



FACILITY OVERVIEW

Massachusetts Biologics

The facilities located in Shrewsbury and Wilmington specialize in a broad range of CGMP *in vitro* and *in vivo* capabilities in support of biologics, cell and gene therapies, vaccines, and biosimilars.

Background

Shrewsbury

- Established in 2006
- Biologics laboratory opened in 2015 and expanded in 2018

Wilmington

- Established in 2002 as part of RMS division
- Joined Biologics group in 2012

Laboratories and Facilities

- Robust CGMP quality systems and infrastructure
- Sample processing, management, and storage via Laboratory Information Management Systems (LIMS)
- 24-hour security and fire monitoring

Shrewsbury

- 15,000 ft² (1,394 m²)
- both R&D and CGMP lab space available for method development through release testing
- stability storage
- LN₂ storage

Wilmington

- 4,000 ft² (372 m²)
- Animal holding rooms, formulations, and serology laboratories

Staff

Shrewsbury

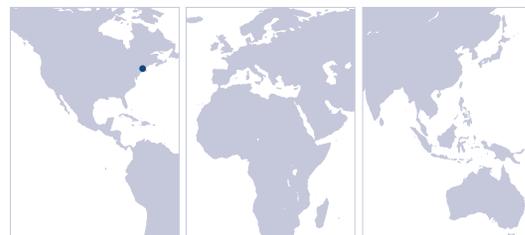
- 70+ employees

Wilmington

- 25+ employees

Service Areas/Study Types

- Product type and purpose-built packages
 - protein/peptide formulation development
 - cell and gene therapies
 - vaccines
 - antibody-drug conjugates (ADCs)
 - biosimilars
 - reference standard characterization and support
 - stability
 - lot and final drug substance/product release



EVERY STEP OF THE WAY

Service Areas/Study Types (continued)

Shrewsbury

- Potency/Bioassay
- Cell bank storage
- Stability storage
- Analytical services
 - mass spectrometry
 - glycosylation/glycan characterization
 - chromatography
 - spectroscopy
 - electrophoresis
 - activity/potency assays
 - amino acid analysis (AAA)
 - N-terminal sequencing
- Biophysical characterization

Wilmington

- *In vivo* adventitious agents testing
 - designed to meet various regulatory requirements (FDA, European Pharmacopeia)
- Mouse, rat, and hamster antibody production testing (MAP, RAP, HAP)
- *In vivo* potency and immunopotency
- General safety testing
- Tumorigenicity

Compliance, Certifications, Accreditations and Professional Affiliations

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

Shrewsbury

- United States Food and Drug Administration (FDA)

Wilmington

- United States Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- International Conference on Harmonization (ICH)
- Health Products Regulatory Authority (HPRA) - formerly Irish Medicines Board (IMB)
- Association of Assessment and Accreditation of Laboratory Animal Care (AAALAC)

Quality and Process Initiatives

- Excellent regulatory compliance audit history
- Operational Excellence – Lean Program
- Online data collection and integrated instrumentation
- Humane Care Imperative for animal welfare
- On-site IT support and backup

Humane Care Imperative

Charles River is a worldwide leader in the humane care of laboratory animals. We work hand-in-hand with the scientific community to understand how living conditions, handling procedures and stress play an important role in the quality and efficiency of research.