charles river

BIOLOGICS TESTING SOLUTIONS

Viral Clearance and TSE Clearance Studies

Study Design and Support

- Selection of process steps
- Verification of scaled-down process steps
- Design of clearance studies relevant to the lifecycle of the product
- Selection of viruses and TSE spikes
- Performance of study
- Interpretation of results
- Regulatory guidance

Charles River scientists have more than 20 years of experience in the design and performance of viral and transmissible spongiform encephalopathy (TSE) agent clearance studies. With laboratories in Europe and the US, we have the technical and regulatory expertise to ensure studies comply with the relevant guidelines in a client's target market (e.g., EU, US, Japan, and WHO, including ICH Q5A). Intelligent, tailored study designs and robust, timely reporting create successful, cost-effective programs that meet the unique needs of each biopharmaceutical product. We have worked with a range of products, including monoclonal antibodies (mAbs), recombinant proteins, transgenic products, tissue- and blood-derived products, vaccines and medical devices. In addition, our team offers virus cleaning validation.

ClearancePlus℠ Platform

A critical part of the biologic manufacturing process is demonstrating that the process appropriately removes or inactivates any known and potentially unknown contaminants. Manufacturers of biopharmaceutical products or auxiliary material derived from animal or human tissues, such as blood products, recombinant proteins, vaccines, hormones, polyclonal antibodies, enzymes and even some medical devices containing animal or human blood-derived components, are required to demonstrate the ability of their purification and manufacturing processes to inactivate or remove viruses and, for some products, TSE agents. A database of more than 2,500 studies performed for clients guides our ability to develop, execute and evaluate the viral/TSE clearance studies that best meet our clients' needs. From downscale assistance to report generation, we promise a successful study design and execution and a report that will support their regulatory submission without delays in approvals.

Our ClearancePlus℠ platform integrates:

Risk-based assessments – Comprehensive review of a client's viral safety testing program, production processes and raw material quality in order to minimize required viral clearance and ensure an economic study design

Holistic study design – Review of required pretesting, virus spikes, sampling modes, detection methods and assay sensitivities to define the most effective virus clearance study approach

EVERY STEP OF THE WAY

Capabilities/Technology

- Study design optimization
- Charles River staff able to perform all process steps
- Results interpretation and troubleshooting
- Fully qualified and validated ÄKTA chromatography systems
- Human and animal viruses available as high-titer stocks
- Infectivity assays (TCID50 and plaque assay) performed in real time
- PCR assays
- Supporting microbiology and molecular and cellular biology services

Optimized sensitivity – Standard inclusion of large volume plating for all product-relevant samples to improve LRV claims and demonstrate effective and robust virus reduction

Regulatory expertise – Alignment of study design and reporting with the development stage of the product and compliance with national and global regulations outlined in US FDA, EMA, ICH and other country-specific regulatory documents

Customized service – Extensive experience with multiple product types and purification steps, allowing us to provide support and advice tailored to each product and its requirements, including downscale assistance, execution of process steps and interpretation and troubleshooting of results

Industry leadership – Application of best practices as determined by performance of internal studies and as presented in multiple viral safety conferences, symposia, publications and technical reports in order to define the most scientifically sound study design

Facilities

Charles River has viral clearance facilities in the United States and Europe. Procedures at both sites have been harmonized to allow for easy transfer and performance of studies for our global client base. Each facility offers dedicated client labs and private client offices to support maximal productivity during on-site visits. Available at the sites is an assortment of fully qualified and validated ÄKTAexplorer/purifier/pure/avant chromatography systems.

Support Services

Charles River provides a host of supplemental services to support clients throughout the planning and execution of a successful viral clearance program. Charles River scientists are skilled in all process steps, including chromatography, and there is the option for these scientists to perform process steps without the client needing to be onsite. Our regulatory consultants can help to ensure programs meet US, EU, Japanese and other global requirements, and will even accompany clients to agency visits and/or be present during agency audits. We can also provide Expert statements, virus risk assessment, and on-site client seminars and training. We focus on partnership, going above and beyond our clients' expectations of quality. Comprehensive and flexible reporting, the my**charlesriver**SM secure online client data portal, and a dedicated project manager all contribute to our goals to establish clear, consistent communication and deliver projects on time.

charles river

askcharlesriver@criver.com • www.criver.com

© 2016, Charles River Laboratories International, Inc.