# Veeda Clinical Research Limited

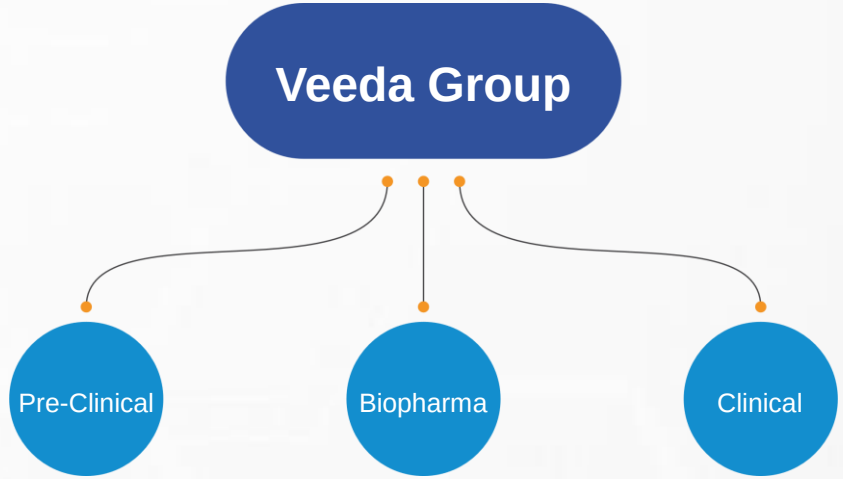
(Biopharma Division)

# Veeda Biopharma:

## A Fully Integrated Biopharma Division of Veeda Clinical Research

- Located within Bangalore's dynamic biotech hub, with ~50,000 square feet campus.

- We specialize in catering to the diverse R&D requirements of global biopharmaceutical and biotechnology clients across an array of therapy areas.




Partners in creating a healthier tomorrow

# Corporate Overview

# Our Global Foot Print

Serving clients across these geographies

Veeda's Team Presence

# Veeda Group Advantage

Extensive Scientific Competence to service a Diverse client base

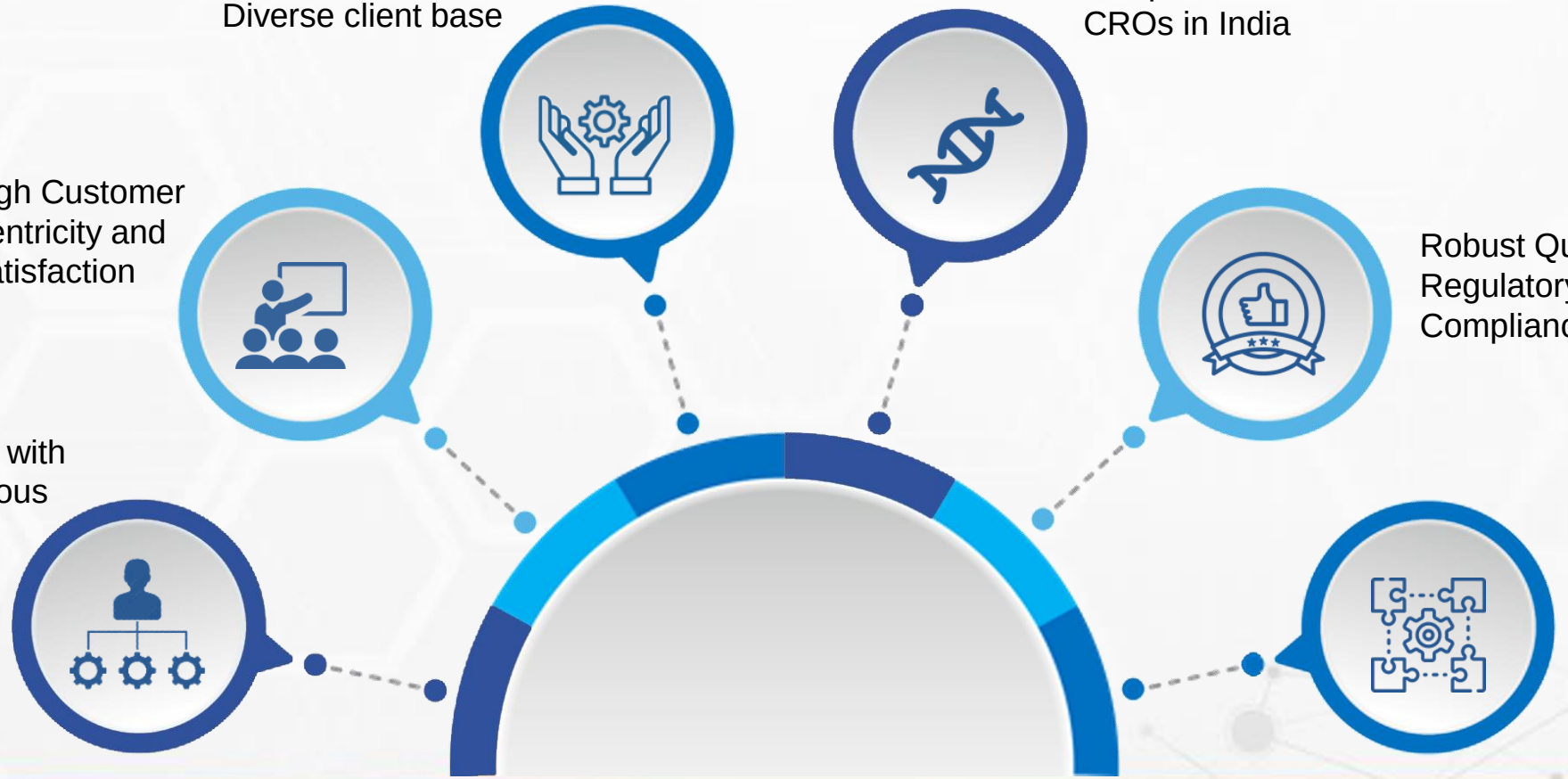
One of the largest Independent Full Service CROs in India

