# Veeda Group

# A Capable, Knowledgeable & Reliable Partner for your Drug Development Programs

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# Corporate Overview

# Veeda Group

- Veeda Clinical Research Limited (“Veeda”) together with its subsidiary, Bioneeds India Private Limited (“Bioneeds”), and Heads, a privately held European CRO (“Heads”), (together referred to as the “Veeda Group”) offers a comprehensive portfolio of clinical, preclinical and bio/analytical services to support innovator, biosimilar and generic drug development programs of our global clientele

- We are an independent, institutional investors owned, board governed and professionally managed contract research group offering scientific leadership, global quality management systems and long term operational and financial stability through a continuing investment in our people, processes, systems, infrastructure and technology and a deep commitment to quality

- Together, we serve clients globally in the following industries:
  - Pharmaceutical and Biopharmaceutical
  - Agrochemical and Industrial Chemicals
  - Herbal/Nutraceuticals
  - Medical Devices

# Purpose, Vision and Mission

## Purpose

*Partners in creating a healthier tomorrow:*

**We contribute to the quality of healthcare for the society by enabling pharma companies to develop and bring high quality medicines to the market – with accuracy, speed and cost efficiency**

## Vision

**In an industry where innovation is increasingly multifaceted and collaborative, we aspire to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide for their critical product development programs**

## Mission

**To be the pre-eminent independent Indian contract research organization, with global execution capabilities, distinguished by the breadth of our services and by excellence in the quality of our: Scientific and regulatory knowledge; Research design, execution and insights; and Client centricity**

# Strategic Merger

## Creating Value for Customers Globally

### Providing Integrated Solutions under Veeda Group

**Holistic Expertise**

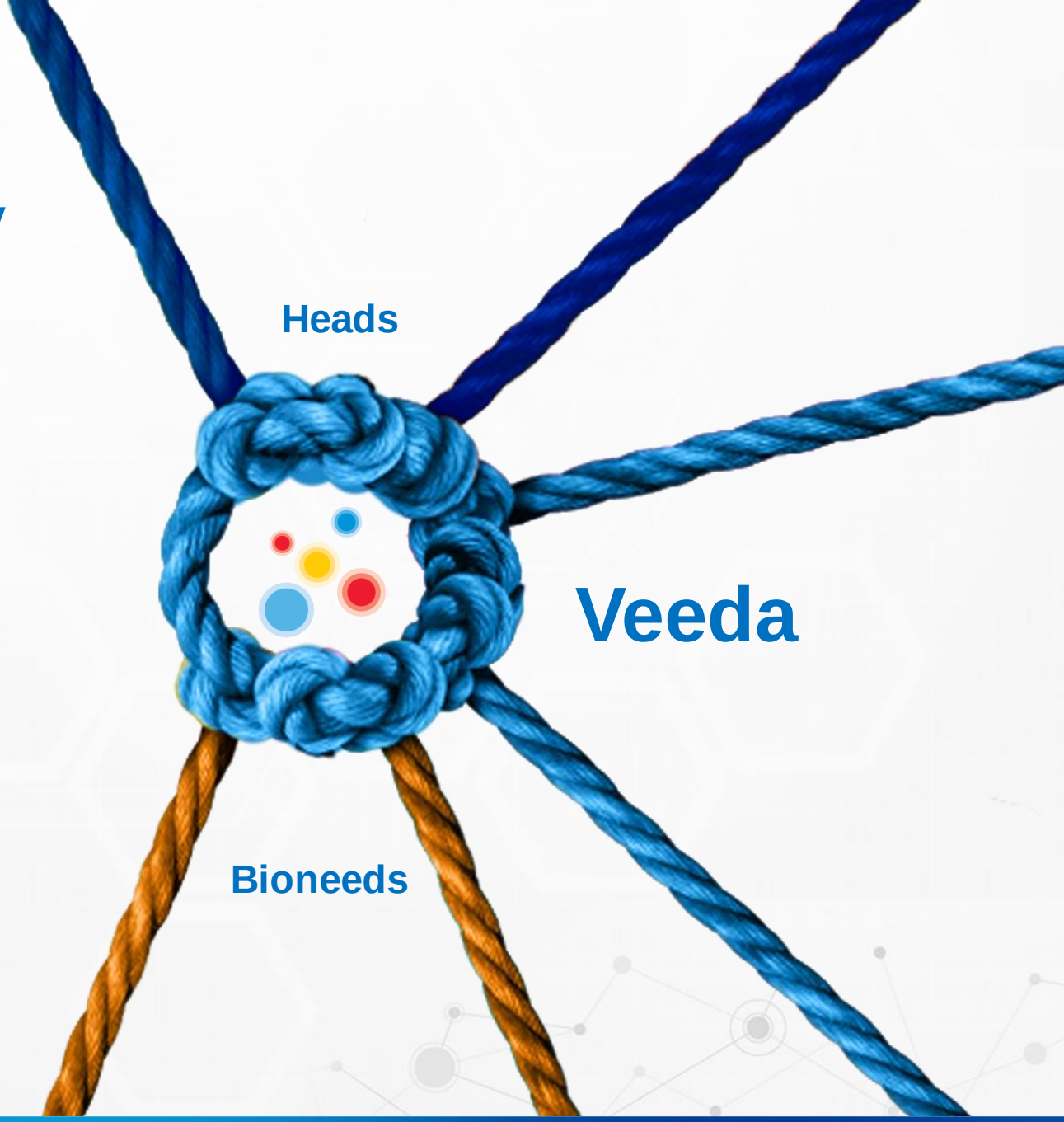
**Innovative Treatments Focus**

**Global Presence**

**Strong KOL Network**

**We are now a Team of 2000+, ensuring Quality, Speed, and Efficiency**

Expanded execution capabilities across 26 Geographies Globally



# Progression towards an Integrated Contract Research Organization

Continue to add more capabilities thereby progressing towards becoming a 'Full Service CRO'

| | Early stage | | | | Mid Stage | | Late Stage | | Generics/ Biosimilars | | Bioanalytical | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Discovery Services | Chemistry | Bioanalysis | Toxicology | Phase I | Phase II | Phase III | PV/ RWE | HVS | Patient Based | Small Molecule | Biologics | Biosimilars |
| 2015 | | | | | ✓ | | | | ✓✓ | ✓ | ✓✓ | | |
| 2020 | | | | | ✓ | ✓ | | | ✓✓ | ✓ | ✓✓ | | |
| 2021 | ✓ | ✓ | ✓ | ✓✓ | ✓ | ✓ | | | ✓✓ | ✓✓ | ✓✓ | | ✓ |
| 2024 | ✓ | ✓ | ✓ | ✓✓ | ✓✓ | ✓✓ | ✓✓ | ✓✓ | ✓✓ | ✓✓ | ✓✓ | ✓ | ✓✓ |

