Start conducting your toxicology studies in as little as six months

Direct-to-toxicology viral vector services

Toxicology studies are crucial for supporting pre-IND regulatory requirements and evaluating the risk-benefit ratio of potential drug candidates. However, acquiring high-quality toxicology materials can often stretch timelines, causing delays in drug development. Additionally, the lack of compatibility between toxicology materials generation processes and current good manufacturing practice (cGMP) regulations can impede smooth transitions, requiring the development of new processes or even repeat studies that use materials better suited for future clinical manufacturing.

To address these challenges and more, Thermo Fisher Scientific provides an expedited route to toxicology materials through our adeno-associated virus (AAV) and and lentivirus (LV) production processes, completing them in as little as six months. By leveraging our industry-leading expertise, we produce robust toxicology materials that support regulatory guidelines and align with your project's timeline. Our primary objective is to ensure reliability, validity, and consistent data generation, while also ensuring compatibility with future manufacturing processes.

Expedite your path to toxicology studies with more immediate access to toxicology materials.

Accelerated timeline

- From gene of interest to toxicology materials in as little as six months
- Established and tested vector production processes, reducing risk
- Off-the-shelf or standardized raw materials
- Dedicated program manager throughout the full process

Process flexibility

- Leverages extensive viral vector development expertise to support multiple process paths and accommodate unique circumstances
- Includes all required testing

Scalability

- Toxicology material processes compatible with clinical manufacturing
- Industry expertise in scaling up from pre clinical to clinical and commerical viral vector manufacturing

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Why Thermo Fisher Scientific viral vector services?

Experience and expertise in gene therapy

- 20+ years of expertise in viral vector cGMP
- 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 vector, 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 VV products produced
- Expansive global network offering 650,000 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 Thermo Fisher Scientific technology, cell lines, equipment, products, and logistics
- Access to a range of advanced therapy CDMO services and a global supply chain network

Accelerate your path to toxicology studies with Patheon™ direct-to-toxicology viral vector services. Contact us or visit patheon.com/viralvector-services to learn more.

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