

Viral vector development and manufacturing services

20+ years of unparalleled experience in developing and manufacturing viral vector products

Viral vector production for cell and gene therapies requires complex processes, which can result in various challenges throughout the product's lifecycle. The main challenges revolve around selecting an ideal production system, optimizing product quality, and building standardization to enable a robust CMC approach.

Thermo Fisher Scientific is a leading CDMO, providing a full range of services for developing, manufacturing, and commercializing viral vectors and cell- and gene-therapy-based vaccines. Our end-to-end viral vector capabilities include process and analytical development, process characterization and validation, clinical and commercial manufacturing, in-process and release testing, and fill-finish services.

With an extensive network of production sites, global clinical supply chain capabilities, and in-depth viral vector technical and regulatory expertise, we help to de-risk and expedite your therapy's path to market.

Bioprocess sciences

- Labs in the United States and Europe
- Full process development, process transfer, and scale-up
- Customized optimization based on product quality requirements
- FMEA and process characterization
- Scale-down model qualification
- Satellite campaign batches
- Pilot and preclinical batches

Analytics and quality control (QC)

- Platform methods, full development, tech transfer
- Process development and preclinical
- QC analytical capabilities across network
- Qualification and validation for clinical and commercial
- In-process, release, and stability testing
- Reference standard qualification
- Assay bridging and comparability studies

CGMP manufacturing

- Clinical, PPQ, and commercial
- Adherent and suspension modalities
- Automated DP fill-finish across the network
- Primary drug product packaging and labeling
- Drug substance and/or drug product manufacturing
- Cell and viral banking
- Engineering batches
- Validation support studies

Why Thermo Fisher Scientific for viral vector services?



Experience

- 20+ years of CGMP experience
- 200+ viral vector products manufactured over time
- 900+ viral vector GMP lots manufactured over time
- 3 commercially approved products and several others pending



Capacity

- More than 400,000 square feet
- 38 drug substance suites
- 6 drug product suites
- 3 late-phase/commercial manufacturing facilities



Capabilities

- Full-service viral vector CDMO
- Experience with 12+ AAV serotypes
- 10 manufacturing modalities
- Leverage Thermo Fisher's technology, cell lines, equipment, products, and logistics
- Access to a breadth of integrated services

Save time and effort on your path to commercialization

Our end-to-end, integrated solutions span early translational services all the way to storage and cold chain logistics, helping to reduce complexity and risk in your value chain.

Beyond our comprehensive CDMO services, we also offer the unique opportunity to leverage resources and expertise across the broader Thermo Fisher Scientific 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
• Scaled-down processes, qualifiable assays, high-quality materials • Viral vectors • Cell therapy • Molecular biology • Analytics	• Adherent and suspension modalities • Small- to large-scale manufacturing • AAV, LV, AdV, RV, MVA, VSV, and other viral vectors • Virus-like particles	• Autologous and allogeneic • Viral and non-viral modified gene delivery systems • T-cells, NK cells, iPSCs, MSCs, APCs, hESCs, and more	• Linearization • mRNA synthesis • Post-IVT modification • Encapsulation • Sterile fill-finish	• Specimen collection, cold chain logistics, and cryogenic storage • Clinical and commercial packaging, labeling, and distribution • Qualified shipping solutions and specialty courier services

Learn more at patheon.com/VVS