ALMAC

Partnering to Advance Human Health

Brochure

Think Almac... Analytical Solutions for Biologics

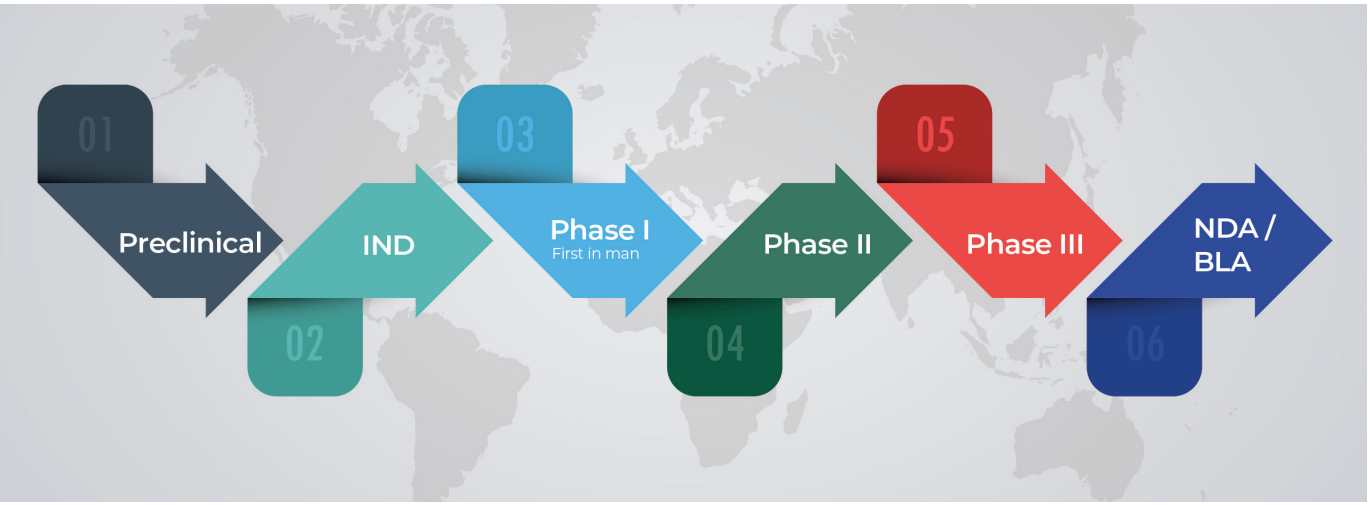
Providing comprehensive and flexible analytical solutions to accelerate the development and approval of biologics

Almac offers a diverse suite of analytical methods with applications across the biologic development space, with extensive experience in the analysis of drug substance, drug product and reference material from pre-clinical phase through to commercial manufacture for:

- Monoclonal antibodies and mAb-like molecules
- Antibody drug conjugates
- Biosimilars and biobetters
- Recombinant proteins
- Long peptides

Key offerings

- State-of-the-art analytical methods to thoroughly assess and characterise critical quality attributes
- Science-driven analytical data and characterisation packages for demonstration of biosimilarity and establishing totality-of-evidence
- Phase-appropriate lifecycle approach to analytics for method development, optimisation and validation
- Release and stability testing to support clients' successful product launch in regulated markets including FDA, EMA and PMDA
- Global cGMP quality systems to support clinical and commercial biologics



Analytical services

Clinical and commercial batch release

Almac provides GMP release testing services to support clients' biologic drug substance and drug product programs for both novel biologics and biosimilars.

ICH stability

Our biologic stability programs are sensitive and robust, and designed in accordance with ICH (Q5C) guidelines. Our most commonly used stability-indicating analytical methods include: SE-HPLC; IEX-HPLC; cIEF; CE-SDS; and, biological assays.

Almac offers a range of stability conditions with various temperature and humidity options to ascertain shelf-life under GMP conditions.

Establishment of analytical methods

Development and optimisation

We offer fit-for-purpose analytical method development based on AQbD paradigm, taking a phase appropriate approach. Almac routinely develop comprehensive analytical methods to support release and stability testing of biologics . Following current industry best practice including draft ICH Q14 guideline. This approach allows us to develop sensitive yet robust analytical methods for release and stability testing of biologics.

