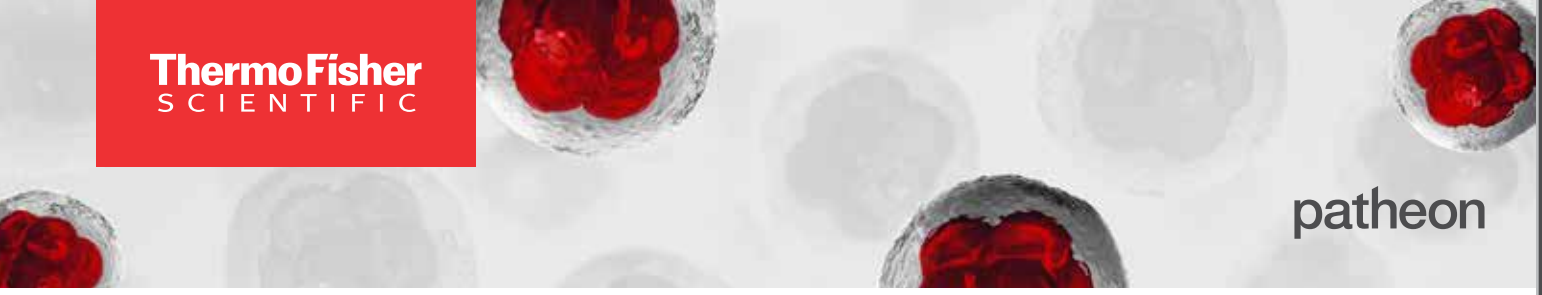

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SUMMARY OF CAPABILITIES FACT SHEET

cGMP cell therapy manufacturing services

Combining technical expertise with agile execution to address your unique project needs

While cell therapies offer an exciting new treatment paradigm for patients, there are many complex factors that may limit their commercial success, including analytics, scalability, regulatory hurdles, and more. At Thermo Fisher Scientific, we recognize the importance of an individualized approach to your development and manufacturing strategy to help navigate these challenges together.

We provide a foundation of support systems and technical expertise in a variety of modalities, including autologous and allogeneic therapies leveraging both modified (viral or nonviral) and non-modified manufacturing processes for immune (T, NK) and stem (iPSC, MSC, and HSC) cells. Our approach to manufacturing readiness balances the need for speed with an unwavering focus on quality, while individual, user-configurable suites ensure long-term scalability as you move toward commercialization. Key elements of our cell therapy service include:

Process development	• 1,400 sq. ft. analytical and process development lab • Methodical approach for process optimization, verification, and confirmation • Expertise in closing and automating processes • Transfer of manufacturing workflow to GMP suites
QC and analytical	• 1,800 sq. ft. QC, micro, and chemistry lab • 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	• 10,000 sq. ft. manufacturing and warehouse space with capacity to expand • 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 • Self-contained HVAC and related infrastructure to protect against cross-contamination

Why Thermo Fisher for cell therapy services?

Technical expertise
Flexible and broad expertise in a variety of existing systems and cell types including both autologous and allogeneic therapies

Manufacturing readiness
Incorporates process and analytical development, raw material management, and cGMP manufacturing

Quality
Robust global quality systems with experiences in novel product approval and commercialization

Integrated services
Combine early translational services, plasmid and viral vector manufacturing, regulatory, and cold chain logistics

Integrated solutions save time and effort on your path to commercialization

Our end-to-end solutions span early translational services all the way to storage and cold chain logistics, helping to reduce complexity and risk in your value chain. In addition to our comprehensive CDMO services, we offer the unique opportunity to leverage resources and expertise across the broader Thermo Fisher network, from industry-leading laboratory products and analytical instrumentation to large-scale bioprocessing equipment.

Process development and optimization, scale-up to cGMP for clinical and commercial manufacturing

Translational services

Scaled-down, established GMP processes to generate proof-of-concept data and de-risk the drug development process

Plasmid DNA

Starting material for viral vector manufacturing, nanoplasmid manufacturing, plasmid as a drug substance, and linearized plasmid DNA for mRNA synthesis

Viral vectors

Viral vector production including AAV, adenovirus, lentivirus, HSV, and retrovirus using a variety of manufacturing platforms

mRNA

Flexible service offering covers linearization, mRNA synthesis, post-IVT modification, encapsulation, and fill-finish

Cell therapy

Autologous and allogeneic therapies leveraging both modified (viral or nonviral) and non-modified manufacturing processes for immune (T, NK) and stem (iPSC, MSC, and HSC) cells

Clinical supply services

- Specimen collection, cold-chain logistics and cryogenic storage
- Clinical packaging, labeling, and distribution
- Qualified shipping solutions and specialty courier services

Contact your local Thermo Fisher Scientific representative to learn more.

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Published 03/23

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