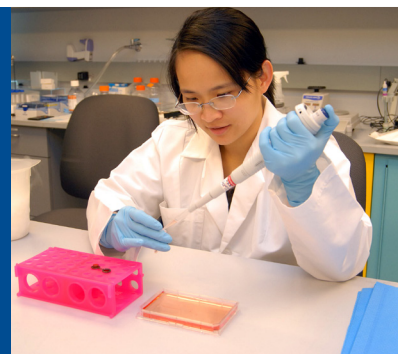


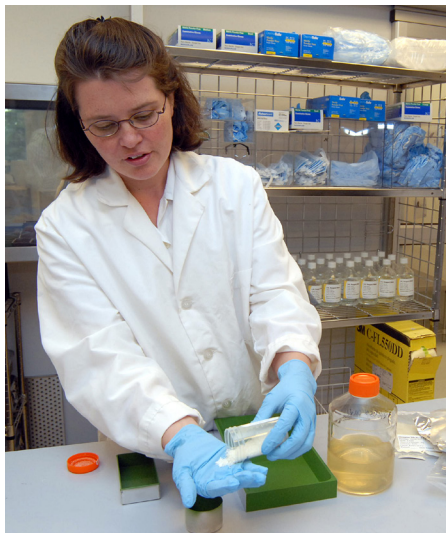
OHSU Bio-Fabrication Clean Room Facility



OHSU Bio-Fabrication and Cell Processing Facility with ISO 6 and ISO 7 Clean Rooms

Staging Room

The facility is entered through the staging room. The staging room is general laboratory space, equipped with a dishwasher, autoclave and a pass-through window to the clean rooms. It currently holds a refrigerator and an -80°C freezer. The space can serve as general laboratory workspace as well as an area to organize materials prior to their transfer into the clean rooms. The autoclave can be accessed from either the staging room or the adjacent ISO 7 clean room.



This unique clean room facility houses an ISO 6 and two ISO 7 classification clean rooms. It consists of 1800 ft² of space and offers, in addition to the three clean rooms, a staging laboratory and gowning room.

The clean room facility has a keyless infra-red security system that allows and tracks access to the facilities. Only personnel with approved clean room training can access these facilities.

Gowning Area

From the staging room, scientists enter the gowning area that leads into the clean rooms. Prior to entering the gowning area scientists put on shoe covers, a facemask, hair bonnet and gloves. They then enter the gowning area where clean room coveralls, shoe covers, and head covers are mandatory to prevent shedding of particles.



OHSU Bio-Fabrication
Clean Room Facility
9555 SW Barnes Road
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ISO 6

ISO 7

CLEAN ROOMS

The ISO 6 area (≤ 1000 particles/ft³)

This area has been used for general cell culture and tissue engineering applications research. Currently it is equipped with standard tissue culture equipment including two biological safety cabinets (6 ft. and 4 ft. laminar flow hoods) and four CO₂ incubators.



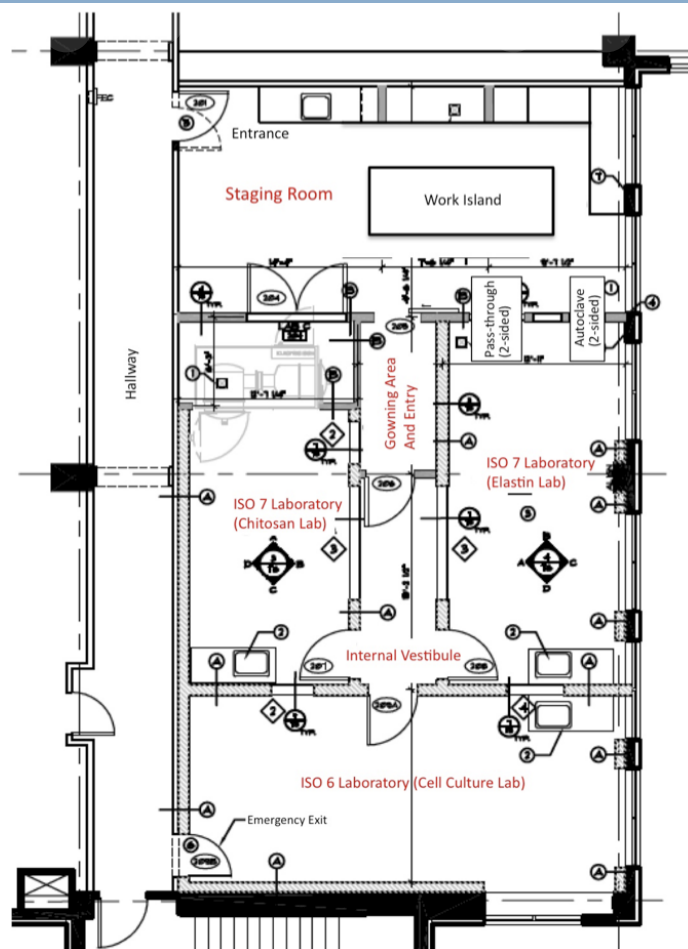
OHSU Clean Room Highlights:

- HEPA air filtration
- DI and UF water
- 2 sided autoclave
- Cell culture ready CO₂ incubators
- Chemical fume hood in each of the ISO 7 labs
- VirTis Benchmark 2000 Lyophilizer with 12 cubic foot product chamber in the chitosan lab.

Two ISO 7 areas ($\leq 10,000$ particles/ft³)

One of the two ISO 7 classification clean rooms has been used for tissue engineering projects employing recombinant elastin protein. This room is equipped with a chemical hood.

The second of the two ISO 7 classification clean rooms has been used for chitosan research. This room is equipped with a chemical hood as well as a VirTis Benchmark 2000-freeze dryer with a 12 cubic foot product chamber and data acquisition capabilities. This system is equipped with 'stopperable' shelves that allow lyophilization of proteins or other materials within sterilized vials for intravenous or intra-arterial studies.



Room particle counts are tracked for each room to maintain the facilities within specifications. Walls and floors are swabbed and cultured on a regular basis to ensure and maintain a minimal bio-burden to the bio-fabrication facility. The clean room facilities receive constant maintenance according to Federal Industry GMP and International Standard (ISO 14644-1) clean room parameters.

Please contact the Center for Regenerative Medicine for further information and opportunities regarding this Bio-Fabrication Clean Room Facility.

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