



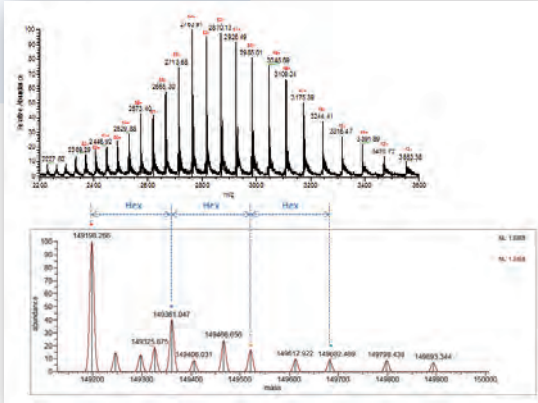
Expert Analytical Services for Biopharmaceuticals



Characterization Services for Monoclonal Antibodies

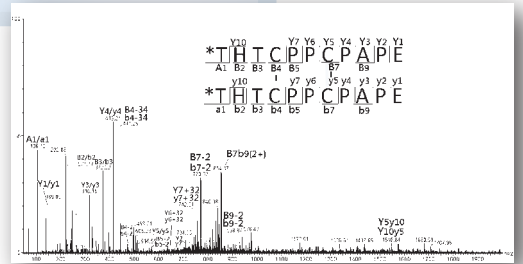
Molecular Weight Determination

- ▶ Intact mAb
- ▶ Reduced/Deglycosylated form



PTM Identification

- ▶ Disulfide bond
- ▶ N-term pyroglutamate
- ▶ C-term Lys clipping
- ▶ Oxidation, Deamidation

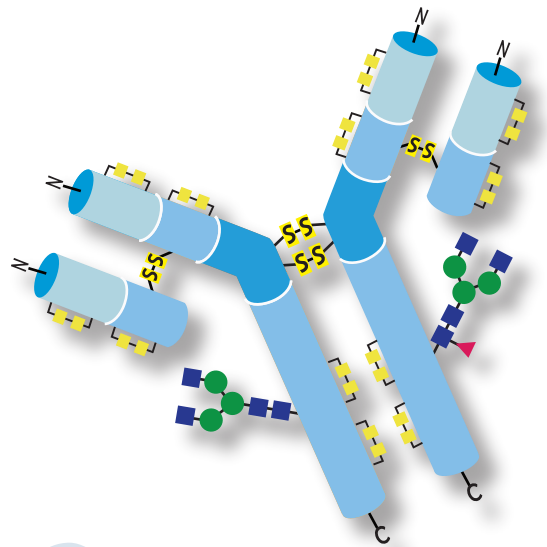


Full Sequencing

- ▶ N-term, C-term sequence
- ▶ N-glycosylation site

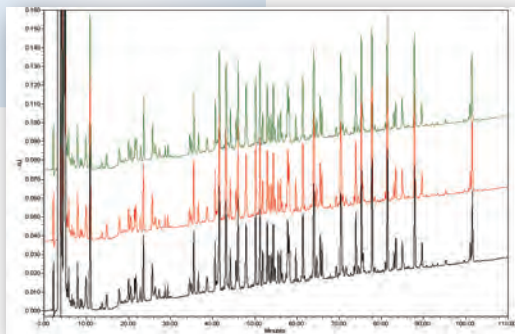
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XVVSVLTVLHQDWLNGKXXXXXXXXXXALPAPIEK
XXXXXXXXXXXXXXXXXXXXYKCKVSNKALPAPIEX
RVVSVLXXXXXXXXXXNGKEYXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXLNGKEYKCKVSNKXXXXXXXX
    
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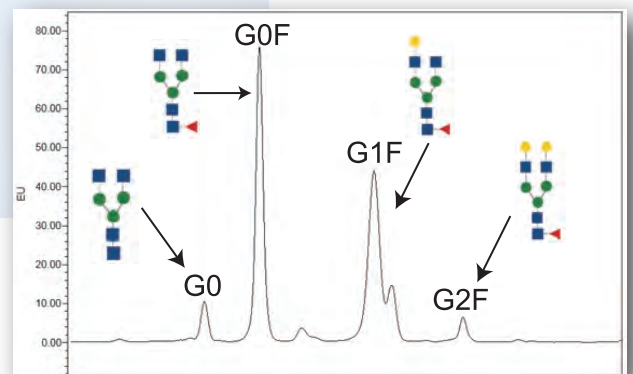


