CMC biologics
Right. On Time.

ANALYTICAL, FORMULATION AND STABILITY CAPABILITIES

Fast, Flexible Development to Speed Your Product to Market

CMC Biologics offers a wide range of analytical, formulation, and stability services for biological products. We have extensive experience with monoclonal antibodies, antibody-drug conjugates, and many other molecule types, including highly-glycosylated proteins and biosimilars.

Our team is able to carry out 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.

ANALYTICAL DEVELOPMENT

HPLC:

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

ELECTROPHORESIS:

SDS-PAGE and IEF, including capillary electrophoresis (Beckman PA-800 for CE-SDS and iCE280 for imaged capillary IEF)

CARBOHYDRATE ANALYSIS:

Released N- and O-linked glycan profiling (fluorescent-tagged HPLC), MALDI-MS characterization of released glycans; quantitative monosaccharide analysis, including sialic acid quantitation

PRIMARY SEQUENCE:

High-resolution intact ESI-MS; reduced and non-reduced peptide mapping (including LC-MS/MS); free thiol quantitation

BIOASSAYS AND BINDING ASSAYS:

Full development of cell-based bioassays and ELISAs; Biacore binding assays; isothermal calorimetry

BIOPHYSICAL CHARACTERIZATION:

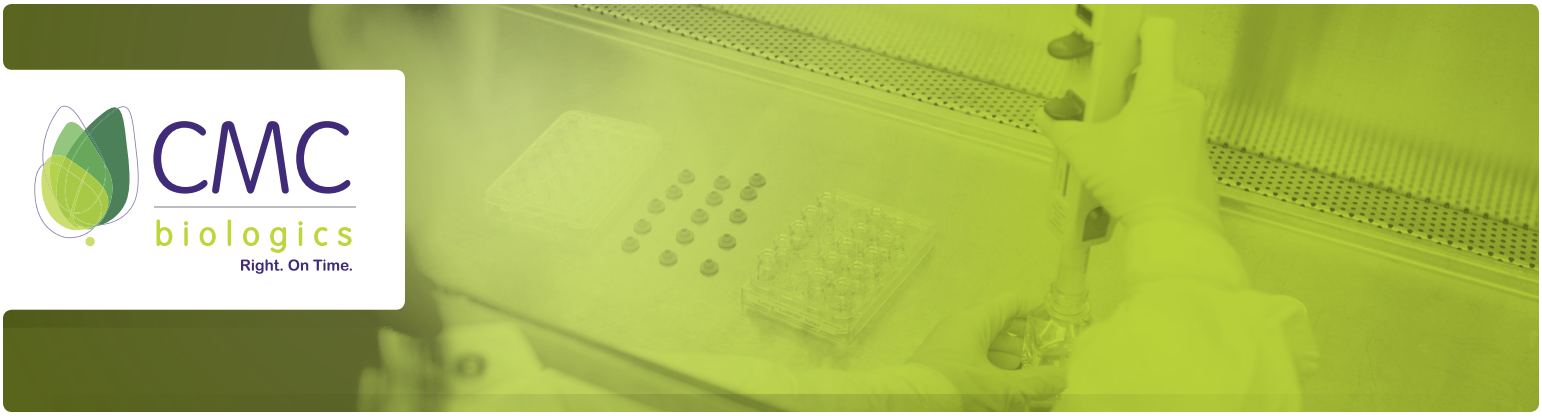
Circular dichroism, fluorescence spectroscopy, and SEC-MALLS

PROCESS IMPURITIES:

Host cell DNA and protein, endotoxin, polysorbate quantitation

FORMULATION SUPPORT:

Visual appearance inspection (liquid and lyophilized), absorbance measurements for concentration and turbidity, HIAC for particle counting, Karl Fischer for residual moisture analysis



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Custom Formulation Programs

CMC 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). Formulation studies typically involve incubation of samples under various conditions, sample pulls at various timepoints, 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, photostability, 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. This may be done in vials or in a high-throughput format.
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 buffer.
LYOPHILIZATION CYCLE DEVELOPMENT:
Using our FTS LyoStar II or VirTis Genesis EL freeze-dryers, 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.

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 AND 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 guidelines