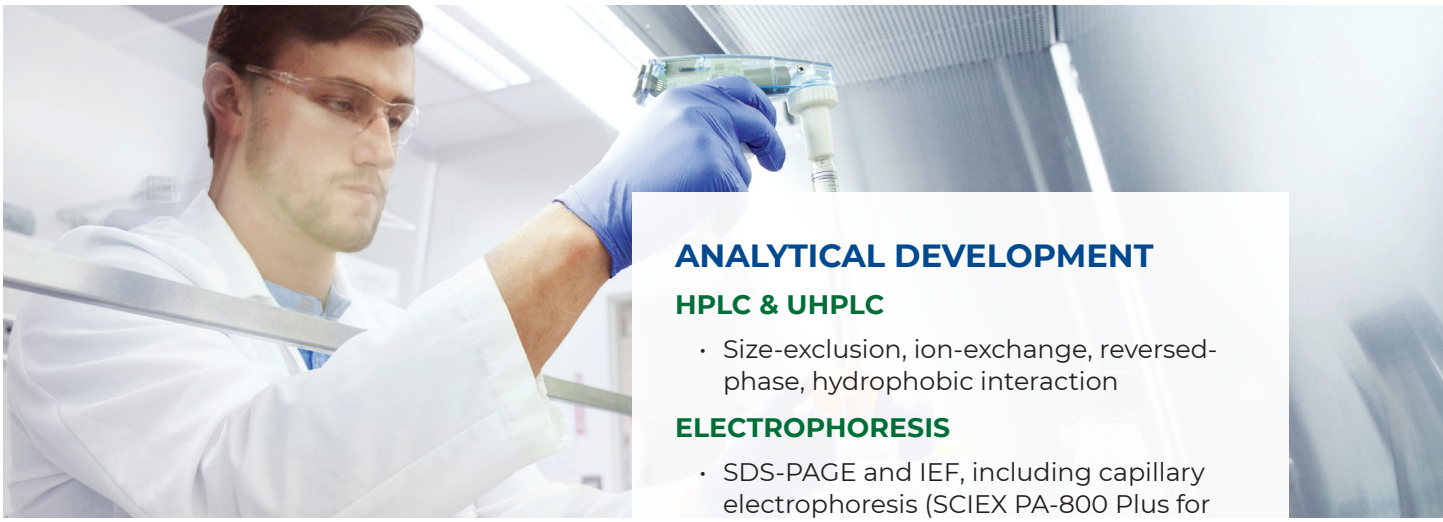
AGC Biologics

Analytical, Formulation & Stability



ANALYTICAL DEVELOPMENT

HPLC & UHPLC

- Size-exclusion, ion-exchange, reversed-phase, hydrophobic interaction

ELECTROPHORESIS

- SDS-PAGE and IEF, including capillary electrophoresis (SCIEX PA-800 Plus for CE-SDS, cIEF, and CZE; ProteinSimple iCE3 for imaged capillary IEF)

CARBOHYDRATE ANALYSIS

- Released N- and O-linked glycan profiling (fluorescent-tagged HPLC with online LC-MS glycan identification); sialic acid quantitation

PRIMARY SEQUENCE

- High-resolution intact ESI-MS (Orbitrap) reduced and non-reduced peptide mapping (including LC-MS/MS); disulfide bond linkage; IdeS digestion of mAbs

BIOASSAYS AND BINDING ASSAYS

- Full development of cell-based bioassays and ELISA; BLI assays (Octet® HTX)

BIOPHYSICAL CHARACTERIZATION

- Circular dichroism, DLS, viscometry

PROCESS IMPURITIES

- Host cell DNA and protein, endotoxin, polysorbate quantitation

Fast, flexible development to speed Your product to market

We have experience with monoclonal antibodies, antibody-drug conjugates, and many other molecule types, including highly glycosylated proteins and biosimilars.

Our experienced team is capable of performing a variety of studies, including analytical method development and method qualification or validation, in-depth analytical characterization and comparability studies, cGMP drug substance/drug product release testing and stability testing, and full liquid and lyophilized formulation development.

cGMP Services for Every Stage of Drug Development

Many of the analytical development methods can also be qualified or validated, and executed in our cGMP laboratories for purposes of release testing and formal cGMP stability programs.

cGMP Analytical & Stability Capabilities

- Qualification or validation of most analytical methods
- Drug substance and drug product release testing, including QP release to meet EU requirements
- Clinical kit ID testing
- Special request cGMP testing
- Formal cGMP stability program, designed and executed in compliance with ICH guideline

Custom Formulation Programs

AGC Biologics is able to develop formulations for liquid drug substance and drug product, as well as lyophilized drug product formulations (together with optimized lyophilization cycles).

Our formulation studies typically involve incubation of samples under various conditions, sample pulls at various time points, and sample analyses with a panel of analytical methods drawn from the analytical development list on the previous page. Formulation programs are customized to fit the needs of each individual client; the studies listed below are merely examples.

FORMULATION DEVELOPMENT

STRESS-DEGRADATION

Protein is subjected to conditions of elevated temperature, pH extremes, oxidation, photo stability, agitation and freeze-thaw to reveal product sensitivity and identify stability-indicating analytical methods.

FORMULATION SCREENING (PREFORMULATION)

Excipients and pH ranges are screened in one or more short-term studies. Initial DoE screening is performed in a high-throughput fashion using both extrinsic and intrinsic fluorescence.

HIGH DOSE CONCENTRATION RANGING

Candidate formulations are screened for their ability to support the target protein concentration (>100mg/ml) by SEC, DLS, and viscometry.

FORMULATION SELECTION

Final formulation candidates are tested against one another in a 12-week study under several conditions (including both real-time and accelerated conditions) to allow selection of the final formulation composition.

LYOPHILIZATION CYCLE DEVELOPMENT

Using our FTS LyoStar™ II freeze-dryer, experiments are performed to optimize lyophilization cycle parameters (e.g., shelf temperature, freezing rate, primary drying time/temperature, secondary drying time/temperature) to permit cycle transfer to a manufacturing-scale lyophilization fill-finish facility.

MATERIAL COMPATIBILITY AND IN-USE STABILITY

Studies can be performed to understand product compatibility with various materials (e.g., tubing or IV bags), and to understand short-term stability for clinical handling.

BULK FREEZE-THAW

Effects of multiple freeze-thaw cycles are investigated in larger containers representative of manufacturing scale.

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