High Customer Centricity and Satisfaction

Robust Quality & Regulatory Compliance

Skilled personnel with focus on Continuous Professional Development

One stop solution for complex studies



# Corporate Philosophy

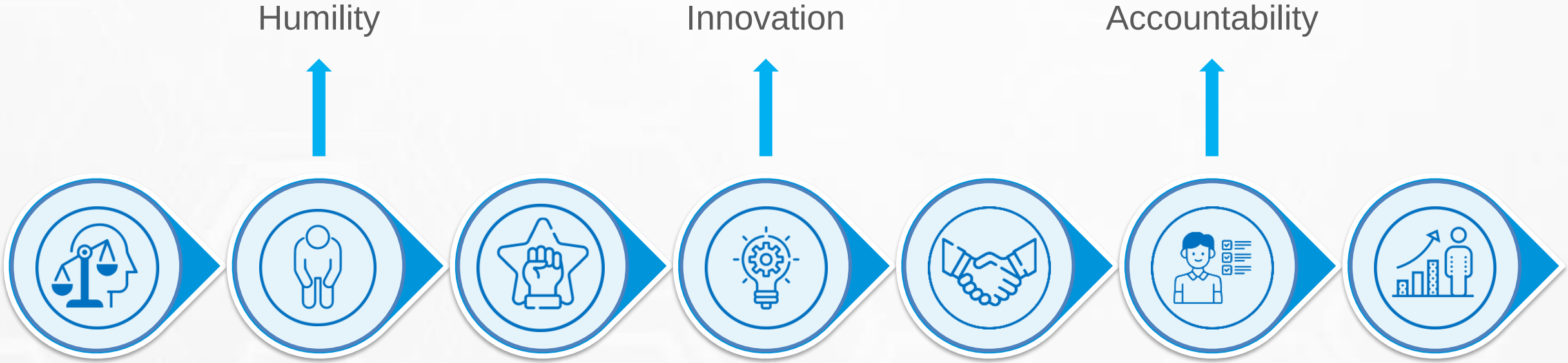
