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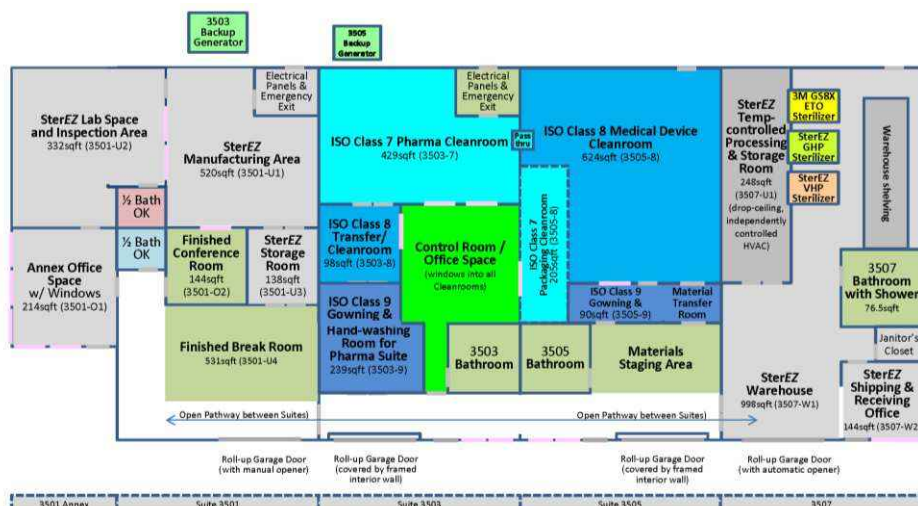
Cleanrooms available for short- and medium-term commitments to manufacture and/or package Medical Devices, Pharmaceuticals, and Biologicals

SterEZ™ is offering short- and medium-term opportunities to access three unique cleanroom spaces in its Menlo Park facility. These spaces were previously certified to ISO cleanroom standards; furthermore, the facility was previously registered & licensed by California FDB and successfully passed on-site inspection by US FDA for pharmaceutical processing and medical device manufacturing.

Each of the cleanrooms can be contracted independently or together with one or both of the others. Manufacturing activities, processing conditions, and personnel can be directly monitored from the **SterEZ Control Room**, which is centrally located and equipped with the **Lighthouse EMS** (environmental monitoring system) to monitor and record operator access, temperature, relative humidity, pressure differentials, airborne particulates, and airborne viable microorganisms. The pharmaceutical cleanrooms are access-controlled by way of a security system.

In addition to the cleanrooms, the SterEZ facility plans to offer on-site, research-scale ETO (ethylene oxide) sterilization capability using its 3M™ Steri-Vac™ GS8X Sterilizer/Aerator. This service will be operated by SterEZ for its clients. Additionally, SterEZ also plans to offer VHP (vapor-phase hydrogen peroxide) and GHP (gaseous-phase hydrogen peroxide) sterilization services in the future.

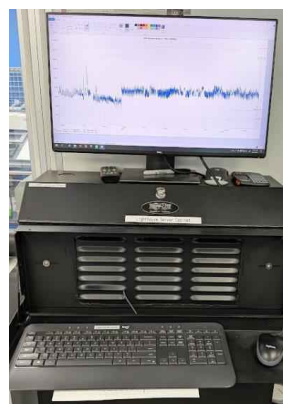
Overall Facility Layout: The facility was previously registered & licensed by California FDB and successfully passed on-site inspection by US FDA for pharmaceutical processing and medical device manufacturing. The overall layout of the facility is composed of 4 legal suites within an industrial park in Menlo Park, CA:





1. **3501 Haven Avenue – 1,671 sqft**
 - Front office, which accommodates 3-4 office workstations and support equipment (e.g., printer/copier, file cabinets).
 - Unfinished back room (exclusively for SterEZ Lab Space and Inspection Area).
 - Unfinished manufacturing room (exclusively for SterEZ Manufacturing Area).
 - 2 powder rooms.
 - Finished conference room (available on prior reservation basis).
 - Finished break room, including: sink, base & wall cabinets; refrigerator, microwaves, and café seating with tables; lockers for personnel (i.e., common area).
2. **3503 Haven Avenue – 1,500 sqft** Equipped with natural gas-powered backup generator.
 - SterEZ “Control Room” office, which accommodates 5-7 office workstations and support equipment (e.g., printer/copier, file cabinets). Occupied by SterEZ personnel and on-site clients.
 - **Pharma Cleanroom Suite:** (available by contract only)
 - ISO Class 7 pharmaceutical-grade cleanroom, 429sqft (3505-7); controlled access by card key.
 - ISO Class 8 staging cleanroom, 98sqft (3505-8); controlled access by card key.
 - ISO Class 9 gowning & hand sanitization room, 239sqft (3505-9)
 - Front hallway & office space, which accommodates 3-4 office workstations and support equipment.
 - All gender bathroom.
3. **3505 Haven Avenue – 1,500 sqft** Equipped with natural gas-powered backup generator.
 - **ISO Class 7 Packaging Cleanroom**, 205sqft (3505-7)
(Available by contract only)
 - **ISO Class 8 Medical Device Cleanroom**, 624sqft (3505-8)
(Available by contract only)
 - **ISO Class 9 Gowning Room and cleanroom staging area**, 90sqft (3505-9)
(Available by contract only)
 - Materials staging area.
 - Front hallway.
 - All gender bathroom.
4. **3507 Haven Avenue – 1,500 sqft.** (Controlled access for SterEZ personnel only)
 - Temperature-controlled processing & storage room, into which 3M GS8X ETO Sterilizer will be installed.
 - Warehouse space, with pallet jack forklift for loading/unloading shipments onto/off of trucks.
 - Shipping/receiving office.
 - All gender bathroom with shower.

