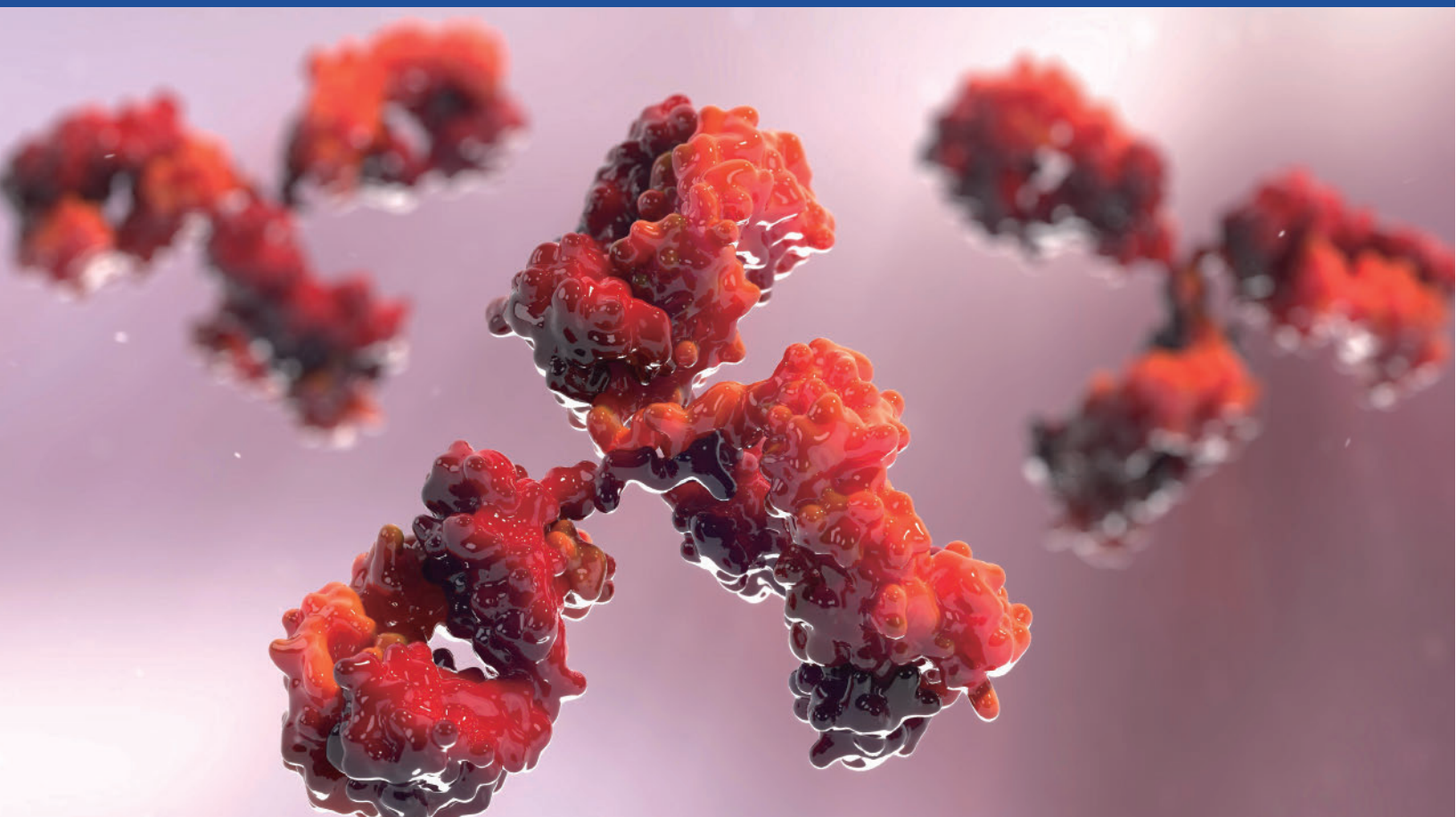




Creative Proteomics

Protein & Antibody Characterization
in Biopharmaceuticals

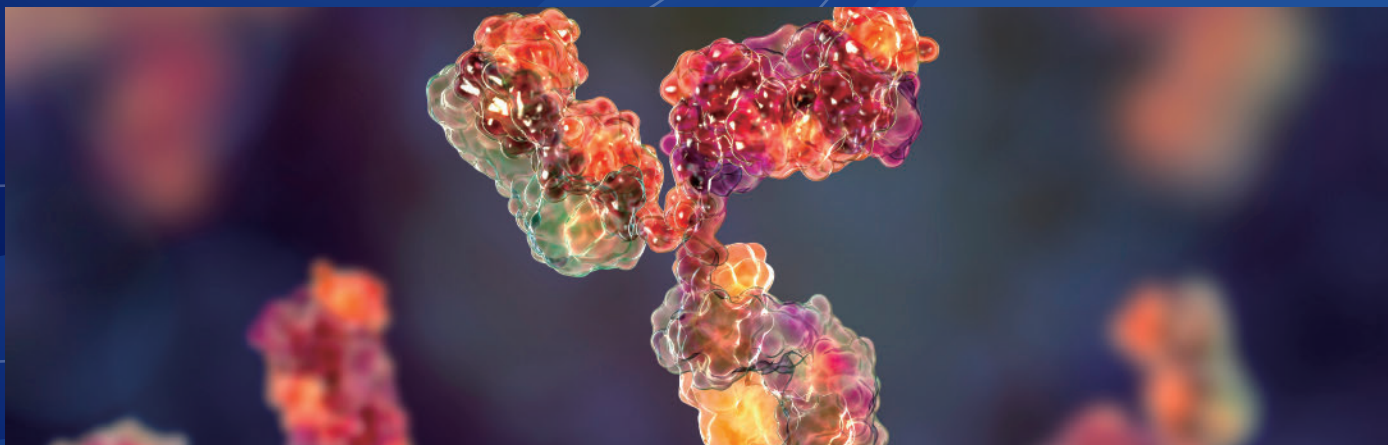


Protein & Antibody Characterization in Biopharmaceuticals



- Setting the Foundation for Success in Your Drug Development

Protein analysis techniques must be used from the beginning of the development process to make sure that a biologic product is fully characterized and meets all of the requirements. This involves determining the protein sequence, secondary and tertiary structure, bioactivity, immunochemical and physicochemical properties, and purity/impurities of the protein molecule, as outlined in the ICH Q6B guidelines. These methods are also crucial in assessing the impact of process variation on protein stability and supporting release testing.



Creative Proteomics' experienced scientists have provided support for protein/antibody drug development projects globally, covering a wide range of biologics including glycoproteins, biosimilars, monoclonal antibodies, PEGylated proteins, antibody drug conjugates, bispecifics, vaccines, multispecifics, and fusion proteins. Our comprehensive services include analyzing the protein's structure, physicochemical properties, bioactivity, immunochemical properties, purity and impurity determinations to ensure the quality and consistency of your products.

ICH Q6B Specifically Requests Data on The Following Characterization Parameters:

RESEARCHABLE BIOMOLECULES

- ✓ Physico-chemical properties
- ✓ Biological activity
- ✓ Immunochemical properties

ADVANTAGES OF SURFACE PLASMON RESONANCE

- ✓ Purity-impurity and contaminants
