



BIOLOGICS DRUG PRODUCT MANUFACTURING AND ANALYTICAL DEVELOPMENT.

PROTEINS. PEPTIDES. MONOCLONAL ANTIBODIES.

YOUR BIOLOGICS PRODUCT. OUR EXPERTISE.

Your biologics product has the potential to reinvent the market and change patients' lives. Alcami can get your product there faster. Bring us your peptides, proteins, and monoclonal antibodies, and we will deliver scalable solutions to reach every milestone on the roadmap to the market.

CAPABILITIES	DRUG SUBSTANCE	DRUG PRODUCT
Binding / Potency	✓	✓
Identification	✓	✓
Structural Characterization	✓	N / A
Purity	✓	✓
Safety	✓	✓
Formulation Development		✓*
Manufacturing		✓
Packaging & Labeling		✓
Stability	✓	✓

**Product Dependent*

DRUG PRODUCT MANUFACTURING.

- Development and manufacture of parenteral drug products
 - Proteins, peptides, and monoclonal antibodies
- Aseptic / sterile fill-finish processing
- Process development, optimization, and validation
- Lyophilization development and manufacturing
- Single-use systems
- In-line monitoring
- Visual inspection
- Automated filling
- In-house extractables / leachables method development and testing
- Vial sizes from 2mL to 50mL with liquid or lyophilization capabilities
- Batch sizes up to 330L and 50,000 vials
 - *1,000L formulation capability in 2021
- FDA, EMA, MHRA, JP, and cGMP-compliant manufacturing facility
- DEA compliant for Schedule 2, 2N, 3, 3N, 4, 5, and L1 compounds



ANALYTICAL DEVELOPMENT AND TESTING.

Dedicated project management will give you a superior customer experience right from the start. Our biologics analytical development team uses a client-centric approach to provide creative, integrated solutions to your biggest challenges through your drug development process.



○ Binding / Potency

- Enzyme Activity
- ELISA
- Cell-Based Assay
- Endotoxin (LAL)

○ Residual Host Cell Protein

- Sterility
- Protein Content
- Western Blot
- Bradford Assay



○ Identification

- Western Blot
- SDS-PAGE
- Sequencing by LC / MS
- Unknown Peak ID
- Accurate Mass

○ iCE™ Capillary IEF Mass Spectrometry



○ Structural Characterization

- Peptide Map
- AAA
- Oligosaccharide Analysis
- Glycosylation Profile
- Extinction Coefficient

○ CE-LIF ProteomeLab™ PA800 Q-TOF LC-MS (ESI, MALDI) PE SCIEX™ API 4000 / 5000 Agilent™-GC MS



○ Purity

- UV-VIS
- Process Impurities
- Product Impurities
- Micro-Flow Imaging

○ RP-HPLC IEX-HPLC SEC-HPLC Gel Permeability

