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
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