

# 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

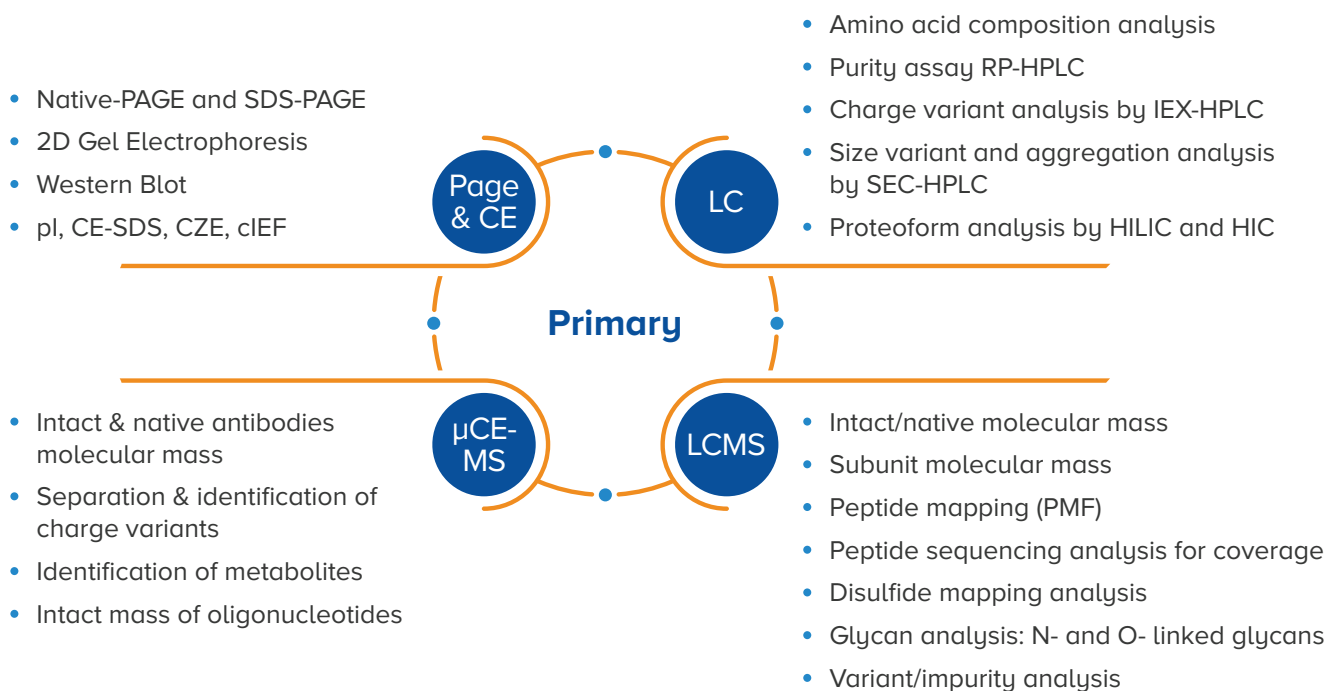
Potency

# Highlights

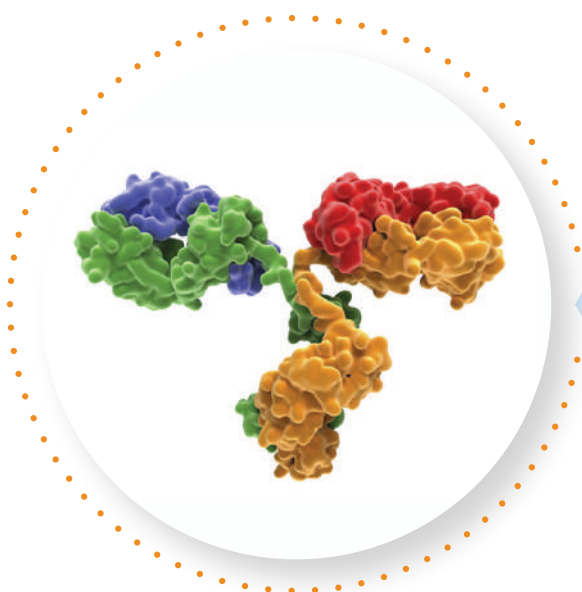
- Advanced technologies with compliance-driven informatics
- Subject matter experts in HRMS and HOS platforms
- Audit-ready laboratories with adherence to DI principles
- Multiple modalities; ranging from peptides to oligo to mAbs and ADCs
- Supports method development, qualification and transfer to 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

