



FACILITY OVERVIEW

Erkrath, Germany

Our facility, located in Erkrath, Germany, offers GMP-compliant services for the QC analysis of biologics, including cell line characterization, stability and lot release programs, impurity testing and cell-based bioassays.

Background

- Founded in 1993 as NewLab BioQuality
- Acquired by Charles River in 2008

Laboratories and Facilities

- 3,940 square meters/42,420 square feet
- Biosafety level 2 laboratories
- Qualified equipment

Staff

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

Service Areas/Study Types

- Testing Services
 - Cell line characterization and bulk harvest testing
 - Biosafety testing of biologics and raw materials
 - Cell-based bioassays (mode of action and potency)
 - Protein and analytical chemistry
 - Host cell protein determination
 - Lot and drug product release testing
 - Process characterization (resin cycling)
 - DNA sequencing and barcoding
 - Residual DNA determination
 - Virus detection by PCR
 - Stability testing for biologics
- Custom method development
- Method transfer and validation
- Genetic testing

Compliance, Certifications, Accreditations and Professional Affiliations

- Good Manufacturing Practice (GMP)
- U.S. Food and Drug Administration (FDA)
- European Medicines Agency (EMA)

Quality and Process Initiatives

- Six Sigma program
- Excellent regulatory compliance history



EVERY STEP OF THE WAY