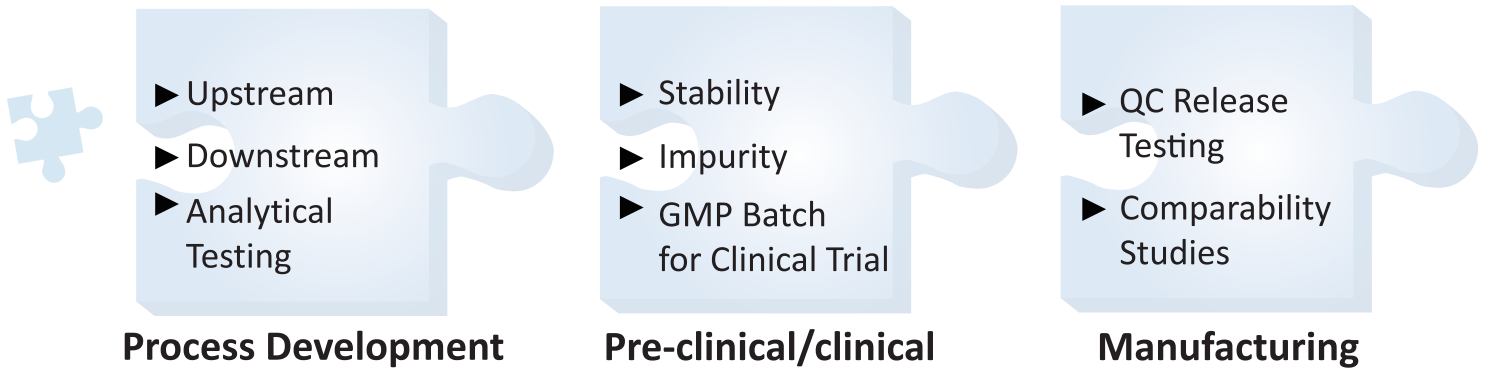
Peptide Mapping

- ▶ Lot to Lot QC
- ▶ Comparability studies



Glycan Structure & Profiling





Applications of Mass Spectrometry in Analytical Characterization

Identification

A selection of analytical tests are available for the characterization of protein drugs, including MW measurement, peptide mapping and amino acid sequencing.



Optimization

Early stages of process development require detailed characterization of the primary structure, PTM analysis and glycan profiling for drug product quality assurance.

Quantification

In addition to conventional immunoassays, LC-MS/MS methods are also used to quantify drug products and related impurities with higher specificity.



Homogeneity

Charge variants and other aggregated forms emerged from manufacturing processes are analyzed by our core techniques.



Stability

Stability testing methods are designed to identify and measure degradation products from the parent drug for potency and safety assessments.

Biosimilarity

Comprehensive physicochemical and structural characterization methods are provided to demonstrate the biosimilarity between a reference drug and the biosimilar product.

Benefits from MST

► Expertise

Experienced in the analysis of numerous types of therapeutic proteins, including mAbs, therapeutic enzymes, growth factors, hormones, interferons and other recombinant proteins.

► Fast

Adhered to strict timelines through effective project schedule management.

► Support

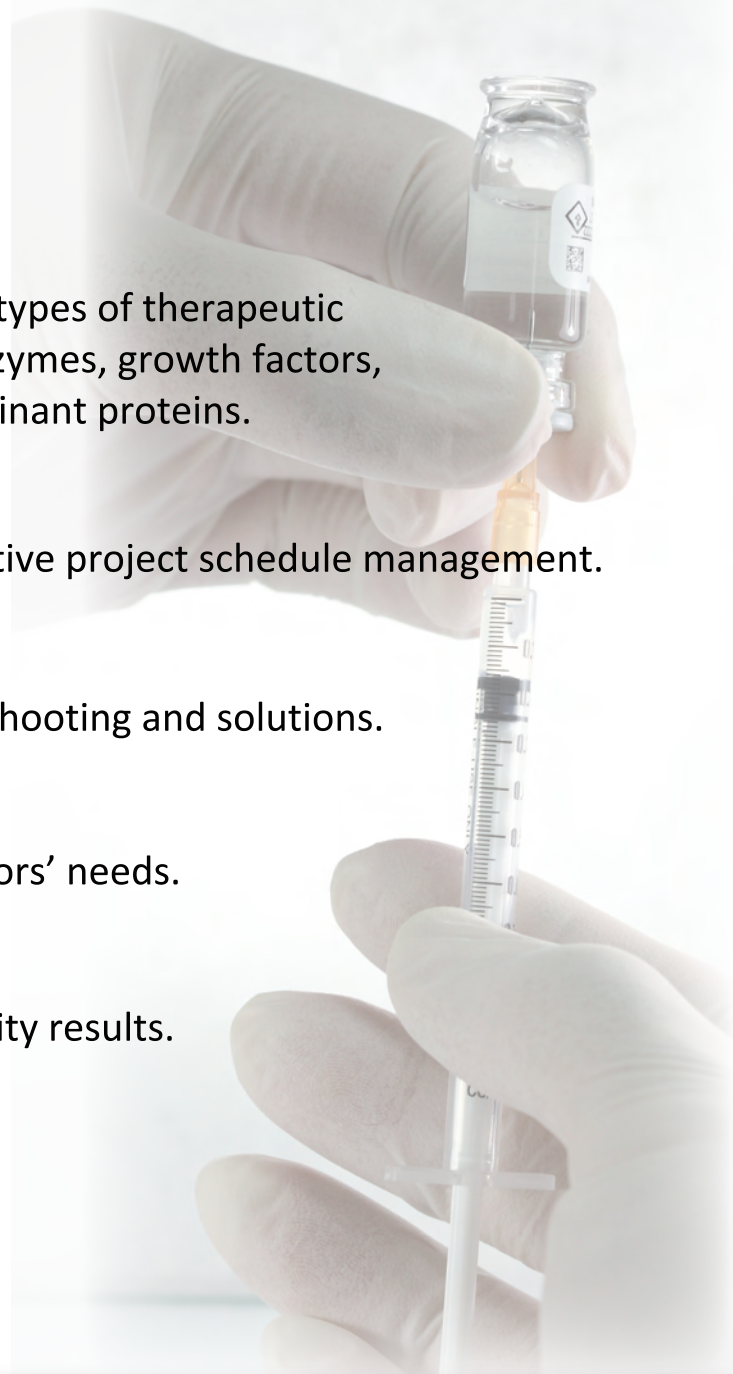
Proficient in providing analytical troubleshooting and solutions.

► Flexibility

Customizable projects to meet the sponsors' needs.

► Quality

Committed to delivering the highest quality results.



- ☑ TFDA-certified GLP system
- ☑ PIC/S GMP contract laboratory
- ☑ Successful external sponsor audits
- ☑ Regular internal audits
- ☑ Standard document management system
- ☑ Implementation of CAPA plan