Bioneeds heads Veeda

# Veeda's growth trajectory is clear and visible

Value

## Earlier

### Indian CRO

- ✓ Expertise in **Pre-clinical, Early phase clinical** and **Bioanalytical** studies for small molecules
- ✓ Large multi-site infrastructure across India catering to Global Clients
- ✓ **Global accreditations** with a long inspection history

## Now

### Global CRO

- ✓ Added expertise in **Late stage clinical, Global Trials** for **large molecules**
- ✓ Working relationship with **large biopharma companies** and **access to KOL's** across multiple countries
- ✓ **Enhanced management breadth** and **depth**
- ✓ **2000+ employees globally**

## Next

### Data and Tech-Driven CRO

- ✓ Become the preferred new-age CRO with **data and technology** as the **cornerstone**
- ✓ **Perfect the "Buy & Build" strategy** to expand portfolio of Data Cos & CROs across markets of interest
- ✓ Design and execute tailored **analytical strategies** for oncology drug development programs
- ✓ Prioritize the application of the **3R principles** in pre-clinical research

# Management Team

## Board of Directors

**Dr. Mahesh Bhalgat**
*Group CEO and MD, Veeda Group,*
25+ years

**Mr. Nirmal Bhatia**
Group CFO
30+ years

**Dr. Kiran Marthak**
*Director, Medical and Regulatory Affairs* 35+ years

**Mr. Ajay Tandon**
CEO, India| 27+ years

**Mr. George Kouvatseas**
CEO, Europe (HeaDS)

**Dr. SN Vinaya Babu**
CEO, Preclinical | 20+ years

**Dr. Venu Madhav**
Chief Quality Officer
25+ years

**Dr. Pranav Dalal**
Chief Technology Officer
25+ years

**Dr. Sanjib Banerjee**
*COO, Biopharma* |20+ years

**Dr. Sivakumar V.**
*COO, CT India*

**Dr. Nitin M Shetty**
COO, Preclinical | 30+ years

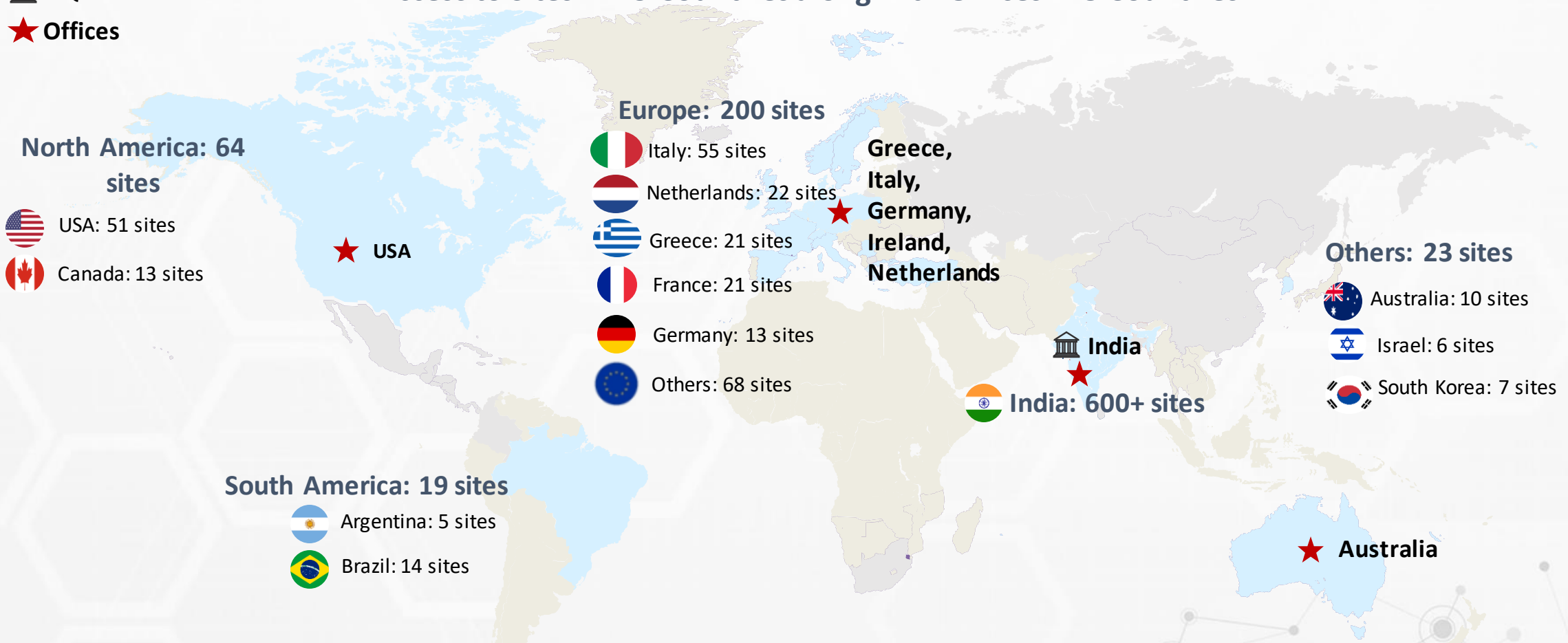
# Global Network of Partnered Sites…

950+ sites worldwide, offering access to diverse patient pool, KOL network, and multi-center study capability

