

# Cell therapy development and 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, etc. 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 non-viral) and non-modified manufacturing processes for numerous cell types (T-cells, NK cells, iPSCs, MSCs, APCs, hESCs, blood and bone marrow-derived stem cells, and more). 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:

<p><b>Process development</b></p>	<ul style="list-style-type: none"> <li>• 1,400 sq. ft. analytical and process development lab</li> <li>• Methodical approach for process optimization, verification, and confirmation</li> <li>• Assessment for opportunity to automate or close existing processes</li> <li>• Transfer of manufacturing workflow to GMP suites</li> </ul>
<p><b>QC and analytical</b></p>	<ul style="list-style-type: none"> <li>• 1,800 sq. ft. QC, micro, and chemistry lab</li> <li>• Assay development, validation, and qualification to accurately characterize your product</li> <li>• Starting, in-process, and final product monitoring and sampling</li> <li>• Assays compliant with industry standards and regulatory guidelines</li> </ul>
<p><b>cGMP manufacturing</b></p>	<ul style="list-style-type: none"> <li>• 10,000 sq. ft. manufacturing and warehouse space with capacity to expand</li> <li>• Comprehensive capabilities span cell manufacturing, harvest, formulation, final fill, and cryopreservation</li> <li>• Expertise in closed automated platforms and a variety of therapeutic strategies and cell types</li> <li>• Individual, user-configurable cGMP production suites with self-contained HVAC and related infrastructure to protect against cross-contamination</li> </ul>

## 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



### Technology innovation

Leverage industry-leading technologies to optimize your workflow, minimize COGs, and get to market faster



### Scientific collaboration

Personalized approach to partnership can include use of optimized in-house processes or development of unique solution based on need








### Integrated services

Option to combine with early translational services, 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.

				
Translational services	Viral vector development and manufacturing	Cell therapy development and manufacturing	mRNA development and manufacturing	Clinical supply services
<ul style="list-style-type: none"> <li>• Scaled-down processes, qualifiable assays, high-quality materials</li> <li>• Viral vectors</li> <li>• Cell therapy</li> <li>• Molecular biology</li> <li>• Analytics</li> </ul>	<ul style="list-style-type: none"> <li>• Adherent and suspension modalities</li> <li>• Small- to large-scale manufacturing</li> <li>• AAV, LV, AdV, RV, MVA, VSV, and other viral vectors</li> <li>• Virus-like particles</li> </ul>	<ul style="list-style-type: none"> <li>• Autologous and allogeneic</li> <li>• Viral and non-viral modified gene delivery systems</li> <li>• T-cells, NK cells, iPSCs, MSCs, APCs, hESCs, and more</li> </ul>	<ul style="list-style-type: none"> <li>• Linearization</li> <li>• mRNA synthesis</li> <li>• Post-IVT modification</li> <li>• Encapsulation</li> <li>• Sterile fill-finish</li> </ul>	<ul style="list-style-type: none"> <li>• Specimen collection, cold chain logistics, and cryogenic storage</li> <li>• Clinical and commercial packaging, labeling, and distribution</li> <li>• Qualified shipping solutions and specialty courier services</li> </ul>

**Contact us to learn more or visit [patheon.com/celltherapyservices](https://patheon.com/celltherapyservices)**