eurofins | BioPharma Product Testing

Viral Clearance Studies

Eurofins BioPharma Product Testing offers comprehensive testing capabilities to ensure our clients' drug products are supported throughout the development process to commercial release. Our Viral Clearance Services team provides fully cGMP-compliant services from research and development assessments through manufacturing, clinical trials, and filing for Biological License Application (BLA). Our staff is experienced with varied perspectives from the research, process development, and manufacturing sectors. This broad background as well as specialized, hands-on experience with execution and compliance to regulatory expectations (e.g. ICH, FDA, and EMA) allows us to assist in the designing, performance, and reporting of viral clearance studies.

Why Choose Eurofins BioPharma Product Testing?

We bring together leading experts in the industry with extensive scientific and regulatory experience.

By supporting you from study planning through postfiling and working at your site, we can optimize your viral clearance study.

Our hands on approach to study management provides you with the attention, and close communication, needed for the success of your viral clearance study through setting achievable timelines and clear and consistent expectations.

What to Consider When Planning a Viral Clearance (VC) Study

- Have you validated your scaled-down method? Your scaled-down process should be representative of the manufacturing process. Choosing which process steps to claim for viral clearance is also crucial – orthogonal methods of removal and/or inactivation are required.
- What is your Log Reduction Value (LRV) target? Knowing your ideal LRV target will determine which steps should be tested and what methods Eurofins uses for sampling and assaying.
- What is your timeframe to receive results? Material availability, preferred service model, and any relevant filing dates will be considered when scheduling your study. Extensive pre-study planning and proactive communication is key to ensure turnaround times can be met. Eurofins VC recommends that clients contact us to plan their studies at least six months ahead of the time results are needed.

What Eurofins BPT Can Offer

Our Lancaster, PA site is capable of supporting both R&D and cGMP work and is equipped with four separate suites dedicated to the execution of viral clearance studies to ensure privacy and confidentiality. Full offerings include:

- Negative-pressure, HEPA-filtered lab suites including an anteroom and private office for client's use.

- GE ÄKTA chromatography units (Pure 25 and Avant 150 models available).
- Biological Safety Cabinets equipped with vacuum line.
- Fully equipped BSL-2 laboratory space with staff trained to handle viruses and cell culture.
- Balances, conductivity and pH meters, UV/Vis spectrophotometers, plus other basic lab equipment.
- Validated, real-time infectivity result assessments on 6-well plate with options for a large volume method for retroviral testing, as well as validated qPCR detection methods.
- Characterized viral stocks with validated titers of ≥10^7 PFU/mL to support animal and human-derived products, including highly purified stocks ideal for viral filtration needs.

Viral Clearance Models

To best meet all client needs, Eurofins BPT offers two models of service:

- Traditional Service Model grants clients access to the above-mentioned suites and use of the ÄKTA systems for performance of purification steps by their staff. In addition to spiking, sampling, and end point testing procedures, Eurofins personnel can perform inactivation and filtration steps, or also host outside filtration vendors.
- Full Service Model entails Eurofins performing all process steps including technology transfer on the scaled-down process and purification steps. Eurofins will provide tailored batch record documentation developed in collaboration with the client for all processes. The client will provide all necessary process materials and scaled-down procedures.

Both service models deliver Certificates of Analysis for each process step performed, as well as a summary report. Regulatory support through post-study applications is available.

Benefits of collaborating with Eurofins Viral Clearance Services

- Support to optimize the viral clearance process through the study planning progression from staff with extensive scientific backgrounds in both performance and regulatory compliance.
- Regular communication updates on study progress to ensure conformity to the specifics of your processes while establishing an achievable timeline for report release.
- Supporting network within Eurofins BPT to facilitate all testing procedures with in-house availability.
- Proven track record conducting studies and reporting results to support IND (Investigational New Drug) and BLA filings.

The Viral Clearance team as part of Eurofins BPT continues to strengthen our experience and service offering to insure support of our clients across biopharma. We are excited to work with companies and individuals across the industry. Contact a member of our Business Development team today to schedule a consultation and start your study.

Contact Us

North America: BioPharmaProductTesting@BPT.EurofinsUS.com
Europe: Information@BPT.EurofinsEU.com
APAC: easl.cserv@BPJP.EurofinsAsia.com
www.Eurofins.com/BPT