Veeda™ Lifesciences

Streamlining Biotherapeutic Development: Analytics and Characterization Solutions

Overview

The analytics and characterization department at Biopharma Division of Veeda is a preferred solution partner for physico-chemical, structural characterization and analytical CMC support for broad range of biotherapeutics ranging from peptides, oligos, recombinant-conjugated-fusion protein, monoclonal antibodies (mAbs), bispecific, antibody (Ab) fragments, antibody-drug conjugates to biopolymers.

The state-of-the-art laboratory boasts of advanced technologies drawn from industry-standard providers with compliance-driven informatics. Right from high resolution mass spectrometers to HOS based technologies are run-of-the-mill for biotherapeutic characterization.

Product Characterization

- Primary Structure
- Higher-order Structure (HOS)

Analytical CMC

- Identity
- Purity
- Heterogeneity
- Variants
- Residuals
- Potency

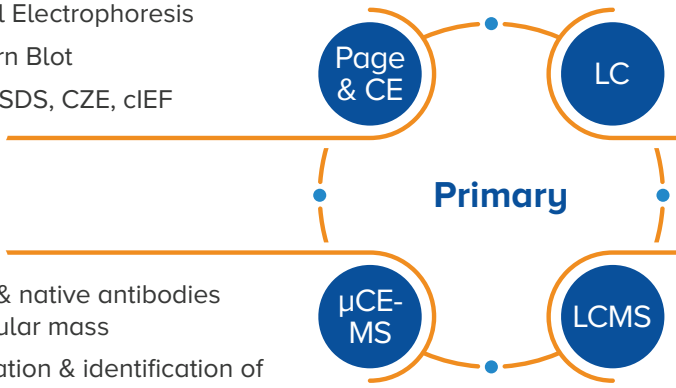
Highlights

- Advanced technologies with compliance-driven informatics
- Subject matter experts in HRMS and HOS platforms
- Audit-ready laboratories with adherence to DI principles
- Multiple modalities; ranging from peptides to oligo to mAbs and ADCs
- Supports method development, qualification and transfer to cGMP labs
- Recognized by DSIR, Ministry of Science and Technology, Government of India
- KOL in leading forums: BioProcess International, Wiley Analytical Science

Product Characterization- Primary Structure
Liquid Chromatography and Mass Spectrometry
Electrophoretic Mobility

- Native-PAGE and SDS-PAGE
- 2D Gel Electrophoresis
- Western Blot
- pI, CE-SDS, CZE, cIEF

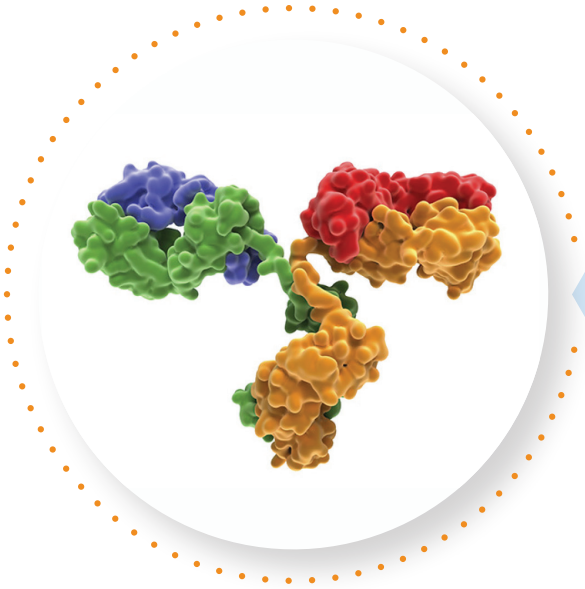
- Amino acid composition analysis
- Purity assay RP-HPLC
- Charge variant analysis by IEX-HPLC
- Size variant and aggregation analysis by SEC-HPLC
- Proteoform analysis by HILIC and HIC



- Intact & native antibodies molecular mass
- Separation & identification of charge variants
- Identification of metabolites
- Intact mass of oligonucleotides

