Summary of capabilities

San Francisco, CA, USA

Cell therapy development and manufacturing facility

Overview:

Located adjacent to numerous oncology hospitals in the Bay Area and approximately 15 minutes from the SFO international airport, this 44,000 sq ft, state-of-the-art facility provides full-service cell therapy process and analytical development capabilities and clinical and commercial cGMP manufacturing services for autologous and allogeneic cell therapies.

Facility facts	
Regulatory approval:	In progress (GMP ready)
Capacity:	6 x ISO 7 pods (~10,000 sq ft GMP warehouse and suites with expansion potential based on client need)
Classification:	ISO 7 (grade B) clean rooms, ISO 8 corridors (grade C), BSL-2 compliant with ISO 5 grade A BSCs
Workforce:	30+ employees
Contact info:	777 Mariposa St, San Francisco, CA Telephone: 415-276-6000 pharmaservices@thermofisher.com
Capabilities:	• Experience in a variety of modalities including viral and non-viral modified gene delivery systems and numerous cell types (T-cells, NK cells, iPSCs, MSCs, and more). • Cell isolation, modification, expansion, fill-finish, and cryopreservation. • AD/PD lab for process optimization, verification, and confirmation, as well as method development/qualification and assay optimization. • QC lab to support in-process, safety, and final product testing. • Individual, user-configurable production suites with self-contained HVAC and related infrastructure. • Collaboration center to provide non-GMP space for training scientists and operators both for tech transfer and process development. • Support for phase 1 through commercial manufacturing. • Potential to expand based on customer need.

Summary of capabilities

Detailed capabilities overview

Process and analytical development

- Methodical approach for process optimization, verification, and confirmation
- Expertise in closing and automating processes
- Transfer of manufacturing workflow to GMP suites

QC and analytical testing

- Starting, in-process, and final product monitoring and sampling
- Assays compliant with industry standards
- Assay development, validation, and qualification to accurately characterize your product

cGMP manufacturing

- Comprehensive capabilities that span cell manufacturing, harvest, formulation, final fill, and cryopreservation
- Expertise in closed automated platforms and a variety of therapeutic strategies and cell types
- Individual, user-configurable cGMP production suites with self-contained HVAC and related infrastructure to protect against cross-contamination

San Francisco key equipment list*

Workflow step	Equipment type
Receipt of apheresis and cell isolation	Thawing and isolation systems
Cell selection and activation	Selection and activation devices
Gene modification	Viral and non-viral (electroporation or others)
Cell expansion	Cell culture and expansion equipment (small and large scale)
Bead removal	Bead removal devices
Cell wash	Wash and concentration systems
Final product formulation and cryopreservation (vials and bag format)	Controlled rate freezer, automated vial and bag fillers

*Facility includes best-in-class equipment, reagents, and protocols from Thermo Fisher Scientific and other leading suppliers (Miltinyi, Cytiva, etc.). Flexibility to bring in specific equipment to support unique customer processes upon request.

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For detailed capabilities and capacity information please contact your Thermo Fisher Scientific representative.

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