SterEZ “Control Room”: Manufacturing activities, processing conditions, and personnel can be directly monitored from this room through viewing windows. It is where the Lighthouse EMS server and computer monitors are located; the EMS system monitor sand records operator access, temperature, relative humidity, pressure differentials, airborne particulates, and airborne viable microorganisms. Also, control room accommodates 5-7 office workstations and support equipment (e.g., printer/copier, file cabinets).





Pharmaceutical Cleanroom Suite: This suite of rooms was previously certified, validated, and used for pharmaceutical processing and is composed of three interconnected rooms:

1. **ISO Class 7 Pharmaceutical Cleanroom (3505-7, 429 sqft):** Pharmaceutical processing is performed in this high-level cleanroom, meeting the required air changes per hour from ceiling HEPA filters. The temperature of the HEPA-filtered, conditioned air is a combination of air which is recycled from low wall air returns and fresh make-up air which is thermostatically controlled. The floor is covered and coved with a pharmaceutical-grade, continuous vinyl flooring; the walls are built with powder-coated aluminum panels and epoxy-painted concrete & drywall; and the ceiling is composed of a grid system with vinyl-coated, waterproof, non-shedding, and cleanable tiles.

The relative humidity, pressure differentials, airborne particulates, and hydrogen peroxide levels are monitored by the Lighthouse EMS. Also, there is a cleanroom pass-through between this pharmaceutical cleanroom and the medical device cleanroom (3505-8).





2. **ISO Class 5 Isolator (3505-5, 11.3 sqft interior):** The customized Nuaire isolator is constructed of stainless steel, polycarbonate glass and fittings, and outfitted with gloves. The isolator's interior is sterilized by a Steris VHP 1000ED biodecontamination unit using VHP (vapor-phase) hydrogen



peroxide) and it is currently configured to perform semi-automatic, batched, sterile fill-&-finish (F&F) operations. SterEZ has developed its PUVIS™ system to sterilize and feed drug containers into the isolator, so that sterile F&F operations can be performed continuously with sterile, packaged drug containers exiting the isolator; this PUVIS system is currently being refined for validation.

The temperature, relative humidity, pressure differentials, airborne particulates, and hydrogen peroxide levels within the isolator are monitored by the Lighthouse EMS; also, the isolator is equipped to collect samples of airborne viable microorganisms for monitoring purposes.





3. **ISO Class 8 Staging Room (3505-8, 98 sqft):** Cleanroom materials and supplies are stored for immediate access by personnel for transfer into the pharmaceutical cleanroom. Clean air flows out of ceiling HEPA filters into low wall air returns. The floor is covered and coved with a pharmaceutical-grade, continuous vinyl flooring; the walls are built with powder-coated aluminum panels and epoxy-painted drywall; and the ceiling is composed of a grid system with vinyl-coated, waterproof, non-shedding, and cleanable tiles.



