

The Fannie Angelos Cellular Therapeutics (FACT) Laboratory

General description

The Fannie Angelos Cellular Therapeutics (FACT) Laboratory is housed within the 9th floor of the Bressler Research Building located on the Baltimore campus of the University of Maryland. The facility is constructed and operated by the Marlene & Stewart Greenebaum Comprehensive Cancer Center in partnership with the University of Maryland School of Medicine. It is a self-contained cleanroom suite custom-designed and constructed using AES modular cleanroom technology and materials. The laboratory features nine (9) rooms occupying a total area of approximately 1,450 square feet (floor plan attached). Six (6) of the nine (9) rooms are maintained as an aseptic environment operating under FDA-cGMP guidelines to produce cell-based therapies in support of early phase clinical trials.

Security and Flow of Personnel, Materials and Waste

Access to the facility is controlled electronically via a HID® card key access to prevent unauthorized access to the suite. A unidirectional flow of personnel and materials is observed in the aseptic area whereby personnel enter at the ISO-8 Gown-in room (9-026) and move into the ISO-7 Prep room (9-030) where materials are prepared and staged for use in either of the two parallel ISO-7 production Cleanrooms (9-032 and 9-034) or in the ISO-7 Transfer room (9-036). Post-production steps are performed in the ISO-7 Transfer room (9-036) where products are processed for storage and distribution. Finally, the ISO-8 Gown-out room (9-040) is used for personnel de-gowning, waste disposal and exit from the facility.

Equipment by room

Prep room, 9-030:

- Reagent refrigerator
- -20 °C freezer
- waterbath

Cleanrooms, 9-032 and 9-034:

- Class 5 Biological safety cabinets
- Refrigerated centrifuges
- 2 stackable CO₂ Incubators (9-032)
- 2 stackable Trigas Incubators (9-034)
- Microscope
- undercounter refrigerators

Transfer room, 9-036:

- Biological safety cabinets
- Refrigerated centrifuge
- Cell counting equipment
- Liquid nitrogen freezer
- controlled rate freezer
- CliniMACS Prodigy® system

Cylinder Storage room (9-038)

- Carbon Dioxide (CO2) supply tanks
- Nitrogen (N2) supply tanks
- Gas supply manifolds
- portable Liquid Nitrogen (LN2) supply tank

Administrative Room (9-042)

- Supplemental HVAC equipment used to support temperature control for the Facility
- Desigo Facility Monitoring System
- Storage

Storage closet (9-028) with pass-thru for supply storage and supply staging.

Construction

The facility is constructed using the AES Clean Technology modular framework. All surfaces are selected for cleanability. All walls, ceilings, and doors of the facility are prefabricated from the AES Production Facility. Ceilings are vinyl faced and sealed cleanroom grade tiles set in a gasketed grid system. Walls are unplasticized PVC (UPVC) coated with welded UPVC joints. Flooring in the facility is poured epoxy with a continuous cove at wall junctions. Interior doors of the facility are UPVC coated for full cleanability, whereas, facility exterior doors leading into the building corridor are painted steel.

A door interlock system has been installed to prevent multiple doors of the classified area boundary to be opened simultaneously.

Heating, Ventilation and Air Conditioning (HVAC) and Building Automation Systems (BAS)

The HVAC system serving the FACT GMP lab utilizes a pressure cascade design to maintain differential pressure based on ISO classification. Classified areas will utilize HEPA filtration on the supply air that is certified to the corresponding ISO classifications. The system leverages existing House Air provided by two air handling units, AHU-4 and AHU-5, from the 9th floor riser with a supplemental heating and cooling units to achieve temperature requirements. House Air is humidified by two (2) electrode steam humidifiers with two (2) duct mounted steam distributors to achieve relative humidity requirements.

The Building Automation System (BAS) is an integrated system that incorporates direct digital control (DDC) for energy management, HVAC equipment monitoring, and control. The control system is an extension of the existing Siemens BAS system used within the building. In addition to full integration with the building BAS, remote access to the BAS is available for remote monitoring.

