charles river

FACILITY OVERVIEW

Woburn, Massachusetts

Our analytical laboratory, located in Woburn, MA, specializes in a broad range of testing techniques, including analytical, mass spectrometric and biophysical, to support characterization and development of protein, glycoprotein, and peptide therapeutics.

Background

- Established as Blue Stream Laboratories in 2006
- Acquired by Charles River in 2016

Laboratories and Facilities

- 15,000 square feet/1,394 square meters
- Extensive monitoring systems
- Sample processing and storage

Staff

- Approximately 40 employees (more than 50% hold advanced degrees, including MSc or PhD)

Service Areas/Study Types

- Biophysical characterization
  - Analytical ultracentrifugation (AUC)
  - Circular dichroism (CD)
  - Differential scanning calorimetry (DSC)
  - Size exclusion chromatography (SEC) with multi-angle laser light (MALLS) detection
  - Dynamic light scattering (DLS)
  - Intrinsic tryptophan fluorescence (ITF)
  - Extrinsic fluorescence – dye binding (e.g., ANS)
  - Fourier transform infrared (FTIR) spectroscopy
  - Surface plasmon resonance (SPR) via Biacore
- Mass spectrometry
  - Intact and subunit MW determination
  - Drug-to-antibody ratio (DAR) determination
  - Glycosylation site(s) mapping/occupancy
  - Disulfide(s) mapping; disulfide bonding conformations/isoforms via peptide mapping LC-MS
  - Post-translational modification (PTM) mapping: sulfation, phosphorylation, myristoylation
  - Degradation/stability analysis, including oxidation and deamidation
  - Glycan structural characterization
  - Chromatographic “fingerprint analysis”
  - Degradation/impurity characterization
  - *De novo* amino acid sequencing and sequence verification
  - Peptide mapping method development, ICH validation, and cGMP lot release support
  - PEGylation site mapping
  - GAGS, heparan and heparan sulfate analysis
  - Isoform characterization

EVERY STEP OF THE WAY

Service Areas/Study Types (Continued)

- Glycosylation/Glycan characterization
  - Glycosylation site(s) occupancy and mapping via peptide mapping LC-MS/MS
  - N-linked oligosaccharide profile via LC-FL-MS/MS
  - O-linked oligosaccharide profile via LC-MS/MS
  - Quantitative monosaccharide analysis
  - Quantitative sialic acid determination
  - Glycan structural characterization/confirmation MSn
  - Glycan profile/isoform via cIEF
  - Exoglycosidase glycan sequence/mapping
- Chromatography
  - Peptide mapping
  - N- & O-linked oligosaccharide profiles
  - Sialic acid quantification
  - Monosaccharide profile analysis
  - SEC – size/aggregation analysis
  - Purity, identity, and/or quantitation methods
  - Development of stability-indicating methods
  - Residuals/impurities/degradants analysis
  - Separation technologies: RPC, SEC, HILIC, HIC, SAX, SCX, NP, WCX, WAX
  - Detectors: UV, VIS, DAD, CAD, ELSD, fluorescence, conductivity
- Spectroscopy
  - UV/Vis absorbance
  - Fluorescence
  - Fourier-transformed infrared
  - Circular dichroism
- Electrophoresis
  - Capillary electrophoresis w/ LIF, UV/Vis
  - SDS-PAGE – reducing/non-reducing
  - Isoelectric focusing (IEF)
  - IPG strips (immobilized pH gradient)
  - Densitometry
  - Immuno/western blotting
- Activity/Potency Assays
  - Surface plasmon resonance – Biacore
  - ELISA with various modes of detection
- Amino acid analysis (AAA)
  - Extinction coefficient determination
  - Mole percent amino acid analysis
  - Timed hydrolysis studies
  - Gamma carboxyglutamic acid (GLA)
  - Tryptophan determination
  - Lysine quantification for polylysine formulations
  - Collagen hydroxyproline and hydroxylysine ratio determinations
- N-Terminal Sequencing
  - Automated Edman degradation
  - *De novo* sequencing
  - PyroGlu deblocking of N-terminus
  - GMP drug substance ID testing
  - Truncation/multiple N-termini determination
- Product type and purpose-built packages
  - Biosimilars
  - Antibody-drug conjugates (ADCs)
  - Protein/peptide formulation development
  - Reference standard characterization and support
  - Stability testing
  - Lot and final drug substance/product release

Compliance, Certifications, Accreditations and Professional Affiliations

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

- Good Manufacturing Practice (GMP)
- U.S. Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- International Conference on Harmonization (ICH) Guidelines

Quality and Process Initiatives

- Excellent regulatory compliance audit history