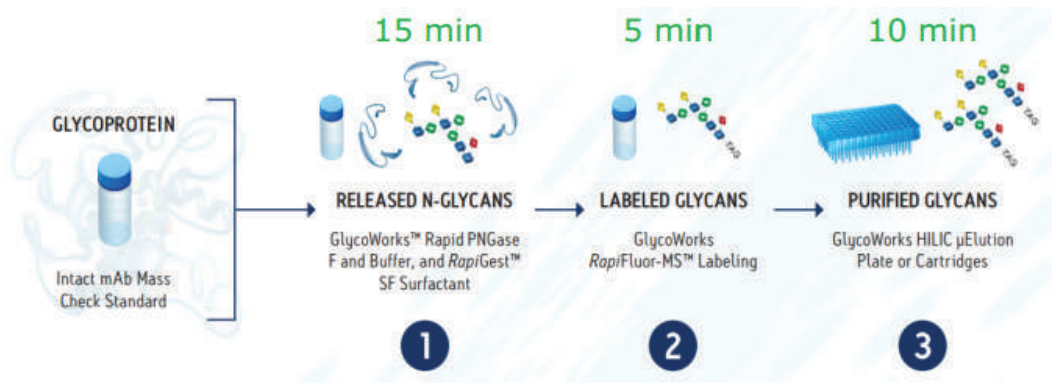
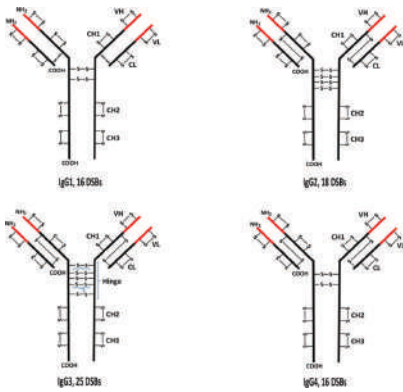
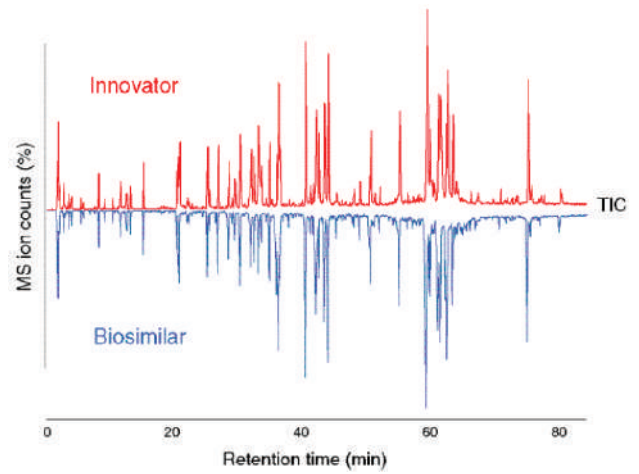
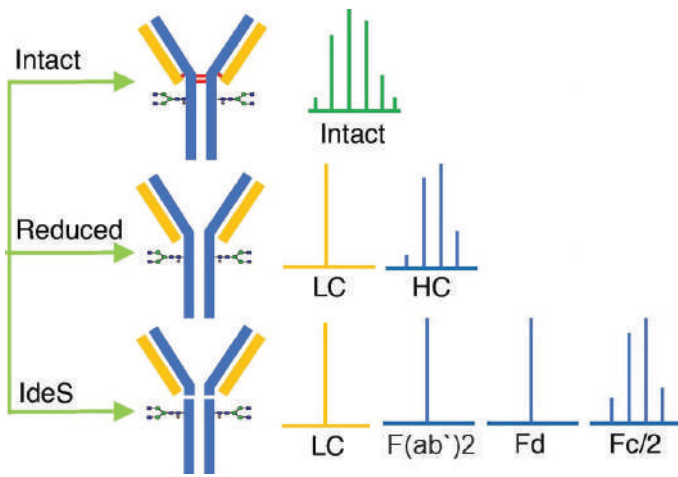