- Intact/native molecular mass
- Subunit molecular mass
- Peptide mapping (PMF)
- Peptide sequencing analysis for coverage
- Disulfide mapping analysis
- Glycan analysis: N- and O- linked glycans
- Variant/impurity analysis

Monoclonal Antibody Characterization

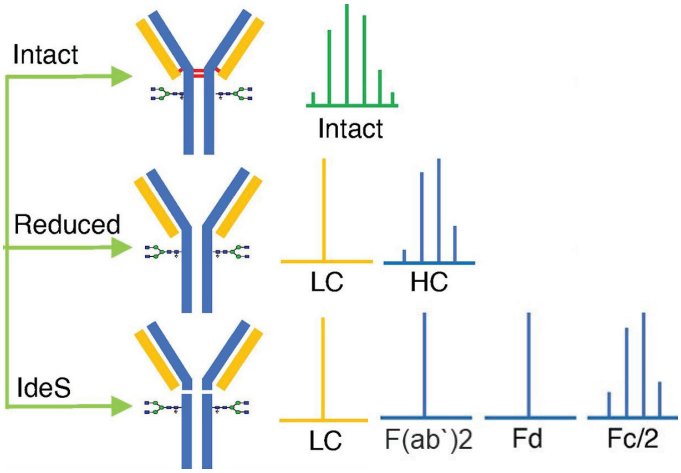


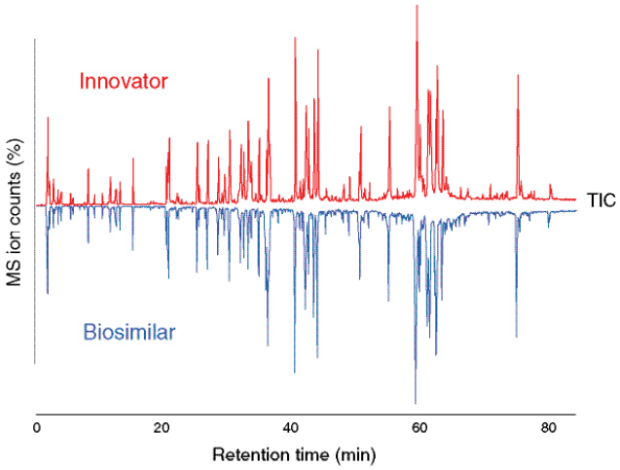
- Disulfide mapping (Native & Scrambled)
- Released N-glycan analysis

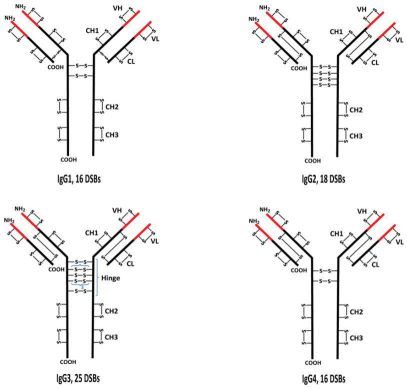
- Size variants (oligomers/aggregates)
- Charge variants (acidic/basic)
- Amino acid analysis
- Secondary & tertiary structure analysis
- Intrinsic & extrinsic fluorescence

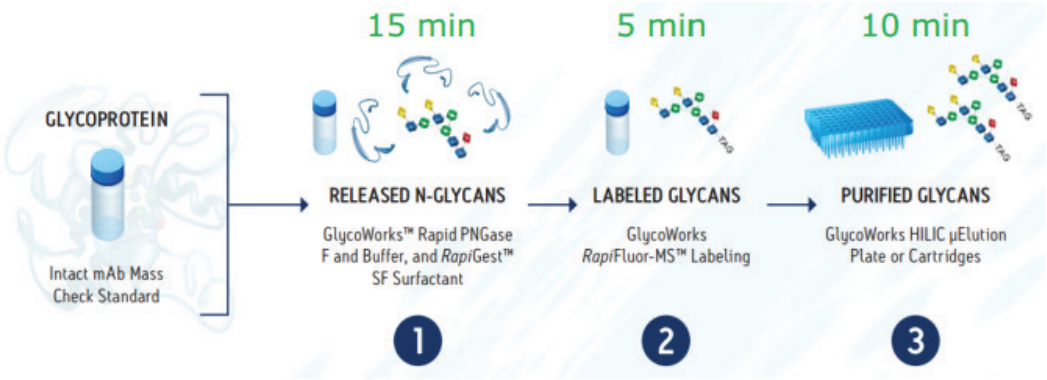
- Peptide mapping (MS)
- Peptide sequencing (MS/MS)
- Glycopeptide analysis
- Post-translational modifications
- Terminal sequencing (N/C Term)

