

Analytical solutions for biologics

Serious about difficult science

EU-based analytical expertise, supporting development to
commercial supply of biologics

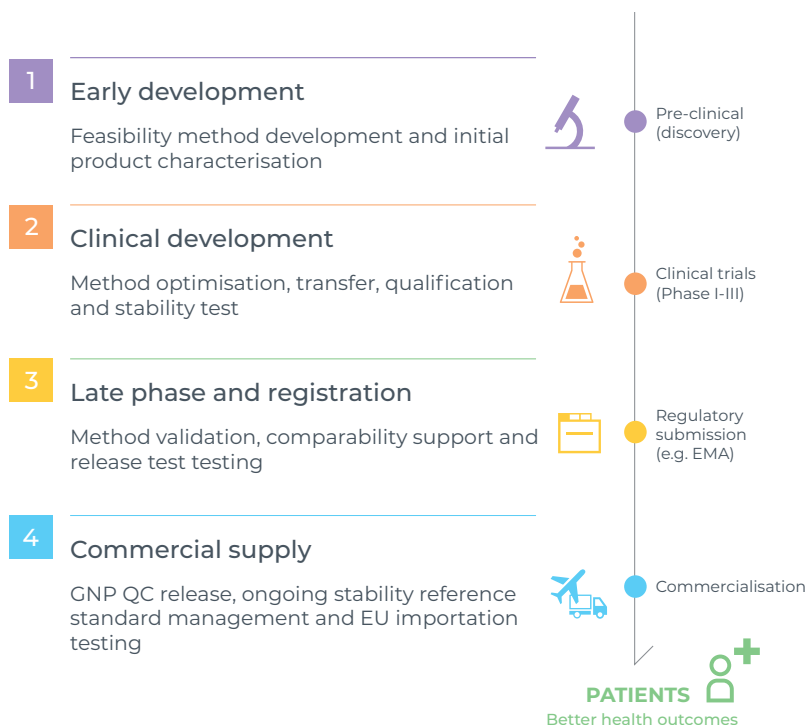


Analytical solutions for biologics

Almac provides flexible, EU-based analytical support for biologics from clinical development through to commercial supply. Our capabilities span method development, transfer and validation, GMP QC release, stability, product characterisation and EU importation testing.

We support monoclonal antibodies, ADCs, biosimilars and biobetters, recombinant proteins and long peptides.

