Viral vector development and manufacturing services

patheon

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 that provides 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 can help de-risk and expedite your therapy's path to market.

Bioprocess sciences	– Labs in US (PLA) and EU (GOS) – Full process development – Customized optimization based on product quality requirements – Process transfer and scale-up – 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

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Why Thermo Fisher Scientific for viral vector services?

Experience and expertise in gene therapy

- 20+ years of expertise in viral vectors, cGMP track record
- Four late-phase/commercial manufacturing facilities
- More than 50 drug substance suites and 12 drug product suites
- Experience with AAV (natural and novel serotypes), LV, adenoviral, herpesvirus, and retroviral vectors, and viral vaccines

Strong foundation of proven success

- Two commercially licensed products
- Multiple regulatory filings in the pipeline
- More than 700 viral vector cGMP clinical and commercial lots manufactured
- More than 160 viral vector products produced
- Expansive global network offering 555,000 sq. ft. capacity

Accelerated product access to patients

- 2,000 team members worldwide, including 200 PhD-level scientists
- Leading viral vector services team of regulatory experts
- Proven technology, cell lines, equipment, products, and logistics
- Access to a range of advanced therapy CDMO services and a global supply chain network

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

- Scaled-down processes, qualifiable assays, high-quality materials
- Viral vectors
- Cell therapy
- Molecular biology
- Analytics

Viral vector development and manufacturing

- Adherent and suspension modalities
- Small- to large-scale manufacturing
- AAV, LV, AdV, RV, MVA, VSV, and other viral vectors
- Virus-like particles

Cell therapy development and manufacturing

- Autologous and allogeneic
- Viral and non-viral modified gene delivery systems
- T-cells, NK cells, iPSCs, MSCs, APCs, hESCs, and more

mRNA development and manufacturing

- Linearization
- mRNA synthesis
- Post-IVT modification
- Encapsulation
- Sterile fill-finish

Clinical supply services

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

Contact us to learn more or visit patheon.com/vvs

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