charles river

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, $CO_2$ and $N_2$ 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
  - myCharlesRiver℠ 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