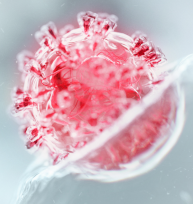
De-risk your therapy development and advance to the clinic more quickly

Patheon Quick to Clinic viral vector services



Moving gene therapies from preclinical studies to clinical and commercial manufacturing is a complex journey that requires significant financial investment — and is filled with risks and challenges.

Thermo Fisher Scientific offers a high-performance, scalable, end-to-end manufacturing service for adeno-associated viral (AAV) and lentiviral (LV) vectors. This service enables you to deliver your gene therapy to the clinic by de-risking timelines and global regulatory filings without surprising out-of-pocket costs.

End-to-end, flexible viral vector manufacturing services

Accelerated timeline

- Raw materials fully released with licenses secured
- Prequalified analytics
- Streamlined batch release
- Supported by a large network of Thermo Fisher Scientific gene therapy products

Global regulatory filing

- Industry expertise in regulatory CMC management and compliance
- Phase-appropriate regulatory support included
- Drug master file (DMF)

Cost-effective and transparent price

- Transparent, single-price structure supports payment plans, alleviating financial risks and potential additional out-of-pocket costs
- All-inclusive up-front price that includes pass-through costs (raw materials), licenses*, cell banking, analytical testing, etc.
- No additional drug substance process development and release testing costs**

* May require additional licensing for proprietary AAV serotype
** Standard Patheon™ Quick to Clinic™ process with the flexibility to add plasmid manufacturing, DP fill and release testing and additional testing for a fee

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Thermo Fisher Scientific viral vector services

Experience and expertise in gene therapy

- 20+ years 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, retroviral vectors, and viral vaccines

Strong foundation of proven success

- Two commercial licensed products
- Multiple regulatory fillings in the pipeline
- More than 700 VV cGMP clinical and commercial lots manufactured
- More than 160 VV products produced
- Expansive global network offering 555,000 sq ft capacity available

Accelerated product access to patients

- 2,000 team members worldwide with 200 PhD-level scientists
- Leading VVS regulatory expert team
- Leverage Thermo Fisher Scientific's technology, cell lines, equipment, products, and logistics
- Access to a range of advanced therapy CDMO services and a global supply chain network

De-risk and accelerate your path to clinic and beyond with Patheon Quick to Clinic viral vector services. Contact us or visit patheon.com/vvs to learn more.

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