charles river

FACILITY OVERVIEW

Cologne, Germany

Our facility, located in Cologne, Germany, offers comprehensive services and support for virus and TSE clearance studies, from study design, process scale-down and execution to generation of reports that meet regulatory expectations.

Background

- Founded in 1994 as Analysis GmbH in Frankfurt, Germany
- Relocated to Cologne, Germany, in 2000
- Acquired by NewLab BioQuality in 2005
- Acquired by Charles River in 2008
- New purpose-built facility opened in 2010
- Lab expansion in 2016
- Harmonized procedures with our King of Prussia, PA, viral clearance site

Laboratories and Facilities

- 2,375 square meters/25,600 square feet, including over 900-square-meter/9,700-square-foot laboratory
- Biosafety Level 2 and Biosafety Level 3** (HIV and prion)
- On-site IT support for client personnel
- Extensive site security, confidentiality and safety measures
- Dedicated client labs and assigned guest offices
- Good Laboratory Practice (GLP)-compliant archive
- State-of-the-art, temperature-monitored laboratories equipped with:
  - DI water, CO and N gas, and pressurized air
  - Fully qualified and validated ÄKTA Explorer and ÄKTA Pure systems
- Dedicated cell culture suite for readily available cell culture stocks

Staff

- Approximately 55 employees, more than 40% with advanced degrees (MSc, PhD)

Service Areas/Study Types

- Regulatory consultation for study planning (Europe, US, Japan)
- Selection of process steps
- Selection of high-titer viruses and TSE agents
- 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)

EVERY STEP OF THE WAY

Service Areas/Study Types (Continued)

- Client Services
  - Comprehensive and flexible reporting
  - Seminars and training at client sites
  - Specific arrangements for long-term agreements
  - myCharlesRiver℠ client portal – Sharepoint® support for document exchange and communication
  - Dedicated project management and study directors to ensure smooth communications and on-time delivery of projects
- Product Experience
  - Monoclonal antibodies
  - Recombinant proteins
  - Transgenic products
  - Tissue-derived products
  - Blood- and plasma-derived products
  - Vaccines
  - Medical devices

Compliance, Certifications, Accreditations and Professional Affiliations

Charles River's Cologne facility operates in compliance with the following regulatory agencies or accredited organizations:

- German Chemical Law
- Directive 2004/9/EC
- Organization for Economic Co-operation and Development (OECD) GLP Certificate
- Code of Federal Regulations (CFR) 21 Part 58
- European Medicines Agency (EMA)
- U.S. Food and Drug Administration (FDA)
- 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