## Monoclonal Antibody Characterization



- 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')<sub>2</sub>, 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

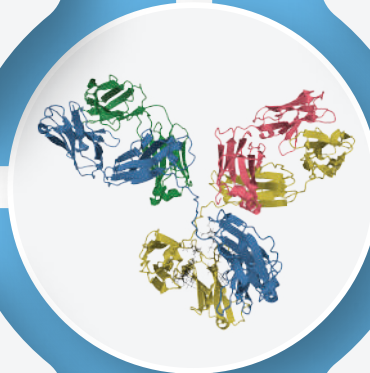
R-group interactions such as ionic & hydrogen bonds, disulphide bridges, hydrophobic & hydrophilic interactions

### Quaternary Structure

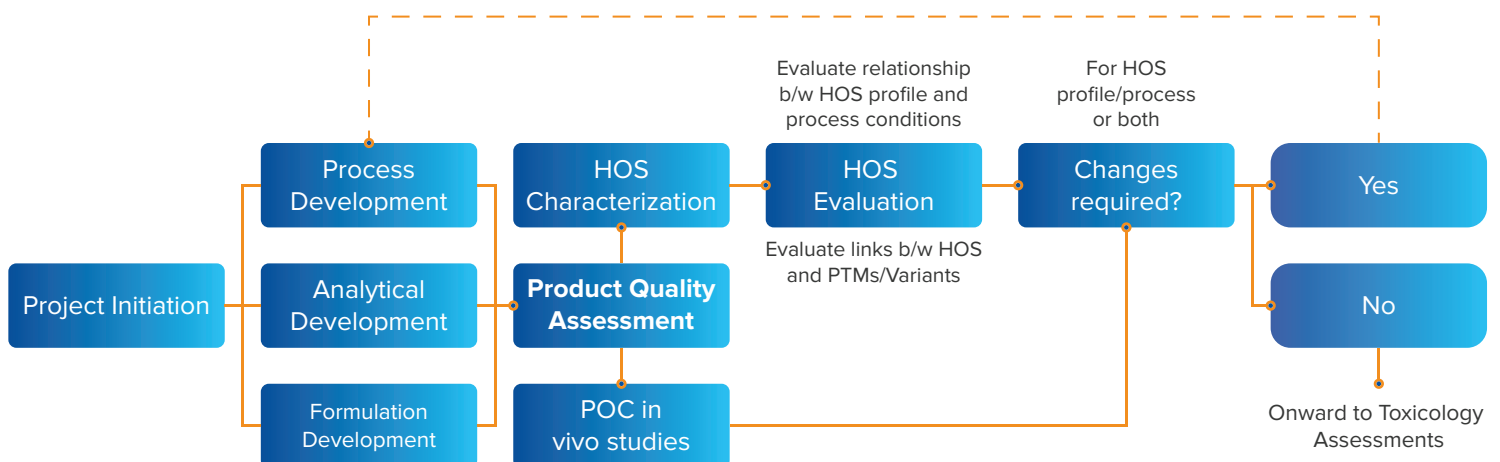
Multi-protein complex such as dimer, trimer and more complex multi-protein subunit systems

