alcami®

Laboratory Services

Talk to us.

alcami.com

Biologics:

Analytical Testing Across the Development Lifecycle

Biologic therapeutics present unique analytical challenges driven by structural complexity, post-translational modifications (PTM), and sensitivity to manufacturing conditions. A comprehensive analytical strategy is required to fully characterize the molecule, control impurities, and ensure consistent product performance across development and commercialization.

Our approach integrates physicochemical characterization, analytical testing, and regulatory-aligned method development. We design assays with long-term scalability in mind—ensuring progression from early development through cGMP release and lifecycle management.

Identification of Critical Quality Attributes (CQAs)

Development of stability-indicating methods

Integration of orthogonal analytical techniques

Alignment with regulatory expectations: FDA, EMA, PMDA, Health Canada, TGA, ANVISA

Analytical Capabilities

Potency & Functional Bioassays

Cell-based potency assays

Enzyme activity

Flow cytometry

ELISA/BLI

Purity, Identity & Impurity Analysis

Chromatographic methods: HPLC/UPLC (SEC, IEX, HILIC, HIC, DAR, RP, IP-RP)

Electrophoretic methods: CE-SDS, icIEF, IEF, SDS-PAGE

High-Resolution Mass Spectrometry (HRMS)

ELISA & qPCR for process related impurities: host cell proteins, residual proteins, residual DNA

Aggregation & Biophysical Characterization

Micro-Flow Imaging (MFI)

Dynamic Light Scattering (DLS)

Multi-Angle Light Scattering (MALS)

Analytical Ultracentrifugation (AUC)

Circular Dichroism (CD)

DSC

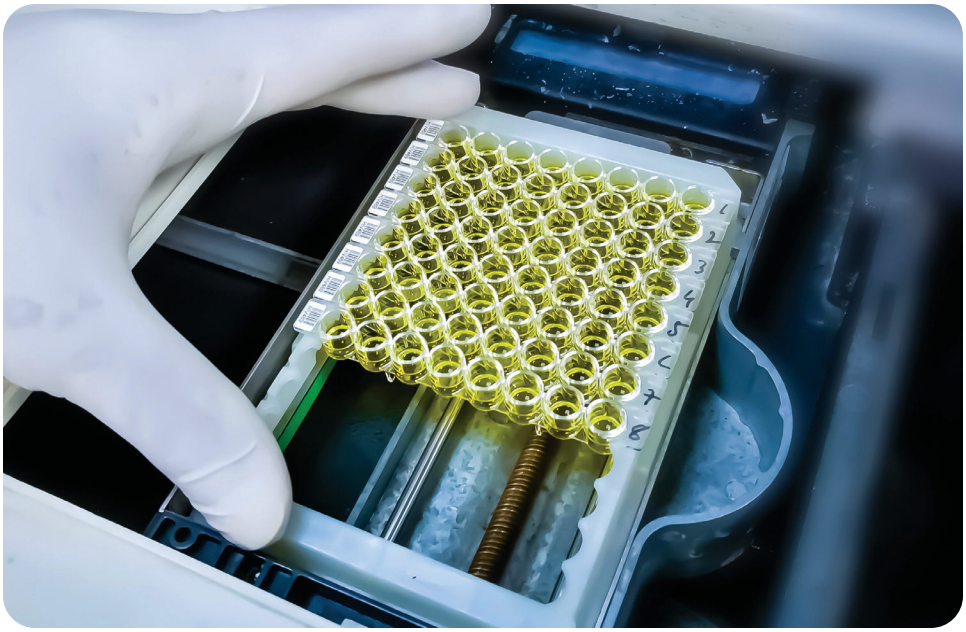
FTIR

Quantitation & Concentration Analysis

SoloVPE, UV/Vis

ELISA / BLI (for concentration and titer)

UPLC with MS/QDa, ELSD, CAD, RI, FLD and DAD detection modes



We provide full service support for pharmaceutical and biotech manufacturers, establishing and maintaining robust environmental control programs required by global cGMP regulations. From initial cleanroom certification to ongoing microbial analysis, we ensure your facility maintains a state of control, mitigating risk and protecting your product integrity.

Applications
Proteins
Peptides
Monoclonal antibodies (mAbs)
Antibody-drug conjugates (ADCs)
Oligonucleotides
Extended characterization: molecular mass, peptide mapping/sequence coverage, PTM, glycan profiling, disulfide mapping, and free thiols

Technical Capabilities by Phase:

Preclinical & Early Development

Establish analytical understanding through structural characterization, impurity identification, and forced degradation studies. Includes peptide mapping, PTM analysis, aggregation assessment, and early potency assays.

Phase 1 & Phase 2 Clinical Development

Transition to validated, cGMP-compliant methods. Perform identity, purity, and impurity testing while supporting formulation development and ICH stability studies.

Phase 3 & BLA Submission

Execute full method validation, comparability studies, and regulatory documentation. Ensure readiness including stability programs, CCIT, and specification setting.

Commercial Manufacturing

Support lifecycle management through routine lot release testing, stability monitoring, and continuous verification of potency, purity, and safety.

alcami®

Laboratory Services

alcami.com

Drug Product Manufacturing
Laboratory Services
Pharma Storage & Services

Charleston, SC • Wilmington, NC
RTP, NC • The Netherlands, Europe
Clinton, TN • St Louis, MO
New England • Reno, NV