- Intact mass
- Subunit mass [HC, LC, F(ab')2, Fd', Fc/2]









Expertise in monoclonal antibodies, fusion proteins, glycosylated proteins, peptides, in achieving 100% sequence coverage with dual and/or multi-enzyme based methods, Expertise in disulfide linkage assessment in mAbs, proteins, cyclic peptides (Linaclotide etc), Established release N-glycan analysis for all monoclonal antibodies and glycosylated proteins. Supported with labelled NIST mAb standard for system and method suitability, biosimilarity comparability and assessments.

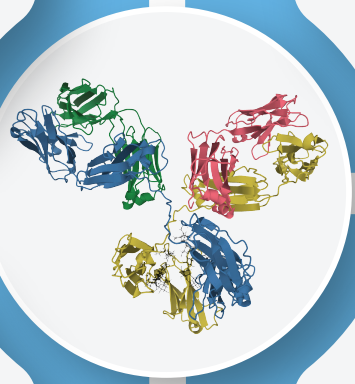
Product Characterization- Higher-order Structure (HOS) Spectroscopy, Calorimetry, Light Scattering

Secondary Structure

Alpha helix, beta sheets, loops, turns; qual & quan

Tertiary Structure

R-group interactions such as ionic & hydrogen bonds, disulphide bridges, hydrophobic & hydrophilic interactions



