity
 - ❖ Differential pressure
 - ❖ Airborne particle count
 - ISO 7 Sterile HD Buffer Room Environmental Controls:
 - Negative pressure between 0.01" to 0.03" WC
 - Minimum of 30 Air Exchanges Per Hour (ACPH) compliant with USP 800
 - 100% Outside Supply Air (into room)
 - High Efficiency Particulate Air (HEPA) filtered supply air

- Externally Vented 100% of Air Exhausted Directly Outside
- Zero recirculation of HD Buffer Room air
- 24/7 Real-time Environmental Room Monitor providing:
 - ❖ Temperature
 - ❖ Humidity
 - ❖ Differential pressure
 - ❖ Airborne particle count
- 24/7 Real-time Monitoring of RFID Refrigerator interior temperature to ensure drug safety
- ISO 7 Sterile Non-HD Buffer Room Environmental Controls:
 - Positive pressure
 - Minimum of 30 Air Exchanges Per Hour (ACPH) compliant with USP 800
 - High Efficiency Particulate Air (HEPA) filtered supply air
 - 24/7 Real-time Environmental Room Monitor providing:
 - ❖ Temperature
 - ❖ Humidity
 - ❖ Differential pressure
 - ❖ Airborne particle count
 - ❖ 24/7 Real-time Monitoring of RFID Refrigerator interior temperature to ensure drug safety

COMMISSIONING & CERTIFICATION

- Delivery
- Set-up
- On-site Test & Balance Certification
- Certification Supervision
- On-site Training