## Vision

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

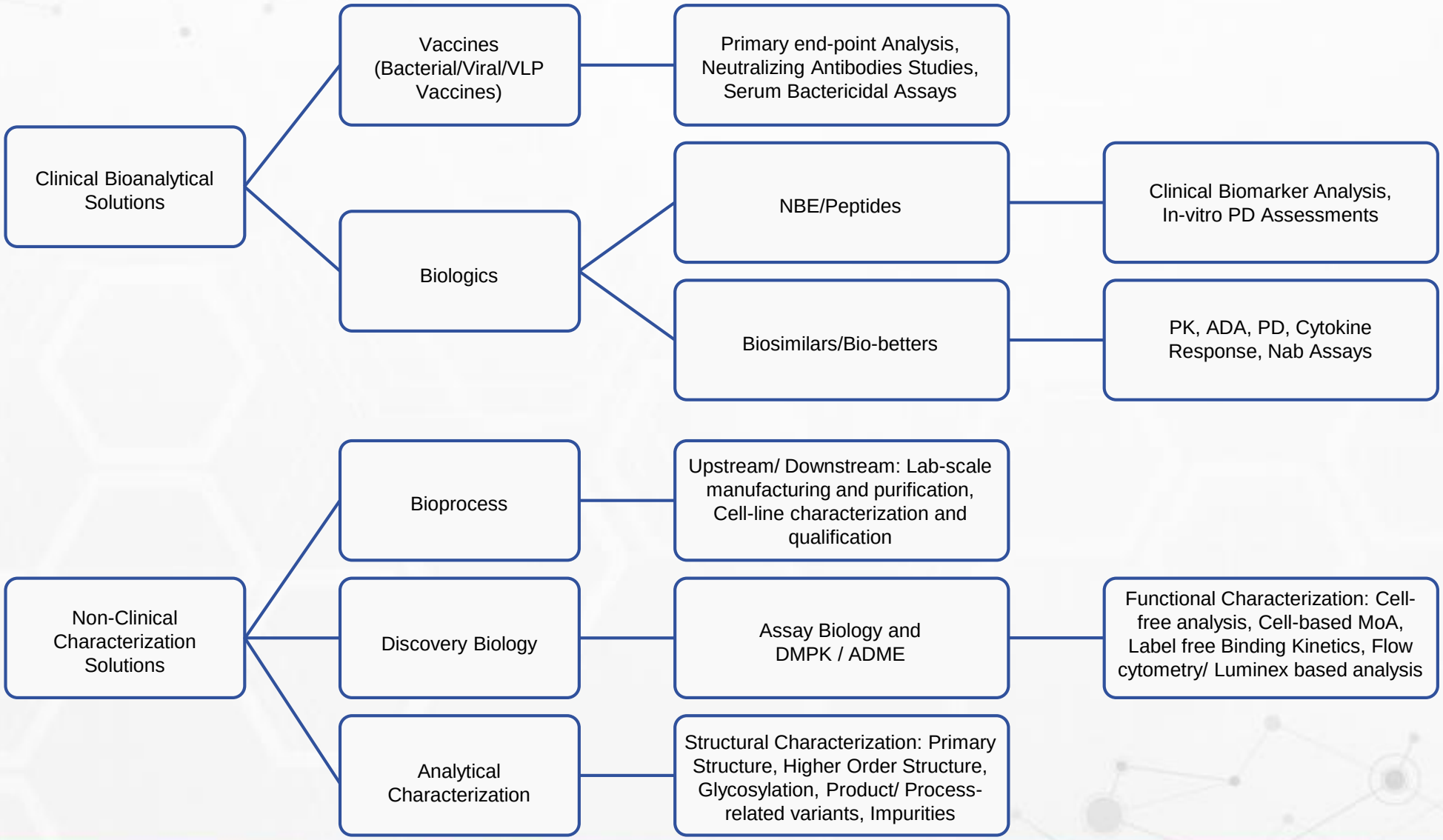
# Our Values


Humility
Innovation
Accountability
Integrity
Excellence
Collaboration
Nurturing Individual Growth