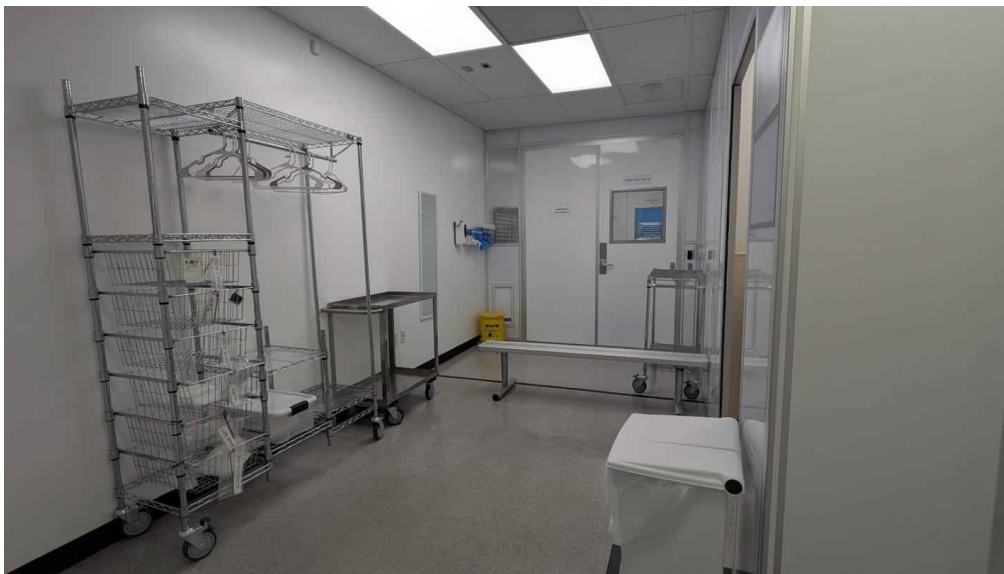
Temperature, relative humidity, and pressure differentials are monitored by the Lighthouse EMS. The contents and activities within the entire room can be visually monitored from the Control Room.





4. **ISO Class 9 Handwashing and Gowning Room (3505-9, 239 sqft):** Personnel wash their hands, change into full bunny suits, and can transfer themselves from the unclassified office areas into the cleanrooms. It is also where materials and supplies are prepped for transfer into the cleanrooms. The floor is sealed vinyl tile flooring; the walls are built with powder-coated aluminum panels and epoxy-painted drywall; and the ceiling is composed of a grid system with vinyl-coated, waterproof, non-shedding, and cleanable tiles.

Pressure differentials are monitored by the Lighthouse EMS, the temperature is controlled thermostatically, and access to the ISO 8 & ISO 7 cleanroom is controlled & monitored via the security system.





Medical Device Cleanroom (3505-8, 624 sqft): Medical device assembly and packaging is performed in this cleanroom. The temperature of the HEPA-filtered air is thermostatically controlled and composed of a combination of air recycled from ceiling air returns and fresh make-up air. The floor is sealed vinyl tile flooring; the walls are built with powder-coated aluminum panels and epoxy-painted drywall & concrete; and the ceiling is composed of a grid system with vinyl-coated, waterproof, non-shedding, and cleanable tiles.



The relative humidity and pressure differentials by the Lighthouse EMS. Also, there is a cleanroom pass-through between this medical device cleanroom and the pharmaceutical cleanroom (3503-7).



The Medical Device Cleanroom is configured with three separate work areas of different features:

- (1.) **Papa Bear:** 80sqft work bench space with a riser shelf; immediately adjacent to Belco Tray Sealer
- (2.) **Mama Bear:** 54sqft work bench space with riser shelves.
- (3.) **Baby Bear:** 44sqft work benches (without riser shelves)



Packaging Cleanroom (3505-7, 205 sqft): This cleanroom is accessible from the Medical Device Cleanroom (3505-8); it can also be configured for access directly from the Gowning and Material Transfer Room (3505-9). The floor is sealed vinyl tile flooring; the hard walls are epoxy-painted drywall and soft walls are continuous, clear vinyl sheeting; and the ceiling is composed of a grid system with vinyl-coated, waterproof, non-shedding, and cleanable tiles.

The temperature, relative humidity, and pressure differentials are monitored by the Lighthouse EMS.

SterEZ can also reconfigure the Packaging Cleanroom for use as an additional medical device cleanroom with private access from the common Gowning and Material Transfer Room.





Gowning and Material Transfer Room (3505-9, 90 sqft): The medical device (3505-8) and packaging (3505-7) cleanrooms are accessed via this room, where personnel can gown-up and sanitize their hands. The floor is sealed vinyl tile flooring; the hard walls are epoxy-painted drywall and soft walls are continuous, clear vinyl sheeting; and the ceiling is composed of a grid system with vinyl-coated,

waterproof, non-shedding, and cleanable tiles. Personnel enter and exit through sliding glass doors; materials can be rolled into and out of the space through access-controlled doors.

The pressure differentials are monitored by the Lighthouse EMS.



Comment [JZ1]:
\$30,000/month ÷ 714 sqft (624+90)
→ \$42.00/sqft-month

Comment [JZ3]:
NEED TO REVISIT PRICING -- PACKAGING CLEANROOM is WAY higher than MedDevice and even Pharma Cleanroom Suite

Comment [JZ2]:
\$25,000/month ÷ 295 sqft (205+90)
→ \$84.75/sqft-month

Comment [JZ3]:
NEED TO REVISIT PRICING -- PACKAGING CLEANROOM is WAY higher than MedDevice and even Pharma Cleanroom Suite

Comment [JZ4]:
\$60,000/month ÷ 766 sqft (429+98+239)
→ \$78.33/sqft-month