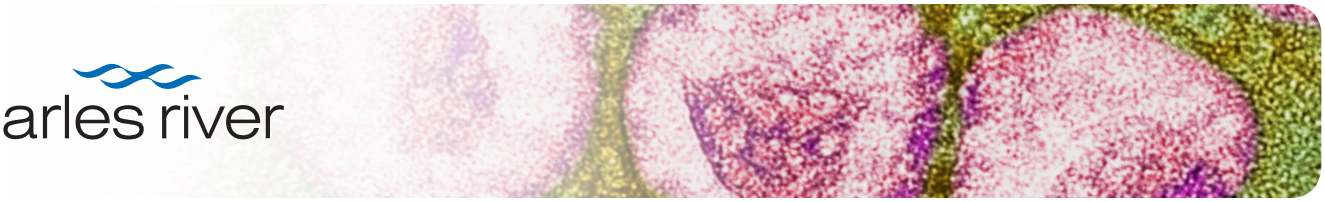
charles river



Viral Clearance Studies

At Charles River, we have expert scientists in both the United States and Europe with more than 20 years of experience in supporting clients throughout the design and performance of viral and transmissible spongiform encephalopathy (TSE) agent clearance studies. Using a customized approach, we are able to provide technical advice and regulatory support to ensure that a successful and cost-effective program is established and reports are generated to meet your deadlines. All viral clearance studies are performed according to ICH Q5A and other European, US, Japanese and WHO regulatory guidelines.

Scope and Design of a Viral Clearance Study

A critical part of the biologic manufacturing process is demonstrating that the process appropriately removes or inactivates any known contaminants. Manufacturers of biopharmaceutical products derived from animal or human tissues, such as blood products, recombinant proteins, vaccines and even some medical devices, are required to assess the ability of their purification and manufacturing processes to inactivate or remove viruses and, for some products, transmissible spongiform encephalopathy (TSE) agents. With a database of over 2,000 studies, Charles River is able to assist clients in developing, executing and evaluating viral clearance studies in the following ways:

- Assistance in the selection of the process steps evaluated
- Verification of the scaled-down process steps
- Selection of viruses or TSE spike solutions
- Determination of test article cytotoxicity (virus) and interference (virus/TSE)
- Performance of the process steps in the presence of virus/TSE spike
- Evaluation of the virus/TSE removal and inactivation

Study Design

- Selection of process steps
- Verification of scaled-down process steps
- Design of viral clearance studies relevant to the lifecycle of the product
- Selection of viruses/TSE spike
- Performance of study
- Interpretation of results
- Regulatory guidance throughout the project and provision of expert statements

Product Experience

- Monoclonal antibodies (mAbs)
- Recombinant proteins
- Transgenic products
- Tissue-derived products
- Blood-derived products
- Medical devices
- Vaccines
- Virus cleaning validation

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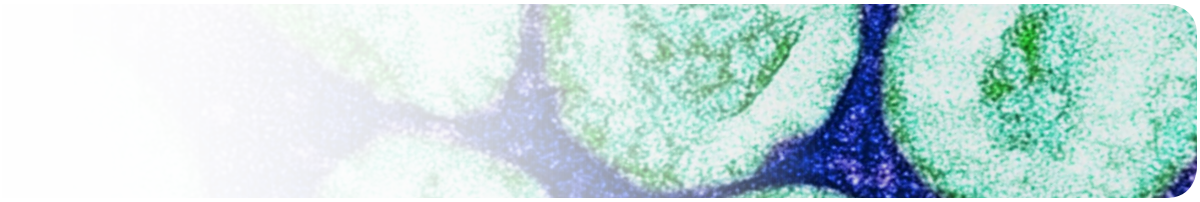

Capabilities and Support Services

Charles River has two new purpose-built facilities for viral clearance studies: one in the United States and one in Europe. The procedures at these sites have been harmonized to allow for easy transfer and performance of studies for our global client base.

Capabilities/Technology

- Optimization of study design
- Option for Charles River staff to perform all process steps (including chromatography steps)
- Interpretation of results and help with troubleshooting
- Fully qualified ÄKTAexplorer/purifier chromatography systems
- Human and animal viruses available as high-titer stocks
- Infectivity assays (TCID50 and plaque assay) performed in real time
- Large-volume assay format available to improve LRV claims
- qPCR assays available
- Supporting microbiology and molecular and cellular biology services

Support Services

- Regulatory consultants in study planning (Europe, US, Japan)
- Expert statements/support in virus risk assessment
- Accompaniment of clients to agency visits (at the agency or during audits)
- Comprehensive and flexible reporting
- Seminars and training at client sites
- Specific arrangements for long-term agreements
- my**Biologics**℠ client portal — Sharepoint® support for document exchange and communication
- Dedicated project management to ensure smooth communication and on-time delivery of projects

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