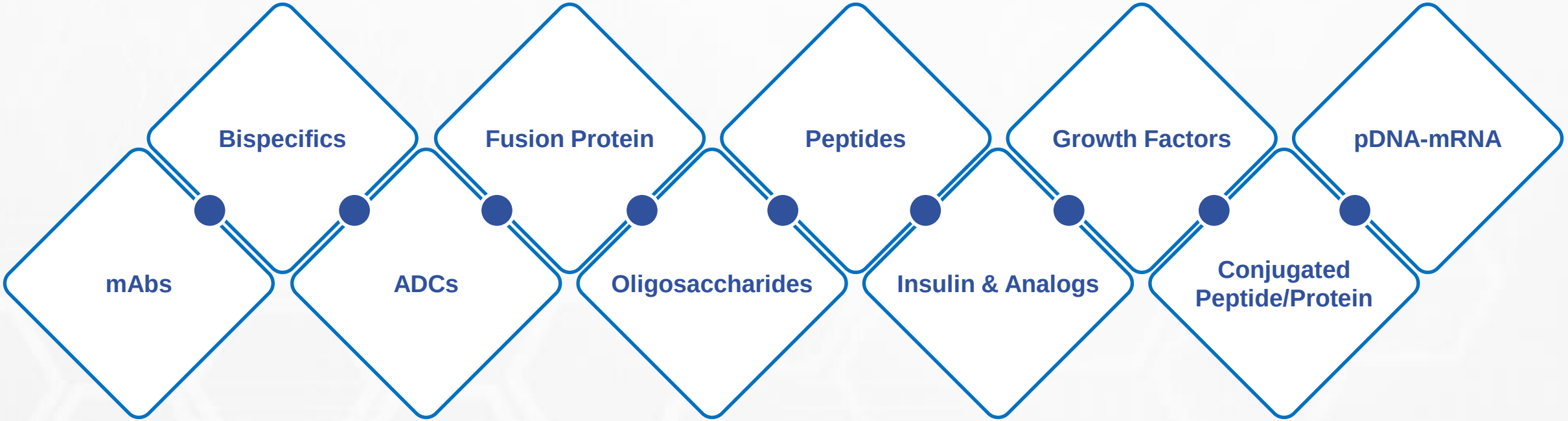
# Customized Integrated Solutions for Your Distinctive Biopharma Assets

Partners in creating a healthier tomorrow

# Veeda Biopharma Solutions



# Modalities: Analytics & Characterization Solutions




We have invested in resources, technology, and expertise to handle the complexities of different biological products

# Analytics & Characterization Solutions

## Primary Structure

- Intact mass
- Subunit mass
- Peptide mapping
- Peptide sequencing
- Disulfide mapping
- Release glycans

## Process & Product Variant

- Sequence variants
- Size variants
- Charge variants
- Proteoforms
- PTMs
- Forced degradation
- Formulation support

## Higher-order Structure*

- Secondary structure
- Tertiary structure
- Conformational changes
- Protein dynamics
- Protein stability

## Bio-similarity Assessment

- Innovator characterization
- Comparative studies
- Multi-batch analysis
- CQA, QTPP comparison
- Support for CTD Module 3

## MD & MQ

- Method development
- Method qualification

MD: Method Development, MQ: Method Qualification, CQA: Critical Quality Attributes, QTPP: Quality Target Product Profile

# Analytics & Characterization:

## Addressing CQA requirements & Bio-similarity Assessments

veeda clinical research | BIONEEDS

## Critical Quality Attributes

| Primary Structure | | Process & Product Variants | | | PTMs – ID & Quan | | HOS | |
|---|---|---|---|---|---|---|---|---|
| Intact & Subunit Mass Analysis | Peptide Mapping & Sequencing | Size & Charge Variants | Impurity Identification | Impurity Characterization | Oxidation & Deamidation | Glycosylation & Release Glycans | Secondary & Tertiary Structure | Conformational Stability |

| Biosimilarity Assessment |
|---|
| Protein sequence verification |
| Sequence variant characterization |
| Post-translational modification analysis |
| Glycosylation analysis |
| De novo sequencing (determining the sequence of a protein without prior information) |
| PTM quantification |
| Monitoring degradation |
| Excipient analysis (analysis of inactive components) |

