



FACILITY OVERVIEW

Malvern, Pennsylvania

Our GMP-compliant facility in Malvern, PA, supports companies developing biological products. Offerings include cell banking and vaccine manufacturing, cell line characterization, contamination testing and stability and lot release programs.

Background

- Established in 1987 by Tektagen
- Acquired in 1998 by Charles River
- Facility expanded in 2008 and 2016

Laboratories and Facilities

- 42,000 square feet/3,900 square meters
- Extensive site security and monitoring systems
- Sample processing and storage
- On-site IT support and backup

Staff

- 150+ employees

Service Areas/Study Types

- Testing
 - Cell line characterization
 - Protein and analytical chemistry
 - Lot and drug product release testing
 - Biosafety testing including detection of adventitious viral agents and retroviruses
 - Microbiology services including sterility, bioburden and mycoplasma testing
 - Molecular biology services
 - Stability testing
 - Custom method development
 - Method transfer and validation
- GMP Manufacturing
 - Cell banking including
 - Mammalian, insect and stem cells
 - Microbial and yeast cells
 - Virus banking
 - Viral vaccine manufacture



EVERY STEP OF THE WAY

Compliance, Certifications, Accreditations and Professional Affiliations

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

- Good Manufacturing Practice (GMP)
- Food and Drug Administration (FDA), USA
- European Medicines Agency (EMA)
- Health Products Regulatory Authority (HPRA) - formerly Irish Medicines Board (IMB)
- United States Department of Agriculture (USDA)

Quality and Process Initiatives

- Operational Excellence - Lean Program