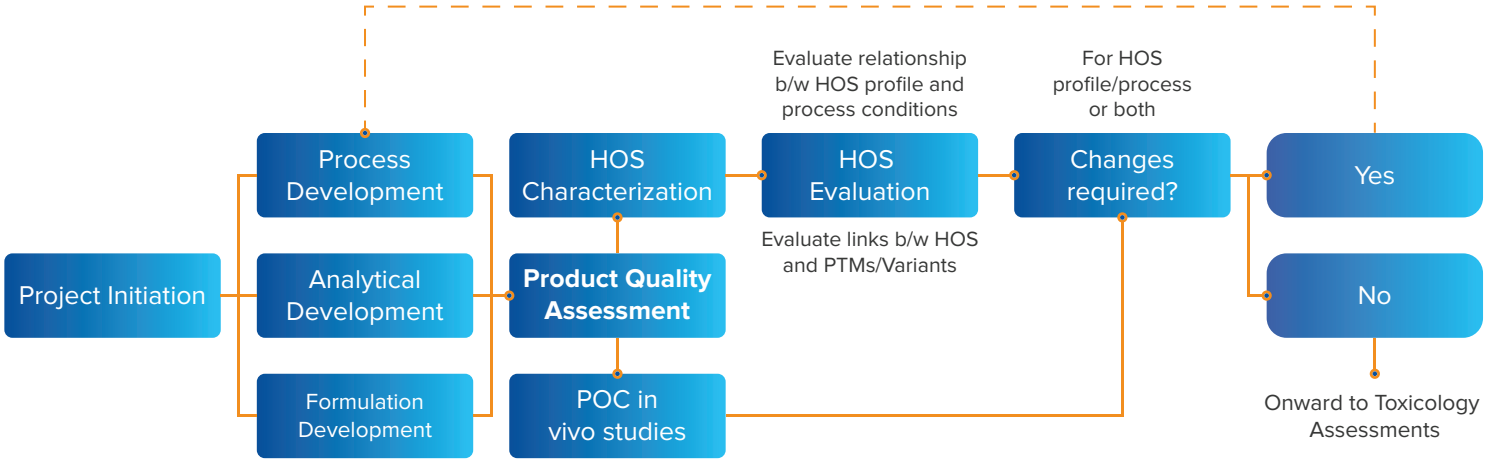
Quaternary Structure

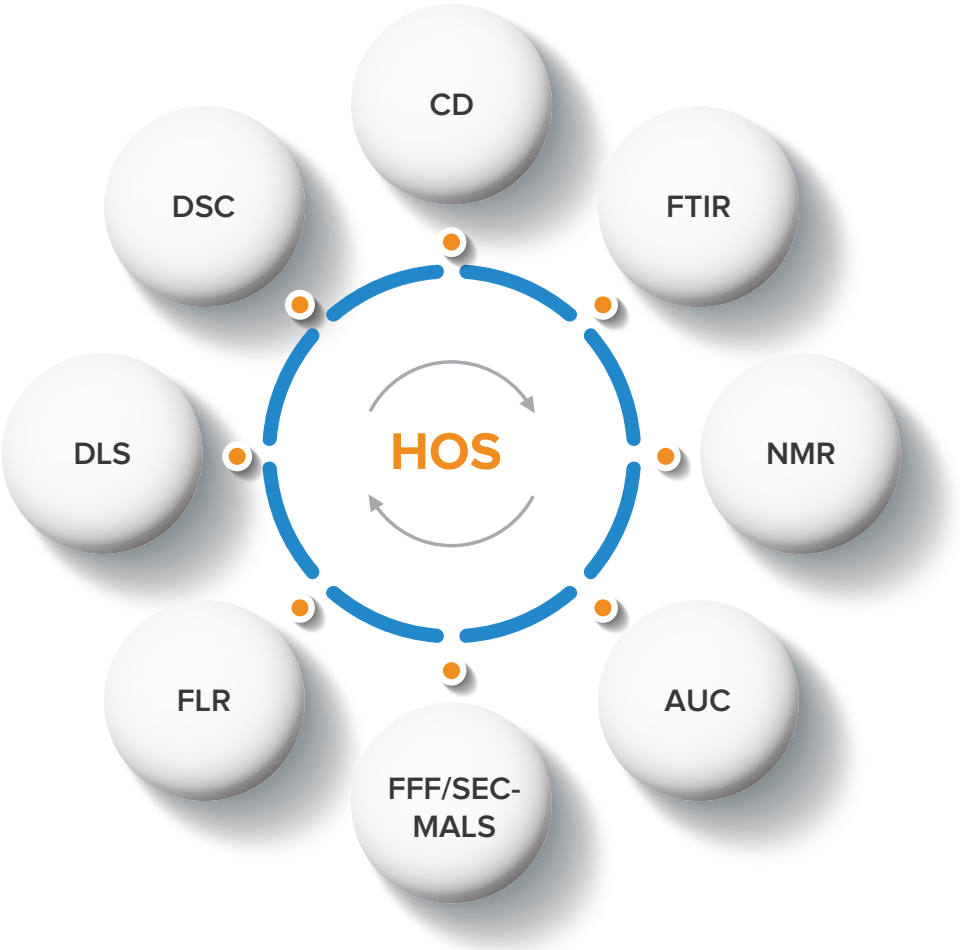
Multi-protein complex such as dimer, trimer and more complex multi-protein subunit systems