Analytical support across the biologics lifecycle



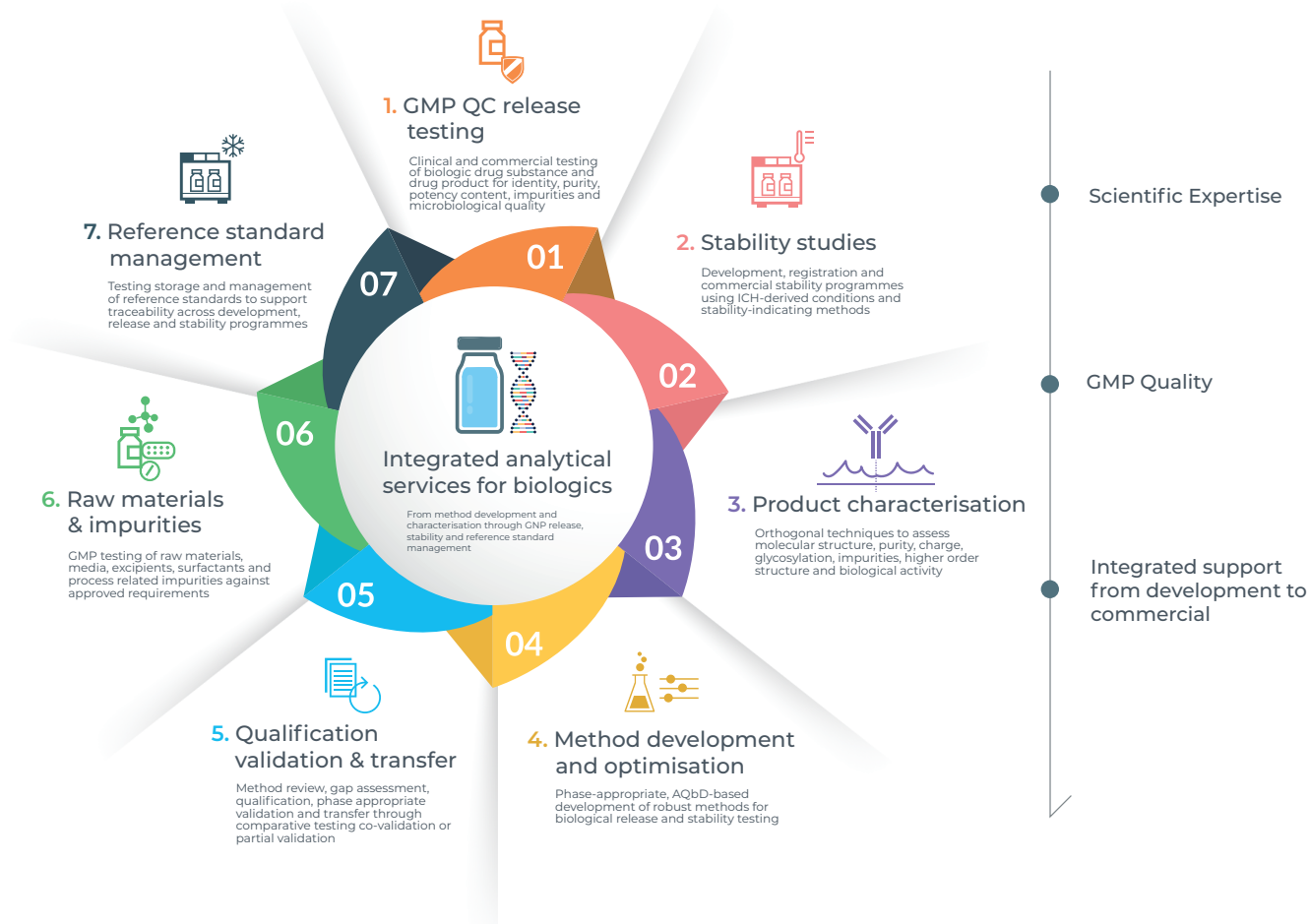
Why partner with Almac?

Almac combines EU-based GMP laboratory expertise with comprehensive analytical capabilities spanning method development and validation, QC release, stability, characterisation and raw material testing. Our experienced scientists work collaboratively with client teams, providing reliable data and technical insight to support clinical and commercial biologics programmes.

Collaborative analytical support for your CMC team

Almac combines clear communication, scientific transparency and defined project oversight to deliver testing in line with the client-approved scope. Our scientists provide reliable data and technical observations to support informed, client-led CMC decisions. Responsive communication and access to subject matter experts help clients manage outsourced analytical activities efficiently while retaining ownership of their product and CMC strategy.

Core biologics analytical services



EU import testing for biologic products

Almac provides EU-based GMP testing for imported biologic drug substance and drug product to support batch certification and release. Testing is performed in line with the approved product specification and agreed importation strategy and may include identity, purity, potency, safety and microbiological testing, as applicable.

Our analytical teams can also support the transfer or verification of relevant methods, helping establish the required testing within an EU-based laboratory environment.



Serious About Difficult Science

Whether supporting established development pathways or helping overcome scientific challenges, Almac Sciences combines technical expertise, advanced technologies and integrated delivery to help clients accelerate development and manufacture with confidence.

Comprehensive analytical testing for biologics

Integrated solutions across the full spectrum of quality attributes

CAPABILITY AREA	EXAMPLE METHODS/ATTRIBUTES
 Identity and structure	Peptide mapping, intact/reduced mass, pI, sequence variance and amino acid related assessments  
 Purity and heterogeneity	SEC, CESDS, SDS-PAGE, IXE, cIEF, CZE and related orthogonal techniques  
 Glycosylation	N- Linked glycan profiling, sialic acid analysis and mono profiling  
 Process-related impurities	Host cell proteins, residual host cell DNA, protein leachate and other process related residuals   
 Products related impurities	Aggregation, fragmentation, degradation, oxidation, deamidation and related quality attributes   
 Potency and biological activity	Finding essays, Fc functional assets and cell-based assets were applicable   
 Safety and microbiology	Bioburden, endotoxin, sterility, mycoplasma and microbial limits testing where applicable   
 Excipients and raw materials	Polysorbates, poloxamers, polyols, preservatives, buffering agents and chemical defined Media components   

Quality. Confidence. Partnership. Supporting your biologic from early development to commercial supply

Contact Us



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