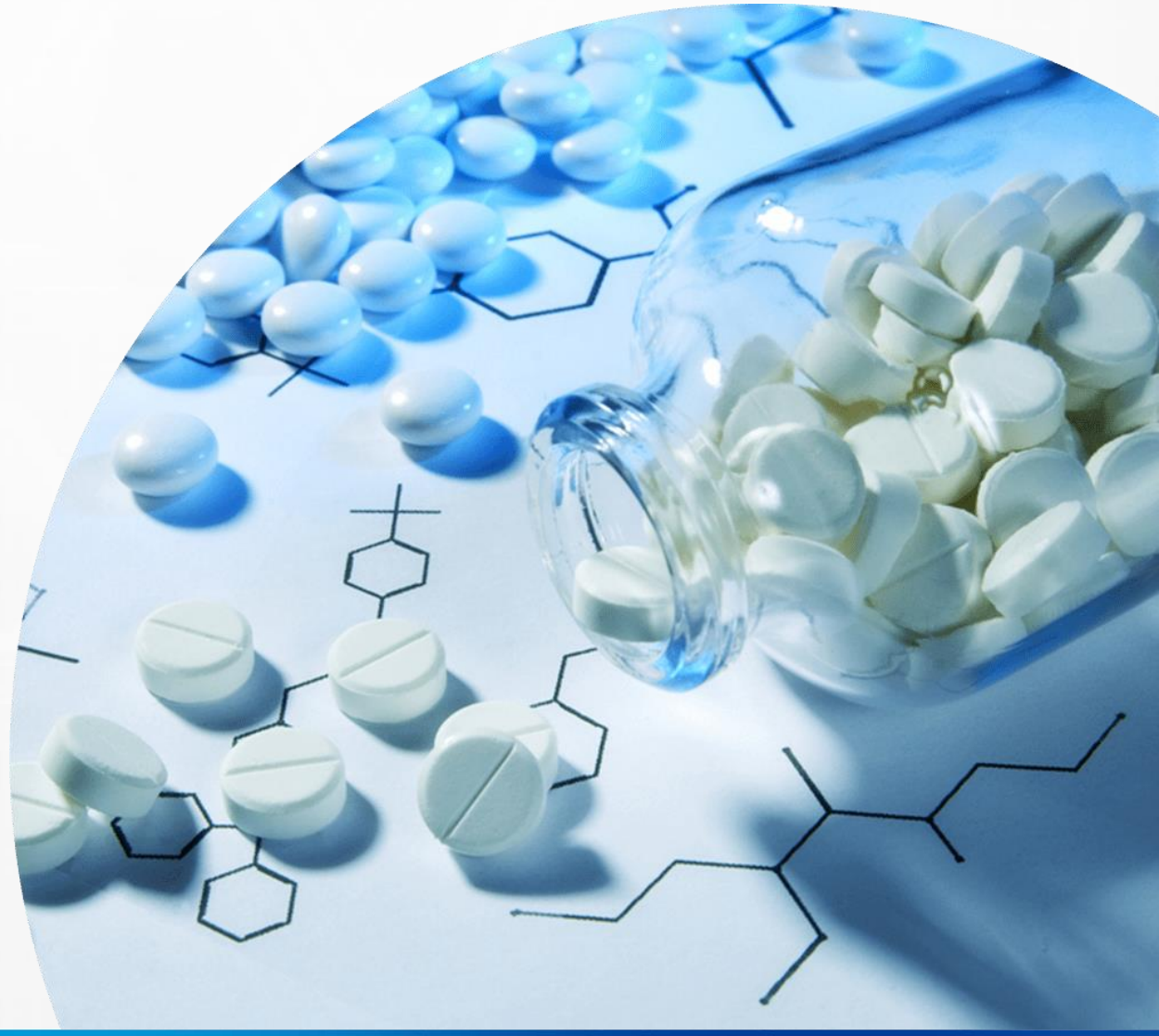
HQ

Offices

## Access to Sites in 25 Countries along with Offices in 8 Countries



# Biopharma Solutions



# Biopharma Solutions – At a Glance


ADC, mAbs (bispecific, Ab fragments), Fusions/Conjugated Proteins, Peptides, Biopolymers, Oligos

**NCE | NBE | Biosimilars | Vaccines**

**Discovery**
(Assay Biology | DMPK)

**Development**
(Cell line | Upstream | Downstream)

**Analytical**
Structural| Functional

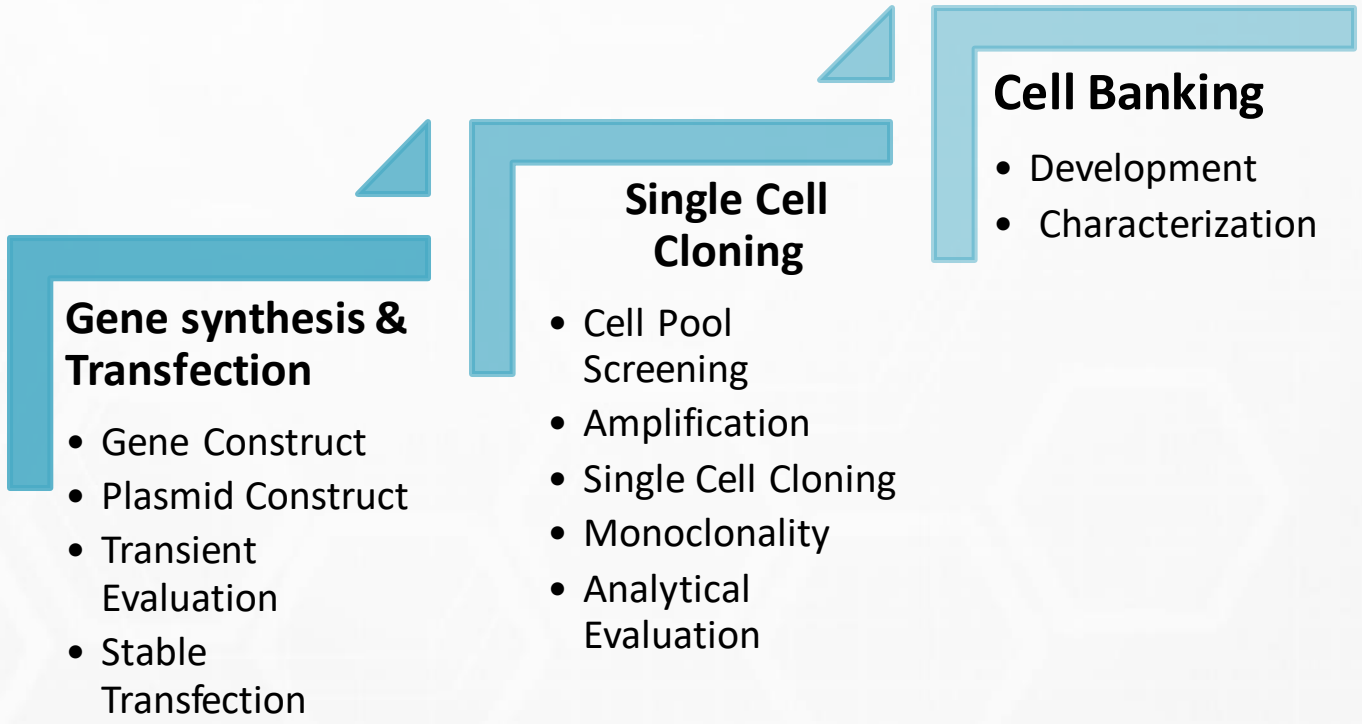
**Manufacturing**
(Lab Scale – 2L & 5L)