PTM: Post Translational Modification, HOS: Higher Order Structure

*Regulatory Guideline: ICH Q6B*

# Stage Appropriate Characterization

| Development Stage | Characterization Services |
|---|---|
| **Early Development** | Primary structure confirmation |
| | Amino acid sequence verification |
| | Basic higher-order structure assessment |
| | Aggregation tendency analysis |
| **Pre-clinical** | Detailed higher-order structure analysis |
| | Impurity profiling |
| | Stability studies under various conditions |
| | Early assessment of potential modifications and variants |
| **Clinical Development** | In-depth higher-order structure analysis |
| | Glycosylation analysis |
| | PTM characterization and quantification |
| | Protein aggregation studies |
| | Comparability studies against earlier stages |
| | Product-related impurity assessment |
| | Process-related variant monitoring |
| **Commercialization & Post-Approval** | Long-term stability studies |
| | Monitoring of critical quality attributes |
| | Batch-to-batch consistency assessment |
| | Comparability studies against clinical batches |
| | Continuous monitoring of PTMs, variants, and impurities |

# Analytics & Characterization: Solutions

| | |
|---|---|
| **Physico-chemical Characterization** | Intact & subunit molecular mass<br>Peptide & disulfide mapping, sequencing<br>Release glycan (N-/O-linked)<br>Post translational modifications & sequence variant |
| **Higher-Order Structure Characterization** | Secondary & tertiary structure<br>Protein conformation<br>Protein dynamics & stability<br>Protein aggregation studies |
| **High-throughput Characterization (ZipChip)** | Intact & Native antibodies<br>Charge variants<br>Metabolites<br>Oligonucleotides |
| **Analytical Services** | Method development – RP, SEC, IEX, HILIC, HIC<br>Impurity identification (charge, size, HIC, HILIC)<br>Impurity characterization<br>Impurity enrichment |

## Molecules

- Monoclonal antibodies
- Bi-specific antibodies
- Antibody drug conjugates
- Fusion proteins
- Antibody fragment
- Peptides
- Recombinant proteins
- Vaccines

## Instruments

- HRMS – Qtof & Orbitrap
- UPLC & HPLC
- SEC/FFF-MALS
- CD Spectrometer
- FTIR
- DSC
- DLS
- CE

# Analytical Solutions at Veeda

**Capillary Electrophoresis**

**High Resolution Mass Spectrometry**

**DLS**

**DSC**

**SEC/FFF-MALSFTIR Spectroscopy**

**CD Spectroscopy**

**High Performance Liquid Chromatography**

**High-throughput (ZipChip)**

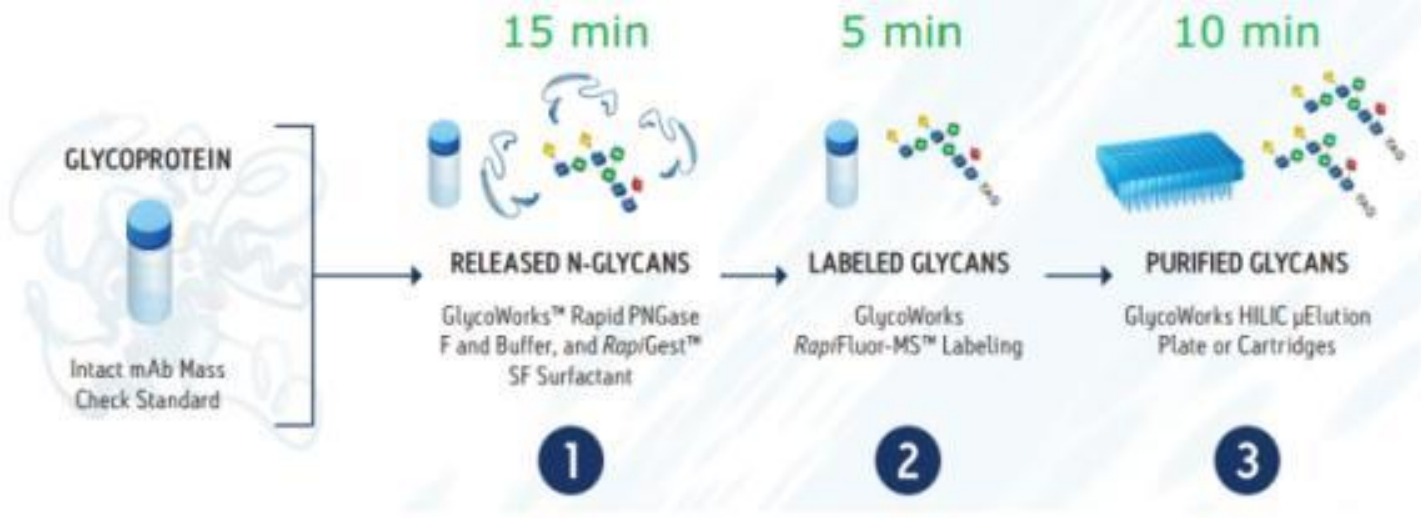
| Primary Structure | HOS | Analyticals |
|---|---|---|
| Intact & subunit mass | Secondary structure | Charge variant |
| Peptide mapping | Tertiary structure | Native mAb |
| Peptide sequencing | Protein conformers | Intact mAb |
| Disulfide mapping | Protein stability | Peptides |
| Release N-&O- glycans | Protein dynamics | Metabolites |
| Native mass | | Oligos |
| Charge heterogeneity | | |