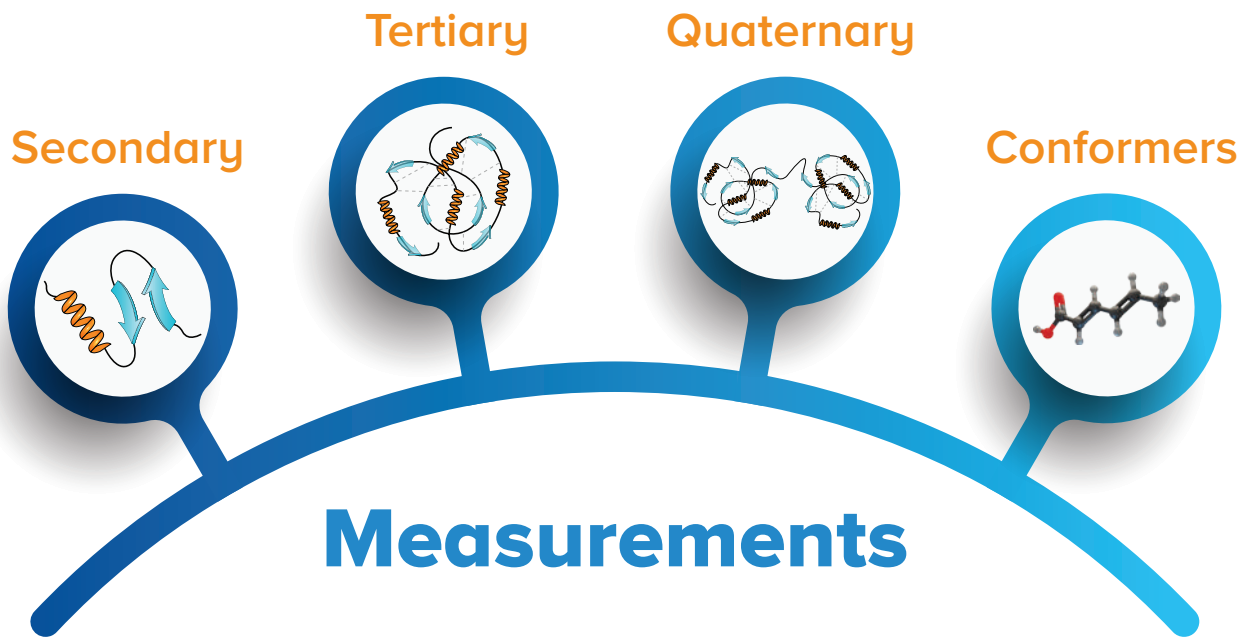
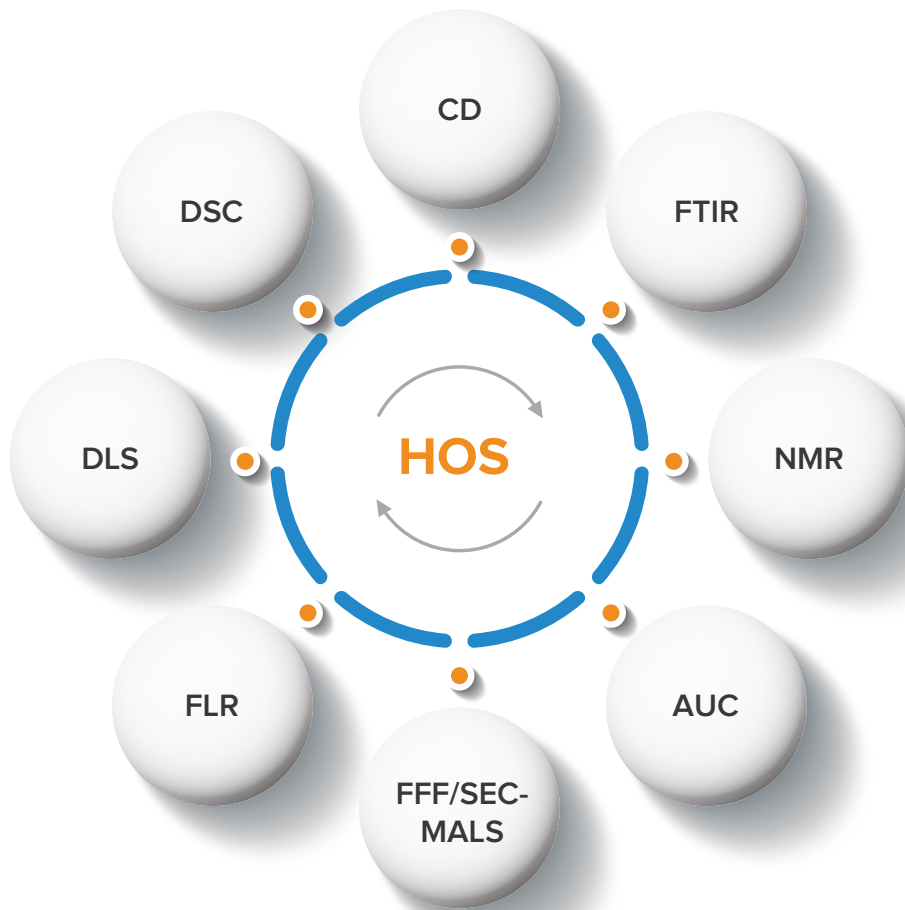
### Protein Conformers