**Clinical Bioanalysis**
(PK, PD, ADA, NAb)

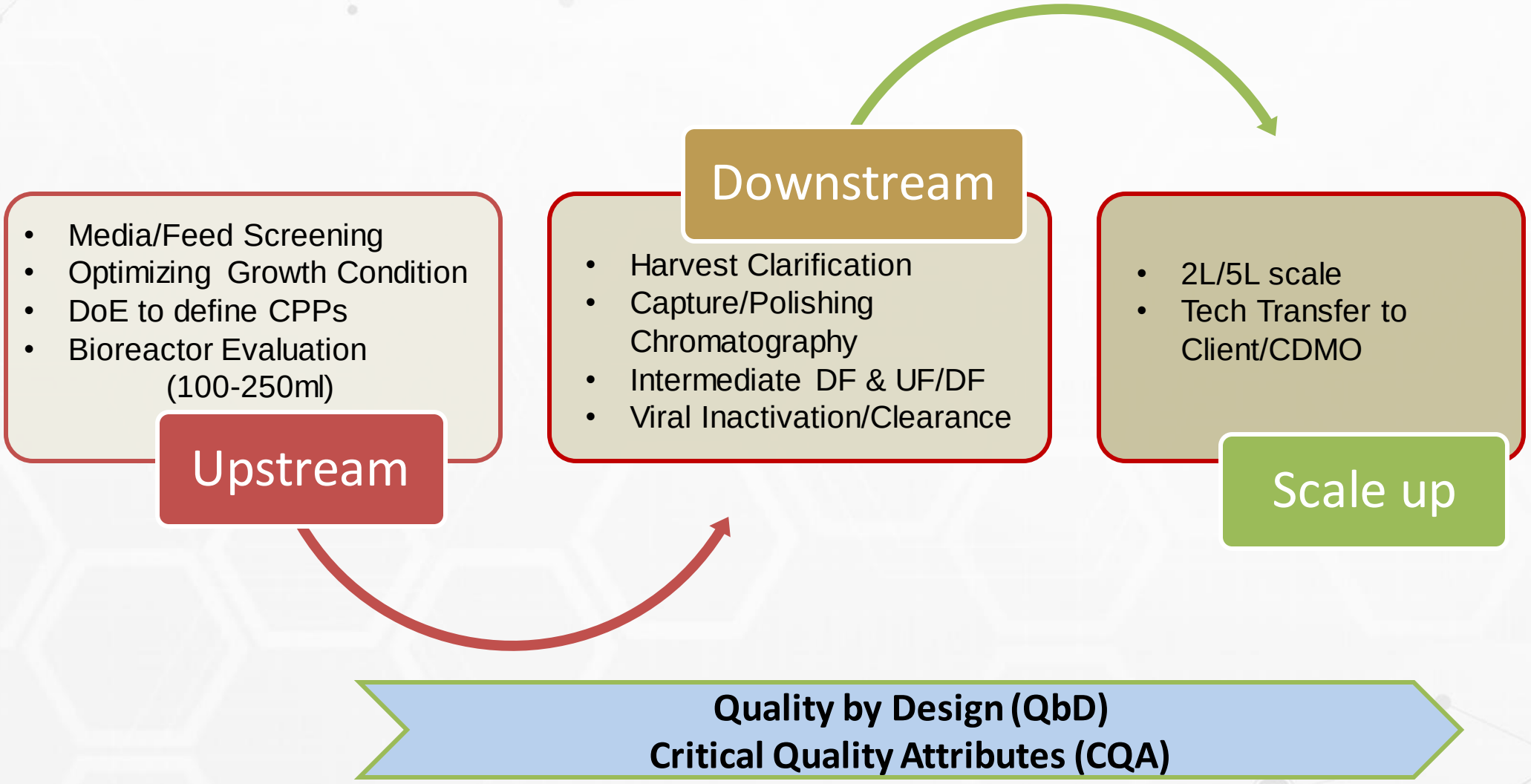
**One Stop Solution | Integrated | Standalone**

# Cell Line Development

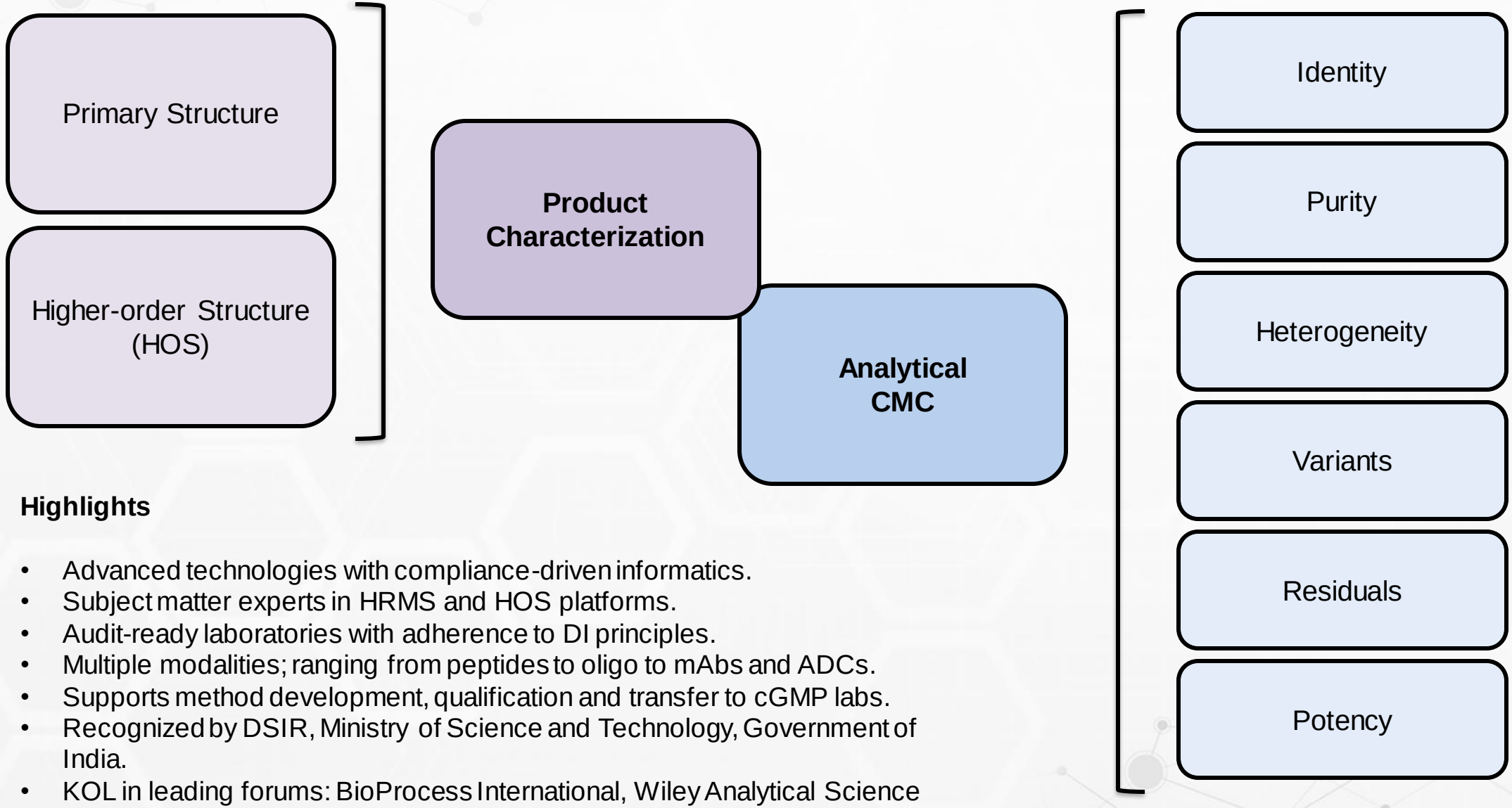
- **Host Cell**
  - Mammalian - CHO, HEK
  - Bacterial - E. *coli*
- **Performance**
  - High Titer, > 5 gm/liter
  - CQA based Quality Assessment
- **Compliance**
  - Traceability
  - Evidence of Monoclonality
- **Gene to Clone**
  - 6-9 months
- **Expert Team**
- **In-house developed four clones**
  - Adalimumab, Trastuzumab, Denosumab, Bevacizumab