# Accomplishment:

## Established N-Glycan Workflow at Biopharma Facility, Bangalore

## Release N-Glycan Analysis for IgGs/Glycosylated Proteins

A robust & rapid “Release N-Glycan Analysis Method” for N-linked Glycoproteins (IgG etc.) is established, with a preparation time of ~30 minutes from deglycosylation of N-glycans to its labelling & purification.




### HIGHLIGHT

Pre-labelled N-glycan standard is used as system suitability standard. Standard mAb is used for verification of release-label-purification process.

*Data generated at Biopharma Facility, Bangalore.

# Analytics & Characterization: Infrastructures

veeda clinical research | BIONEEDS

**High Resolution and High Throughput Technologies**

# State-of-the-Art Mass Spectrometry

## High Resolution Mass Spectrometry (HRMS)

**Ion Trapping Technology**
**Orbitrap**

**Ion Transmission Technology**
**Quadrupole Time-of-Flight**


waters_connect™

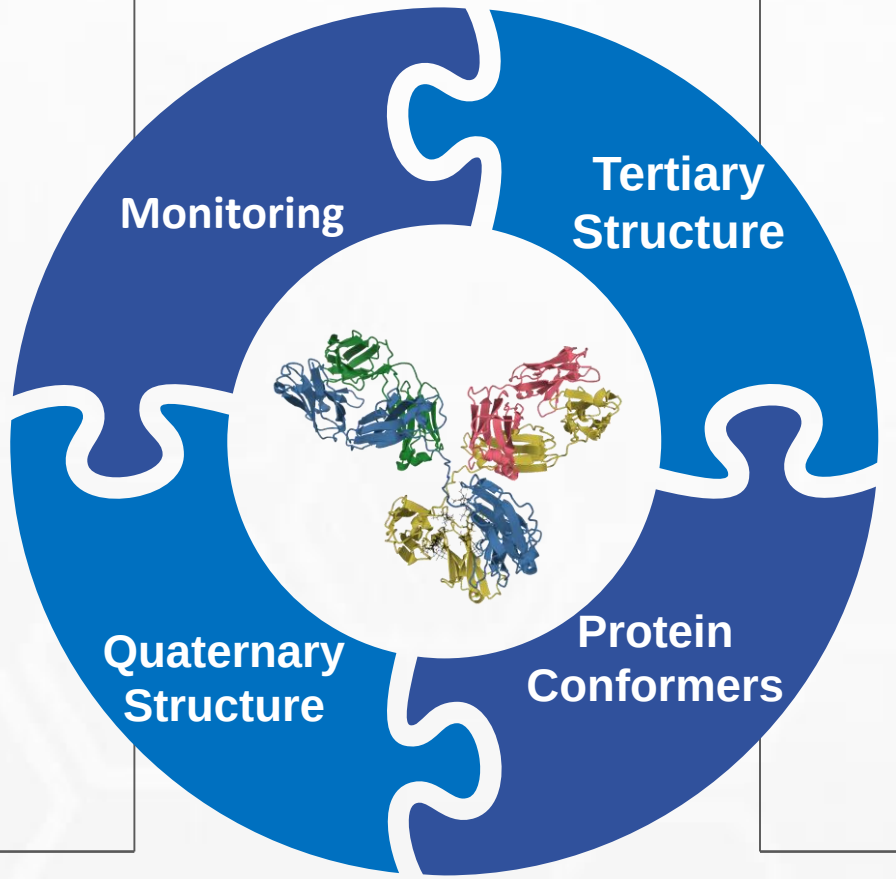
Data Acquisition > Data Processing & Reporting

**21 CFR Part 11 Compliant**

# HOS – Higher Order Structure

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

We have assisted many clients and help them define their goals and deliverables when in comes to Machine Learning Products.




