



FACILITY OVERVIEW

King of Prussia, Pennsylvania

Under the direction of knowledgeable study directors, our viral clearance facility in King of Prussia, PA offers comprehensive viral clearance services and an extensive reference database of more than 2,500 studies.

Background

- Established as Tektagen in 1998
- New location and expanded capacity opened in 2013
- Harmonized procedures with our Cologne, Germany viral clearance site

Laboratories and Facilities

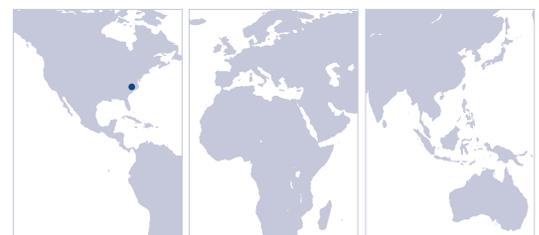
- 24,000 square feet/2,230 square meters
- Biosafety Level 2
- Extensive site security, confidentiality and safety measures
- Dedicated client labs and assigned guest offices
- Document control and archive capacity
- State-of-the-art laboratories equipped with:
 - DI water, CO and N gas, and pressurized air
 - Fully qualified ÄKTA Avant, Explorer, and Purifier chromatography systems
- Dedicated cell culture suite for readily available cell culture stocks
- Dedicated virus production suite

Staff

- Approximately 25 employees

Service Areas/Study Types

- Regulatory consultation for study planning (Europe, US and Japan)
- Selection of process steps
- Selection of high-titer viruses
- Optimization of the design of viral clearance studies
- Performance and support of the down-scaling of manufacturing process steps
- Performance of all process steps (including chromatography)
- Interpretation of results and support with troubleshooting (extensive database of over 2,500 studies)
- Preparation of Expert statements and consultations regarding virus risk assessment
- Accompaniment for agency visits (at the agency or during audits)
- Client Services
 - Comprehensive and flexible reporting
 - Seminars and training at client sites
 - Specific arrangements for long-term agreements
 - myCharlesRiverSM client portal — Sharepoint[®] support for document exchange and communication
 - Dedicated project management to ensure smooth communications and on-time delivery of projects



EVERY STEP OF THE WAY

Service Areas/Study Types (Continued)

- Product Experience
 - Monoclonal antibodies (mAbs)
 - Recombinant proteins
 - Transgenic products
 - Tissue-derived products
 - Blood- and plasma-derived products
 - Vaccines
 - Medical devices

Compliance, Certifications, Accreditations and Professional Affiliations

Charles River's King of Prussia, PA facility operates in compliance with the requirements of the following regulatory agencies or accredited organizations:

- Organisation for Economic Co-operation and Development (OECD) principles, as applicable
- Code of Federal Regulations (CFR) 21 Part 58, as applicable
- U.S. Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- International Conference on Harmonisation (ICH)
- Japanese Ministry of Health, Labour and Welfare (MHLW)
- Korean Food and Drug Administration (KFDA)

Quality and Process Initiatives

- Lean Six Sigma program