# Process Development



# Structural Characterization

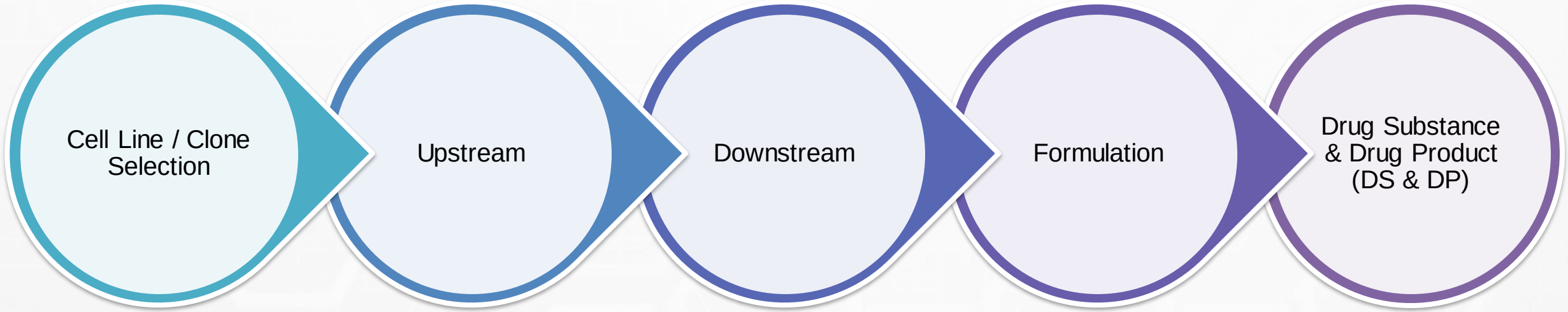



**Highlights**

- 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

# Structural Characterization

**Biosimilarity Assessment across product life cycle starting from Cell Line Development till Drug Product**




- Protein sequence
- Sequence variants characterization
- PTM analysis
- Glycosylation analysis
- *de novo* sequencing

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

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

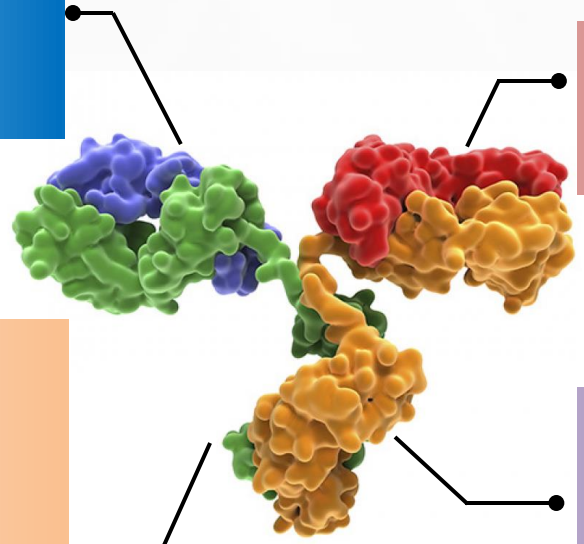
- PTM quantification
- Monitoring degradation

- Identity
- Purity
- Heterogeneity
- Intact mass
- Peptide map
- Glycan analysis
- Residuals
- Potency

# Structural Characterization

## Monoclonal Antibody Characterization for Regulatory Submission

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



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

- Peptide mapping (MS)
- Peptide sequencing (MS/MS)
- Glycopeptide analysis
- Post-translational modifications
  - Pyroglutamation
  - Oxidation
  - Deamidation
  - Terminal Lysine Clipping
  - Truncations & more
- Terminal sequencing (N/C Term)

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

# State-of-the-Art Infrastructure

**Compliance-driven high resolving & sensitive technologies exclusive for global standard characterization.**
Instruments used in data submissions to regulators: FDA, EMA, MHRA, India, ROW

| Category | Technology | Key Differentiator in Analytical Characterization Methodologies |
|---|---|---|
| **LCMS/HRMS** | Waters Acquity Premier - Xevo G3 QTof | Specialized for **automated** N-glycans, MAM and primary structure analysis |
| | Nexera – Thermo QExactive (Orbitrap) | Global standard for PTM and sequence variant monitoring in biosimilars |
| **µCE-MS** | 908 Devices ZipChip | Quick, robust and **on-the-fly CE-MS** analysis for process samples, available only with Veeda as commercial services. |
| **HPLC** | Shimadzu Prominence | Multi-verse chromatography platform: RP, SEC, IEX, HILIC & HIC methods |
| **CE** | Sciex PA800 Plus | Equipped with UV and PDA for CGE, CZE and cIEF methods (pharmacopeial) |
| **CD** | Applied Photophysics Chirascan V100 | Highly sensitive and resolving HOS instrument, equipped with compare mode |
| **FTIR** | Bruker Invenio S (Confocheck) | **BioATR** for secondary structure of biologicals and quantification feature |
| **SEC/FFF-MALS** | Postnova AF2000 – UV/RI/MALS | **21-angle** MALS for Mega Dalton analysis connected to built-in SEC and FFF, orthogonal to AUC |
| **DSC** | TA nanoDSC | **Low sample volume** with nano features with temperature controls |
| **DLS** | Anton Paar Litesizer 500 | **Six parameters** for particle size measurements |
| **PAGE, WB** | BioRad GelDoc XR+, Protean i12 IEF cell | Established gel-based electrophoresis systems |

Compliance: ALCOA++, User licences, Audit-trail enabled, 21 CFR Part 11 compliant, CSV, GxP Compliant

# Expertise on Molecule Modalities

| # | Analytical Characterization | Molecules |
|---|---|---|
| 1 | Physico-chemical (Primary structure)<br>• Intact & subunit mass<br>• Peptide mapping & sequencing<br>• Terminal sequencing<br>• Disulfide mapping<br>• Glycopeptide analysis<br>• N-linked & O-linked glycan analysis | Dupilumab, Infliximab, Ustekinumab, Emicizumab (bispecific), Trastuzumab, Bevacizumab, Tocilizumab, Adalimumab, Pembrolizumab, Pertuzumab, Denosumab, Influenza vaccine, Galsulfase (fusion),<br><br>Linaclotide, Pancreatic Lipase, Tirzepatide, Oligonucleotide |
| 2 | Higher-order Structure (HOS)<br>• Secondary & tertiary structure by CD spectroscopy | Pembrolizumab, Pertuzumab, Denosumab, Insulin, Insulin Analogs |
| 3 | Electrophoretic Mobility<br>• cIEF<br>• µCE-MS | Tirzepatide, NIST mAb, Trastuzumab (native and stressed) |
| 4 | HOS<br>• Secondary structure by FTIR<br>• Stability by DSC and DLS<br>• Aggregation by SEC/FFF-MALS | Demo data/POC available for peptide, protein and mAbs |