- ✓ Quantity

Regulatory Requirements and ICH Q6B

The regulatory guidelines most pertinent to biopharmaceutical characterization are described in the ICH Q6B (Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products).

- ✓ Structure /Sequence
- ✓ Identity
- ✓ Size
- ✓ Aggregates
- ✓ Precipitates/Particles
- ✓ Conformation

- ✓ Purity
- ✓ Surface charge
- ✓ Shape
- ✓ Concentration
- ✓ Formulation characteristics
- ✓ Biological activity

Protein Drug Characterization Service

PROTEIN DRUG CHARACTERIZATION	RESEARCH PROJECT	METHOD
Protein Identification	Molecular Weight	ESI-MS
		MALDI-TOF-MS
	Primary Sequence	Peptide Mapping
		N-terminal sequencing by Edman degradation
		N- or C-terminal sequencing with MALDI-MSD
	Isoelectric Point	Isoelectric Focusing
		Capillary Isoelectric Focusing
Protein Homogeneity Analysis	Protein Aggregation Analysis	SEC
	Protein Purity Analysis	HPLC
	Protein Fragment Analysis	HPLC
	Protein Isoform Analysis	Capillary Isoelectric Focusing
	Host Cell Proteins Analysis	ELISA, 2D western blot, LC-MS/MS
	Host Cell Residual DNA Analysis	qPCR/dd PCR
Glycosylation Analysis	Glycan Analysis	MALDI-TOF
	Glycopeptide Analysis	LC-MS/MS
Other Protein PTMs Analysis	Disulfide Bond, Phosphorylation, Acetylation, etc.	LC-MS/MS
Advanced Structure Analysis	Secondary Structure Analysis	Circular Dichroism Spectra (Far UV)
		Fluorescence Spectroscopy
		NMR Spectroscopy
		FT-infrared Spectroscopy
	Tertiary Structure Analysis	NMR Spectroscopy
		HDX-MS

Structure of Antibody Drug

Biopharmaceuticals possessed complex structures and high heterogeneities. Product quality is affected by the production process, storage conditions, etc.