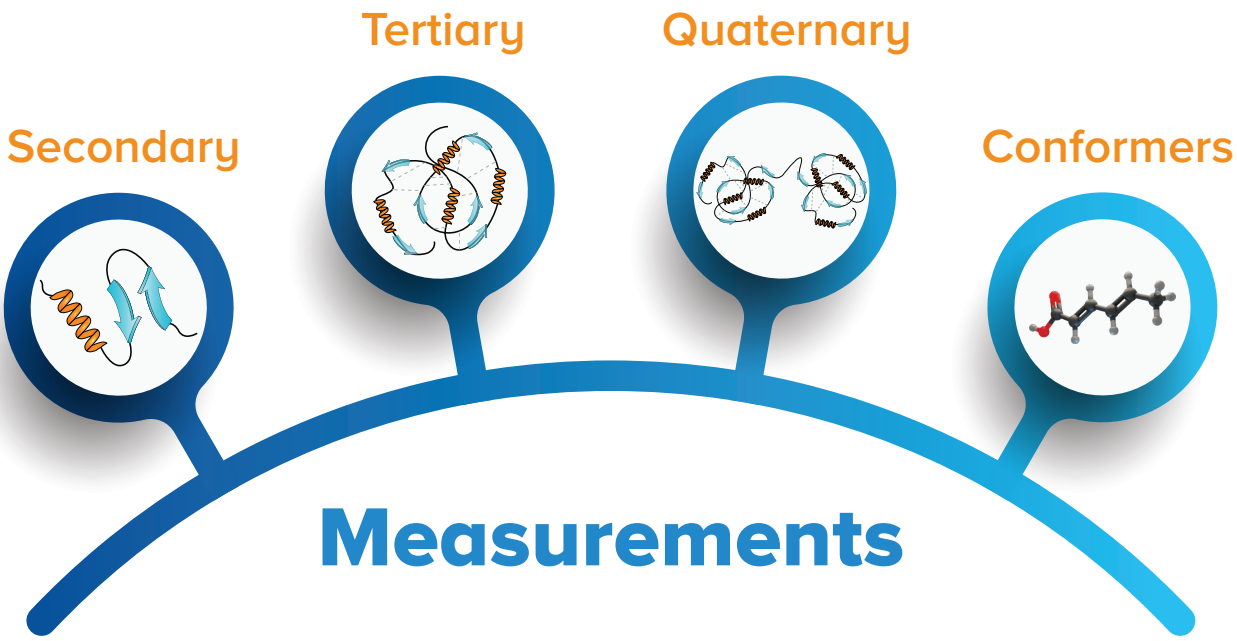
Protein Conformers

Change in structure due to PTMs / variants generated during process or product related

Typical Development Path in Biotherapeutics for HOS Monitoring




CD
DSC
FTIR
DLS
HOS
NMR
FLR
AUC
FFF/SEC-
MALS


Tertiary
Quaternary
Secondary
Conformers
Measurements

Analytical CMC Services
Analytical Support to Cell, Process and Formulation Development | Drug Substance & Drug Product Testing

Cell Line / Clone Selection
- Protein sequence
- Sequence variants characterization
- PTM analysis
- Glycosylation analysis
- de novo sequencing

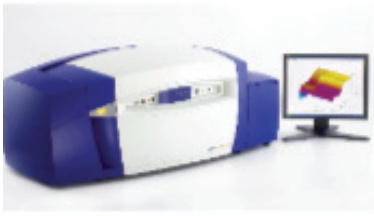
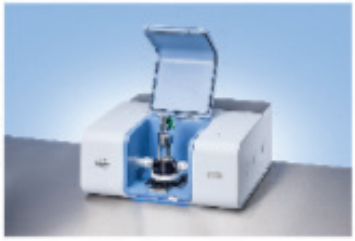
Upstream
- Harvest titers
- Identity
- Purity
- Glycosylation analysis
- PTM analysis

Downstream
- Size/charge variants
- Refolding efficiency
- Identity
- Purity
- Heterogeneity
- Impurity
- N-/O-glycans
- Residuals (HCD, HCP, rProA)
- Potency

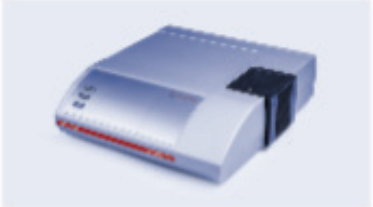
Formulation
- PTM quantification
- Monitoring degradation

Drug Substance & Drug Product (DS & DP)
- DS & DP Testing:
  - Identity
  - Purity
  - Heterogeneity
  - Intact mass
  - Peptide map
  - Glycan analysis
  - Residuals
  - Potency

State-of-the-Art Analytical Technologies



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Excellence In Everything