# Structural Characterization - Peptides

- Insulin
- Insulin Analogues
- Linaclotide
- Liraglutide
- Semaglutide
- Glatiramer Acetate

Molecular weight determination

Peptide mapping

Peptide sequencing

Subunit analysis (A & B chain)

pI, Heterogeneity analysis

Disulfide analysis

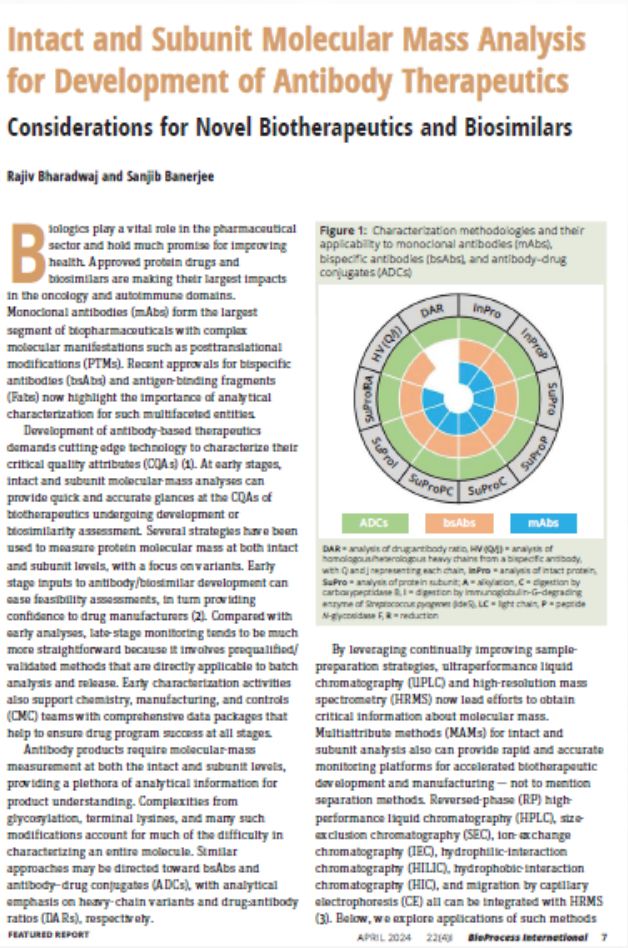
Impurity identification

Impurity characterization

RS method development (related substances)

CD, FTIR, DSC, DLS, SEC/FFF MALS

# Publications

## Intact and Subunit Molecular Mass Analysis for Development of Antibody Therapeutics

### Considerations for Novel Biotherapeutics and Biosimilars

Rajiv Bharadwaj and Sanjib Banerjee

Biologics play a vital role in the pharmaceutical sector and hold much promise for improving health. Approved protein drugs and biosimilars are making their largest impacts in the oncology and autoimmune domains. Monoclonal antibodies (mAbs) form the largest segment of biopharmaceuticals with complex molecular manifestations such as posttranslational modifications (PTMs). Recent approvals for bispecific antibodies (bsAbs) and antigen-binding fragments (Fabs) now highlight the importance of analytical characterization for such multifaceted entities.

Development of antibody-based therapeutics demands cutting-edge technology to characterize their critical quality attributes (CQAs) (1). At early stages, intact and subunit molecular-mass analyses can provide quick and accurate glances at the CQAs of biotherapeutics undergoing development or biosimilarity assessment. Several strategies have been used to measure protein molecular mass at both intact and subunit levels, with a focus on variants. Early stage inputs to antibody/biosimilar development can ease feasibility assessments, in turn providing confidence to drug manufacturers (2). Compared with early analyses, late-stage monitoring tends to be much more straightforward because it involves prequalified/validated methods that are directly applicable to batch analysis and release. Early characterization activities also support chemistry, manufacturing, and controls (CMC) teams with comprehensive data packages that help to ensure drug program success at all stages.

Antibody products require molecular-mass measurement at both the intact and subunit levels, providing a plethora of analytical information for product understanding. Complexities from glycosylation, terminal lysines, and many such modifications account for much of the difficulty in characterizing an entire molecule. Similar approaches may be directed toward bsAbs and antibody–drug conjugates (ADCs), with analytical emphasis on heavy-chain variants and drug-antibody ratios (DARs), respectively.

Figure 1: Characterization methodologies and their applicability to monoclonal antibodies (mAbs), bispecific antibodies (bsAbs), and antibody–drug conjugates (ADCs)




DAR = analysis of drug:antibody ratio, HV (Q/J) = analysis of homologous/heterologous heavy chains from a bispecific antibody, with Q and J representing each chain, InPro = analysis of intact protein, SuPro = analysis of protein subunit; A = alkylation, C = digestion by carboxypeptidase B, I = digestion by immunoglobulin-G–degrading enzyme of Streptococcus pyogenes (IdeS), LC = light chain, P = peptide N-glycosidase F, R = reduction

By leveraging continually improving sample-preparation strategies, ultraperformance liquid chromatography (UPLC) and high-resolution mass spectrometry (HRMS) now lead efforts to obtain critical information about molecular mass. Multiattribute methods (MAMs) for intact and subunit analysis also can provide rapid and accurate monitoring platforms for accelerated biotherapeutic development and manufacturing — not to mention separation methods. Reversed-phase (RP) high-performance liquid chromatography (HPLC), size-exclusion chromatography (SEC), ion-exchange chromatography (IEC), hydrophilic-interaction chromatography (HILIC), hydrophobic-interaction chromatography (HIC), and migration by capillary electrophoresis (CE) all can be integrated with HRMS (3). Below, we explore applications of such methods



WILEY Analytical Science

Article | Bioanalysis Spectroscopy Separation 4 April 2024

## Enabling ultrafast characterization of mAbs - The ZipChip precision

Rapid characterization of glyco-proteoforms and charge variants in mAb using µCE-MS platform