Qualification and validation

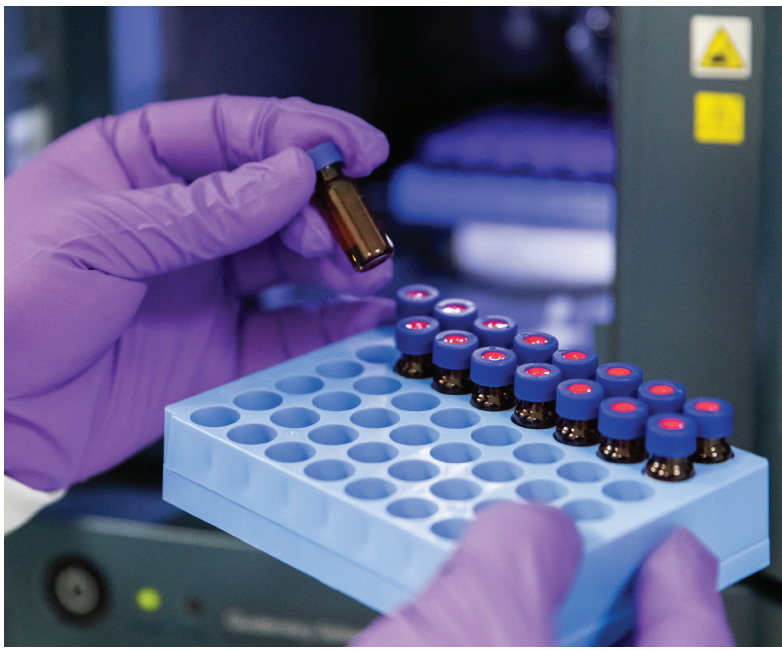
Once suitable analytical methods are established, Almac offers phase appropriate validation in line with ICH Q14 (R1) guidelines. As part of validation Almac perform a gap analysis of any previously validated analytical methods to de-risk the programme and maximise the success of a regulatory dossier.

Transfer

Almac offers method transfer services to support GMP clinical/commercial release and stability testing, as well as characterisation. Our unparalleled expertise in seamless method transfer between laboratories through either comparative testing or co-validation of biologics ensures smooth transition. Almac supports the transfer of methods into and out of our labs as required by our clients. Depending on the status of the analytical methods we can support transfer by comparative testing, co-validation or partial validation. Our technical experts are contactable throughout the transfer process to ensure a smooth transition.

Key techniques

- Quantity: protein concentration by A280 (SoloVPE)
- Process related impurities: host cell protein (ELISA), Protein-A leachate (ELISA), host cell DNA (qPCR), culture media components and detergents
- Product related impurities: protein oxidation, deamidation and degradation
- Identity: pI determination by cIEF, peptide mapping by UPLC
- Glycan profile: glycan analysis by UPLC, sialic acids, monosaccharide profiling
- Excipients: polysorbates, poloxamers, polyols, preservatives (phenol, benzyl alcohol) and buffering agents
- Purity and heterogeneity: aggregation (SEC), fragmentation (CE-SDS), charge variants (cIEF, CZE and IEX)
- Potency: binding ELISA assays, Fc functional assays, cell-based bioassays



Raw material testing

In addition, Almac supports the manufacture of biologics and biosimilars in the release of raw materials into the manufacturing site per client specification or Pharmacopoeial requirements in a GMP compliant environment.

Chemically defined media

- Amino acid analysis
- pH, osmolality, and appearance
- Sugar, vitamin, and metabolite profiles
- Trace metal analysis by ICP-MS
- Bioburden and endotoxin testing

Excipients and surfactants

- Polysorbate-80, Polysorbate-20
- Triton
- Anti-foam
- Polyols

Analytical techniques

Chromatographic methods

- Size exclusion chromatography
- Glycan analysis
- Sialic acid analysis
- Thiol and disulfide bridges
- Sequence variants analysis
- Reversed-phase chromatography
- Ion exchange chromatography
- Excipient analysis
- Hydrophobic interaction chromatography
- Protein-A chromatography
- Peptide mapping

Electrophoresis methods

- SDS-PAGE
- IEF gels
- Western blot
- Agarose gel electrophoresis
- Capillary gel electrophoresis, non-reduced
- Capillary gel electrophoresis, reduced
- Capillary isoelectric focussing
- Capillary zone electrophoresis

Molecular biology

- Residual host cell DNA by qPCR
- Residual HCP by ELISA
- Residual insulin
- Protein-A ELISA
- ELISA
- BCA assay

Amino acid analysis

- Ninhydrin positive substances
- Amino acid ratios by acid hydrolysis
- Content uniformity
- Extinction coefficient determination

Physico-chemical attributes

- pH
- Colour and clarity
- Appearance
- Osmolality
- Visible particles
- Sub-visible particles
- Container closure integrity
- Karl Fischer - volumetric and coulometric
- Protein concentration by spectrophotometer
- Protein concentration by SoloVPE
- Ellmans assay
- Free thiol

Spectroscopic techniques

- High resolution LC-MS capabilities
- Determination of intact and reduced molecular mass
- Identification of glycoforms
- Extensive coverage of amino acid sequences
- Peptide mapping (top down / middle down)
- Terminal amino acid sequence
- Disulfide bridge and sulfhydroxyl group analysis
- Post translational modifications identification
- LC-MS/MS analysis

Microbiology testing

- Microbial limits testing (MLT)
- Microbial limits testing validation (MLTV)
- Preservative efficacy testing (P.E.T)
- Preservative efficacy testing validation (P.E.T.V)
- Endotoxin validation and testing using kinetic turbidimetric and chromogenic methods
- Growth promotion testing of cultured media
- Bioburden validation and analysis
- Specialist microbiology services for the medical device industry
- Identifications of bacterial cultures using phenotypic method
- Water system routine and validation testing in process , purified, WFI, clean steam etc

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