



FACILITY OVERVIEW

Wayne, Pennsylvania

Our cGMP-compliant facility in Wayne, PA supports companies developing biological products. Offerings include cell line characterization, contamination testing, stability programs, lot release testing, and comprehensive viral clearance services.

Background

- Formerly occupied by Merck & Co. and PPD
- Building leased by Charles River in 2018

Laboratories and Facilities

- 72,000 square feet/6,689 square meters
- Extensive site security and monitoring systems
- Document control and archive capacity
- Sample processing and storage
- On-site IT support services
- Biosafety Level 2 capabilities
- Dedicated client labs and assigned guest offices for viral clearance study performance
- State-of-the-art laboratories equipped with DI water, CO₂ and N₂ gas, and pressurized air

Staff

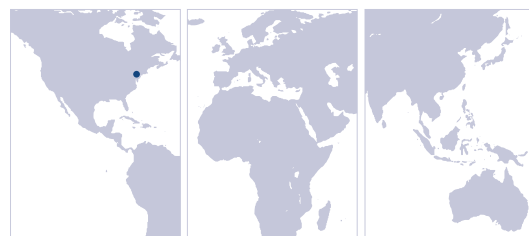
- 160+ employees

Service Areas/Study Types

- Testing
 - Cell line characterization
 - Biosafety testing including detection of adventitious viral agents and retroviruses
 - Microbiology services including bioburden and mycoplasma testing
 - Release testing
 - Stability testing
 - Method development, transfer, and validation

- Viral Clearance

- Regulatory (Europe, US, Japan) consultation for study planning
- Selection of process steps
- Selection of high titer viruses
- Optimization of viral clearance studies design
- Performance and support of the downscaling of manufacturing process steps
- Performance of all process steps (including chromatography)
- Fully qualified ÄKTA Avant, Explorer, and Purifier chromatography systems
- Interpretation of results and troubleshooting support (includes access to 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
 - myCharlesRiverSM client portal — Sharepoint[®] support for document exchange and communication
 - Dedicated project management
- 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

The Devon Park facility will operate in compliance with the following regulatory agencies or accredited organizations.

- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- Health Products Regulatory Authority (HPRA) – formerly Irish Medicines Board (IMB)
- US Department of Agriculture (USDA)

Quality and Process Initiatives:

- Lean Six Sigma