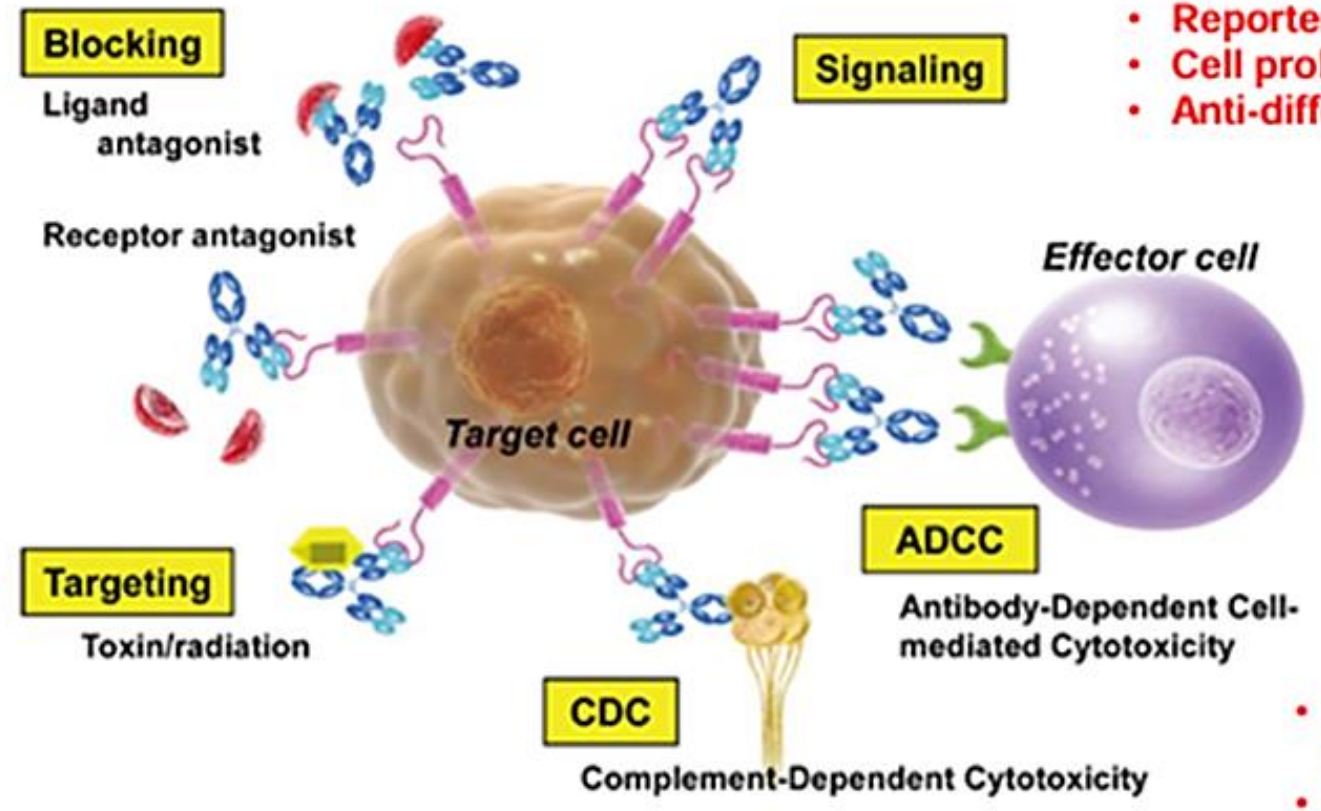
Jothi Prabha, Suryakant Kumar, Varun Eranna, Rajiv Bharadwaj, Sanjib Banerjee

©Image courtesy of Biobeams and 908devices

# Functional Characterization

## Common MOAs and Potency Assays for Therapeutic Antibodies

- Binding assay




- Receptor phosphorylation
- Reporter gene assay
- Cell proliferation
- Anti-differentiation

- Cytotoxicity assay

- Surrogate FcγIIIa or C1q binding
- Cell-based ADCC or CDC assays

Suzuki M, Kato C and Kato A, J Toxicol Pathol 2015; 28: 133–139

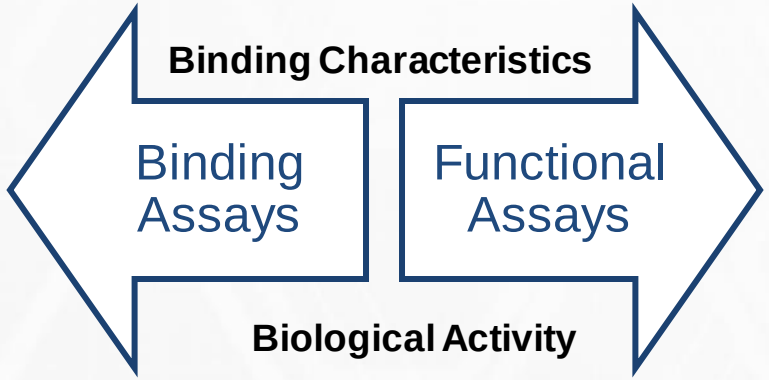
# Functional Characterization

## mAbs Binding and Biological Assays

**Fab Target Binding**
- Binding kinetics to target
- Binding Soluble target Ag – SPR/ELISA
- Transmembrane target bound Ag – ELISA/Flow cytometry

**Fc (SPR/ELISA) – ECD Based**
- C1q binding
- FcRn binding
- FcγR binding: FcgRI, FcgRIIa, FcgRIIb, FcγRIIIa, FcgRIIIb

**Highlights of Inhouse Capability**
- PBMC: Effector cells
- PBMC: Isolated NK cells
- PBMC: Isolated CD16 cells
- PBMC: In-house isolated specific cell population
- ADCC Reporter assay with cells stably expressing FcγRIIIa




**Fab**
Functional activity related to MoA (Target Neutralization receptor activation/blockade)

**Fc (ELISA/Flow Cytometry) – Cell Based**
Effector functions
- ADCC
- ADCP
- CDC
- C1q binding

**Fc**
- In vivo half-life
- PK

- Apoptosis
- Cell proliferation and inhibition of proliferation
- Cell migration
- T-cell Activation, Cytokines Estimation
- Potency estimation by competitive LBA
- GLP1 analogue cAMP assays
- Insulin bioassay

# Functional Characterization

**Sensitive, High throughput capable and globally renowned platforms**

| Category | Technology | Advantage |
|---|---|---|
| **Multimode Plate Reader** | Tecan Spark<br>BioTek Synergy H1 | All Spectrophotometry modes: Absorbance, FI, FP, TR-FRET, Luminescence, AlphaScreen®<br>Kinetic/Endpoint, Filter/Monochromator option, 96 and 384 well option.<br>25 plate stacker |
| **SPR** | Cytiva Biacore 1S+ | Highest sensitive SPR instrument for bioassays<br>(so far only 100 systems in global labs)<br>The only 1S+ in CRO space in India of now. |
| **Flow Cytometry** | BD FACS Lyric<br>Agilent Novocyte | All 3 laser, 12-15 color, plate loading systems from BD and Agilent for a wide range of flow cytometry assays. |
| **ELISpot** | AID vSpot Spectrum | Equipped with 7&1 position filter wheel for customized selection of up to 7 individual narrow band, hard coated fluorescent filters |
| **Multiplex** | Luminex Intellipex | Capable of 500 plex; Proven multiplex system in global labs |
| **Robotic Liquid Handler** | Integra Assist + | Automated liquid handling for bioassays |

Compliance: ALCOA++, User licences, Audit-trail enabled, 21 CFR Part 11 compliant, CSV, GxP Compliant

# Functional Characterization - Peptides

- Salmon Calcitonin
- Vasopressin
- Teriparatide
- Liraglutide
- Semaglutide
- Linaclotide

