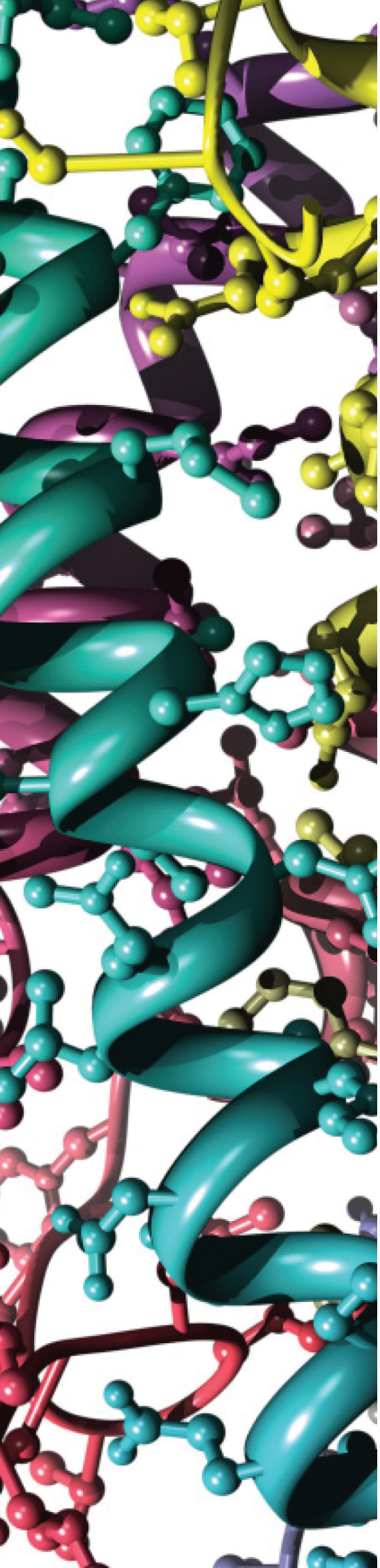

PROTEIN AND GLYCOPROTEIN ANALYSIS

IN ACCORDANCE WITH ICH GUIDELINES (ICH Q6B)

Biotechnological and biological products should be characterized according to ICH Guidelines. ICH Topic Q6B outlines procedures for analysis of peptide, protein, glycoprotein and antibody products. SGS provides a full analysis package for physicochemical characterization, formulation and stability to GLP/cGMP.

ICH REQUIRES	SGS PROVIDES
Amino Acid Sequencing	✓
Amino Acid Composition	✓
N- and C-Terminal Sequencing	✓
Peptide Mapping	✓
S-S Bridge Analysis	✓
Glycosylation Analysis	✓
Post Translational Modifications	✓
Molecular Weight	✓
Isoform and Electrophoretic Patterns	✓
Extinction Coefficient	✓
Liquid Chromatographic Patterns	✓
Spectroscopic Profiles	✓
Process and Product Related Impurities	✓
Aggregation Analysis	✓
Formulation Studies	✓
Stability Studies	✓

SGS provides a full analytical package or individual analyses depending on your needs:

- Amino acid sequence analysis using automated Edman sequencing and/or MS/MS
- Amino acid composition to provide protein concentration, extinction coefficient and/or amino acid molar ratios
- N- and C-Terminal analysis using automated Edman and/or MS sequencing
- Peptide Mapping by MS
- Disulphide bridge analysis using MS and MS/MS
- Glycan characterization including:
  - Monosaccharide composition
  - Sialic acid analysis
  - Oligosaccharide population by HPAEC-PAD, HILIC-FLD and MS
  - Linkage analysis
  - Glycosylation site analysis

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- Identification of post-translational modifications e.g. acetylation, phosphorylation etc
- Determination of intact molecular weight by MS
- Binding Affinity - Biacore
- Electrophoretic and isoform patterns - isoelectric focusing, cIEF and SDS-PAGE or CE/SDS
- Liquid chromatographic patterns - RP-HPLC, SEC and IEX
- Spectroscopic profiles - CD, NMR and FTIR
- Aggregation by AUC, SEC-MALS and DLS
- Thermal stability characterization
  - DSC
  - Thermal Unfolding curves with spectroscopic probes
- Analysis of process and product related impurities and degradation products e.g. isomerisation, deamidation, oxidation, mismatched S-S bridge forms
- Extractables and leachables from packaging/containers and closure systems by MS
- Validation of Cleaning Protocols to CFR Title 21 Part 211.67 using TOC
- Analysis of residual solvents by TD GC-MS

CONTACT INFORMATION

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WHEN YOU NEED TO BE SURE