charles river

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 $ft^2$ (1,394 $m^2$)
- both R&D and CGMP lab space available for method development through release testing
- stability storage
- $LN_2$ storage

### Wilmington

- 4,000 $ft^2$ (372 $m^2$)
- 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.