- SPR Binding Assay : Peptide : GLP-1R Interaction
- cAMP Production Assay : HTRF Format
- Impurity Induced Immunogenicity Assay
  - Innate – Human PBMC, Reporter Cell line
  - Adaptive – PBMCs without CD8+ T-cells, Monocyte Derived Dendritic Cell and CD4+ T-cells, PBMC derived T-cell Assay, Purified CD4+ T-cells co-cultured with Irradiated PBMCs

# Clinical Bioanalysis

**PK/PD**

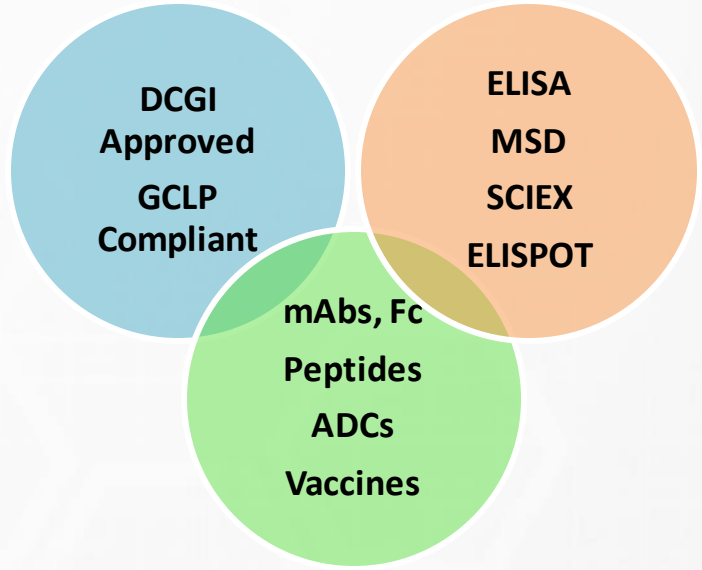
- Primary and secondary clinical endpoints
- PK parameters – Cmax, Tmax, AUC, t1/2
- Biosimilar Equivalence – One assay approach
- Incurred Sample Reanalysis

**Immunogenicity**

- Tier based approach – Regulatory Acceptance
- Screening, confirmatory and titer assays
- Functional Nab Assays - Cell based/competitive ELISA

**Vaccines**

- Antibody titer and concentration estimations (GMT/GMC)
- Seroconversion and seropositivity estimations
- Cell mediated immunity (CMI Response)
- Viral neutralization assays (SNT, PRNT, Pseudo virion assays)
- Functional assays (SBA, HAI,…)



# Veeda Group Advantage

Extensive Scientific Competence to service a Diverse client base

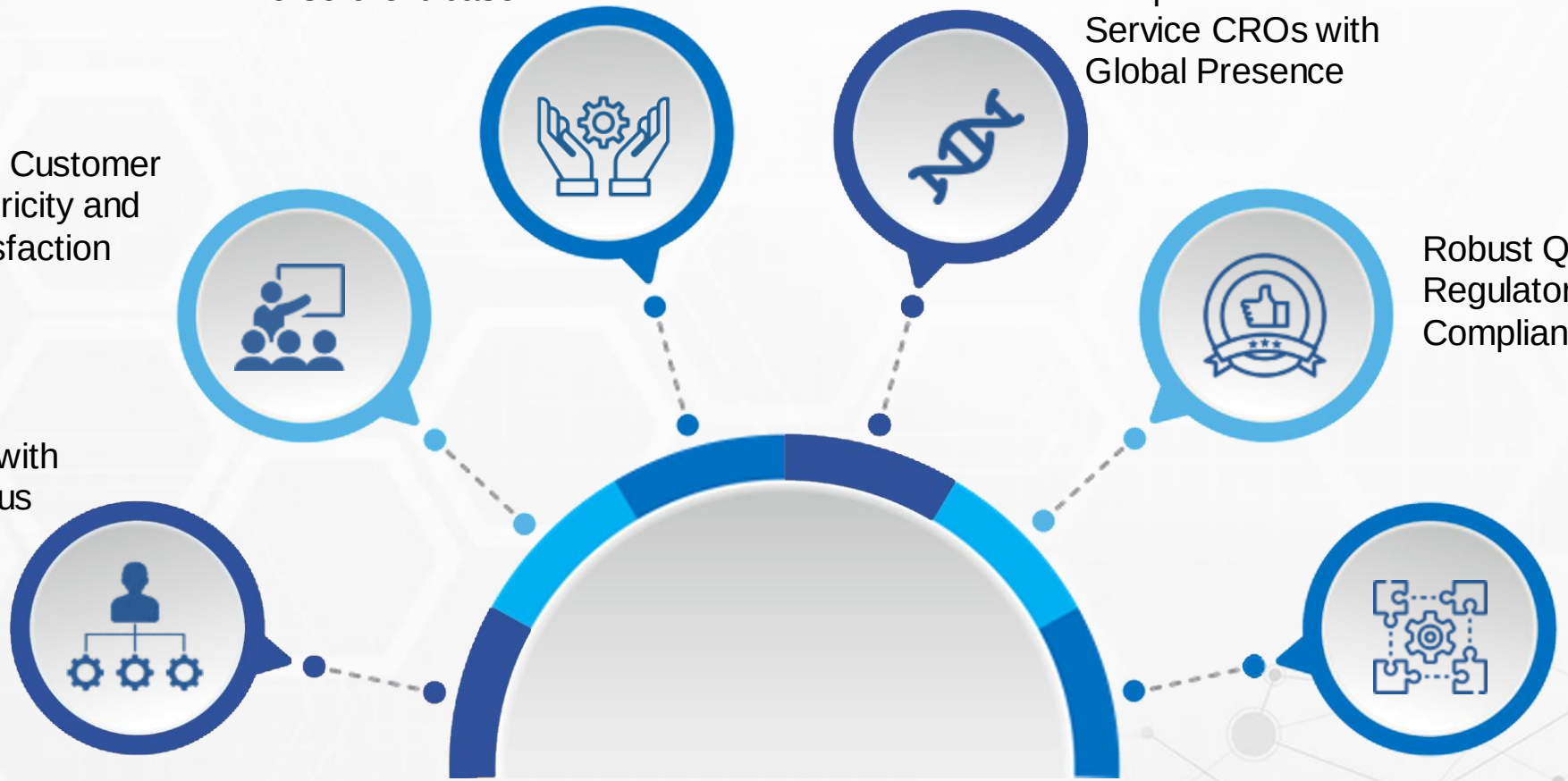
One of the largest Independent Full Service CROs with Global Presence

High Customer Centricity and Satisfaction

Robust Quality & Regulatory Compliance

Skilled personnel with focus on Continuous Professional Development

One stop solution for complex studies



# Thank You

Partners in creating

## a healthier tomorrow

For any further assistance kindly write to us at info@veedacr.com or visit us at www.veedacr.com