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



## Typical Development Path in Biotherapeutics for HOS Monitoring

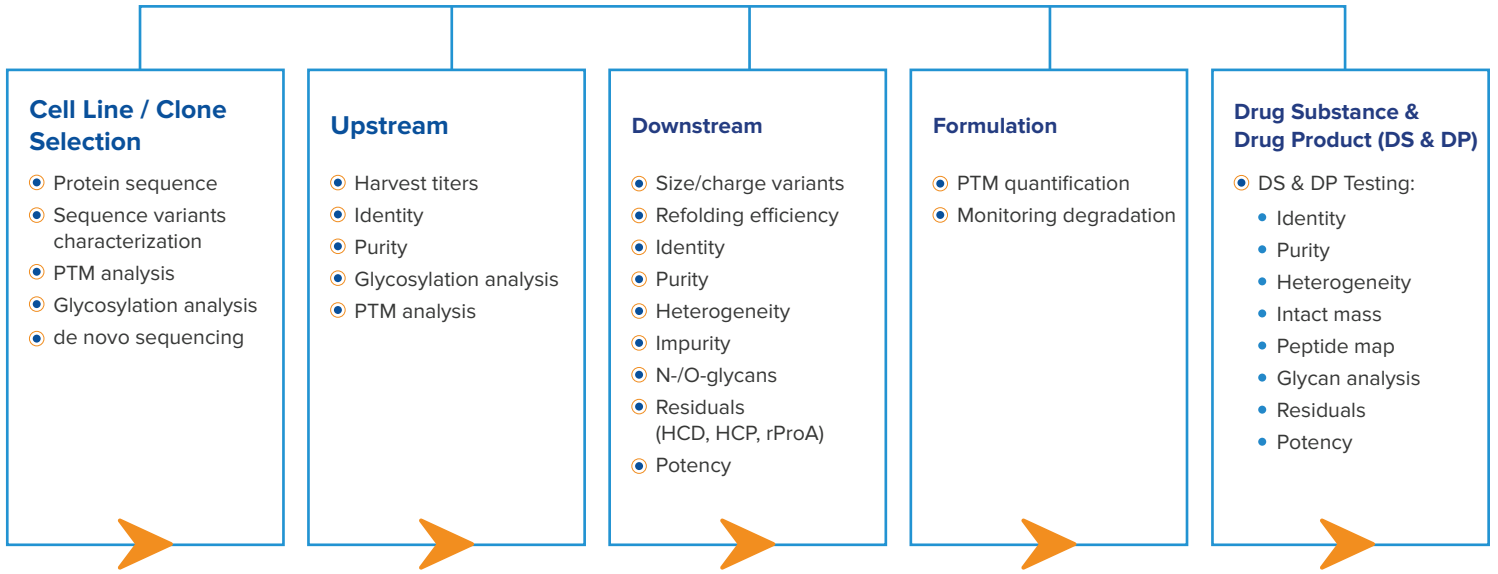






# Analytical CMC Services

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



# State-of-the-Art Analytical Technologies



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