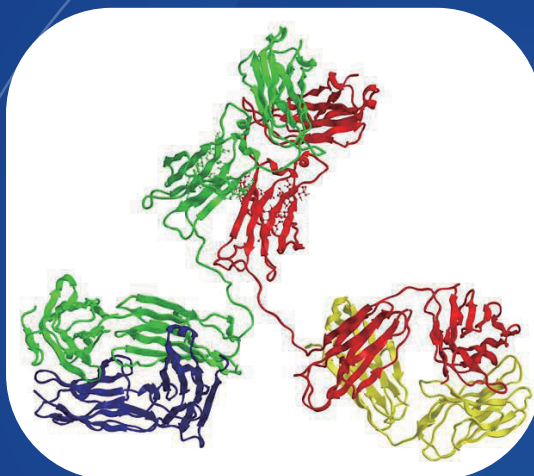
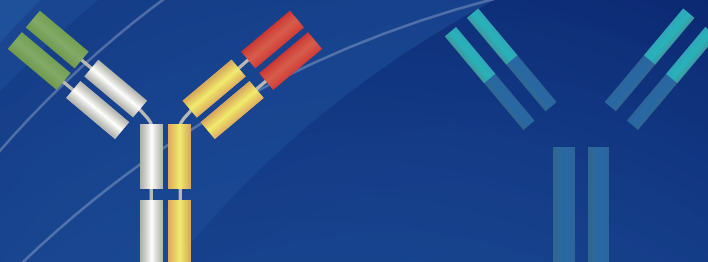
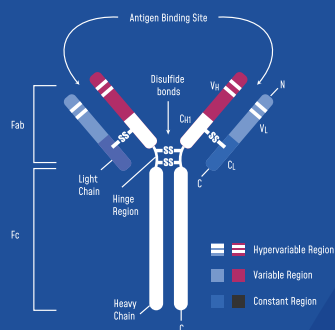
Amino acid sequence and variants

Glyco-variants

Charge variant

Cysteine variants

Primary Structure



Advanced Structure

Antibody Drug Characterization Service

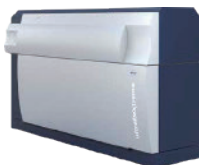
ANTIBODY DRUG CHARACTERIZATION	RESEARCH PROJECT	METHOD
Molecular Weight Determination	Intact molecular weight	ESI-Orbitrap MS /
	Light and heavy chain molecular weight	ESI-Orbitrap MS /MALDI-TOF MS
	Fab fragment and Fc fragment molecular weight	ESI-Orbitrap MS /MALDI-TOF MS
	ADC molecular weight and DAR value analysis	HPLC-MS
Protein Homogeneity Analysis	Peptide mapping (protein amino acid sequence confirmation)	LC-MS/MS
Other Analysis	Charge heterogeneity analysis	IEF/CE-IEF /cIEF
	Protein aggregation analysis	SEC/GPC
Modification Analysis	Disulfide bond analysis	LC-MS/MS
	Glycosylation analysis <ul style="list-style-type: none"> Glycan analysis Glycopeptide analysis 	MALDI-TOF / LC-MS/MS
	Phosphorylation analysis	LC-MS/MS
	Deamidation and oxidation	LC-MS/MS
Purity Analysis	Monomer and polymer purity analysis	SEC-HPLC
	Non-glycosylated heavy chain and small molecule fragments	SEC-HPLC / SDS-PAGE / CE-SDS
Binding Assay	Protein binding/inhibition analysis	ELISA (EC50, IC50)
	Cell binding/inhibition analysis	FACS (EC50, IC50)
Impurity Detection and Analysis	HCP assay	2D-DIGE / LC-MS/MS
	Host residual DNA detection	Real-time

Mass Spectrometry Platform at Creative Proteomics

Agilent 6530/6545 Q-TOF



Bruker AutoFlex MALDI TOF/TOF



Thermo LTQ Orbitrap Velos



Thermo Q-Exactive Orbitrap



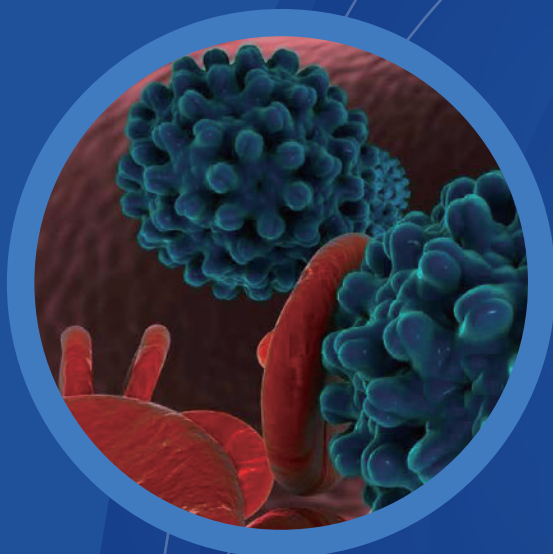
Thermo Q-Exactive Plus Orbitrap



Thermo Orbitrap Fusion



We Reserved In-depth Analytical Service Experiences in Biopharmaceuticals for



- ✓ Glycoprotein/Recombinant Proteins
- ✓ PEGylated Proteins
- ✓ Biosimilars
- ✓ Vaccines
- ✓ Therapeutic Enzymes
- ✓ Oligonucleotides
- ✓ Antibody Drug Conjugates (ADC)
- ✓ Antibodies
- ✓ Monoclonal Antibodies
- ✓ Bispecific Antibodies
- ✓ Fab Fragment
- ✓ Fusion Proteins