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

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

# HOS Capabilities & Expertise

| Technology | Provider | Compliance |
|---|---|---|
| Circular Dichroism Spectroscopy (CD) | Applied Photophysics | Good laboratory practices<br>Good documentation practices<br>21 CFR Part 11 |
| Fourier-Transform Infrared Spectroscopy (FTIR) | Bruker | |
| Size Exclusion Chromatography/Field-Flow Fractionation – Multi-Angle Light Scattering (SEC-MALS) | Postnova | |
| Differential Scanning Calorimetry (DSC) | TA Instruments | |
| Dynamic Light Scattering (DLS) | Anton Paar | |

## mAbs

Pertuzumab
Pembrolizumab
Bevacizumab
Trastuzumab
and many more..

## Peptides, Recombinant, Fusion Proteins & CGT

Insulin and analogs
Filgrastim
Pegfilgrastim
Etanercept
VLPs

# HOS Expertise

DSC

DLS

MALS

FTIR

CD

Method Development Approach

Early Screening → Full Characterization → Routine Monitoring

# Analytics & Characterization: Infrastructures

**Chromatography & Mass Spectrometry**

HPLC

LCMS (Orbitrap)

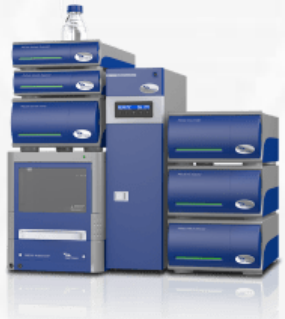
HRMS (QTof)

**Electrophoresis**

CE-SDS CIEF

SDS IEF 2D Gel

**Higher Order Structure**



SEC MALS

CD Spectrometer

FTIR

DSC

DLS

# Expertise at Biopharma Division

# Characterization of Biomolecules

Peptides - Oligosaccharides - Oligonucleotides

# Characterization of Biomolecules: Solutions

| Peptides- Characterization Solutions | Oligosaccharides- Characterization Solutions | Oligonucleotides- Characterization Solutions |
|---|---|---|
| • Molecular weight determination<br>• Peptide mapping<br>• Peptide sequencing<br>• Subunit analysis (A & B chain)<br>• Disulfide analysis<br>• Peptide bioanalysis<br>• Impurity identification<br>• Impurity characterization<br>• RS method development (related substances | • Molecular weight determination<br>• Identification of dp's (degree of polymerization)<br>• Sulfation pattern<br>• Enzymatic depolymerization<br>• Quantification of disaccharides<br>• Impurity identification<br>• Impurity characterization | • Molecular weight determination<br>• Separation of isoforms (OC, SC, Dimers)<br>• Impurity identification<br>• Impurity characterization |

# Bioprocesses

# Upstream And Downstream Capabilities

## Upstream

- Gene construct preparation & sequence confirmation
- CQA-based cell line development in CHO cell line
- Clone development in E. coli cells
- Process development at 2 L & 5 L scale
- Process optimization for increasing the cell density and protein yield
- Consistency batch runs for preclinical material generation
- Critical reagents wrt cell lines and recombinant proteins production

## Downstream

- Process development and optimization for purification of recombinant proteins and mAbs
- Consistency batches for material generation
- Purification of critical reagent generation
- Drug substance preparation

## Cell Line Characterization

- Research cell bank preparation and maintenance
- Cell line purity and sterility checking
- Cell line stability studies
- Gene copy number
- Plasmid copy number

# Upstream & Downstream: Infrastructures

Electroporator
(Neon, Thermo)

Automated cell
counter (Beckman)

Bioreactors
(2L& 5L, Sartorius)

Multiskan, FC
(Thermo)

Cassette holder
(Sartorius)

*Biochemical
Analyser

*Cell Select Imager

AKTA Pure 150
(Cytiva)

Filtration unit, Tripod
(Omega)

*TFF system

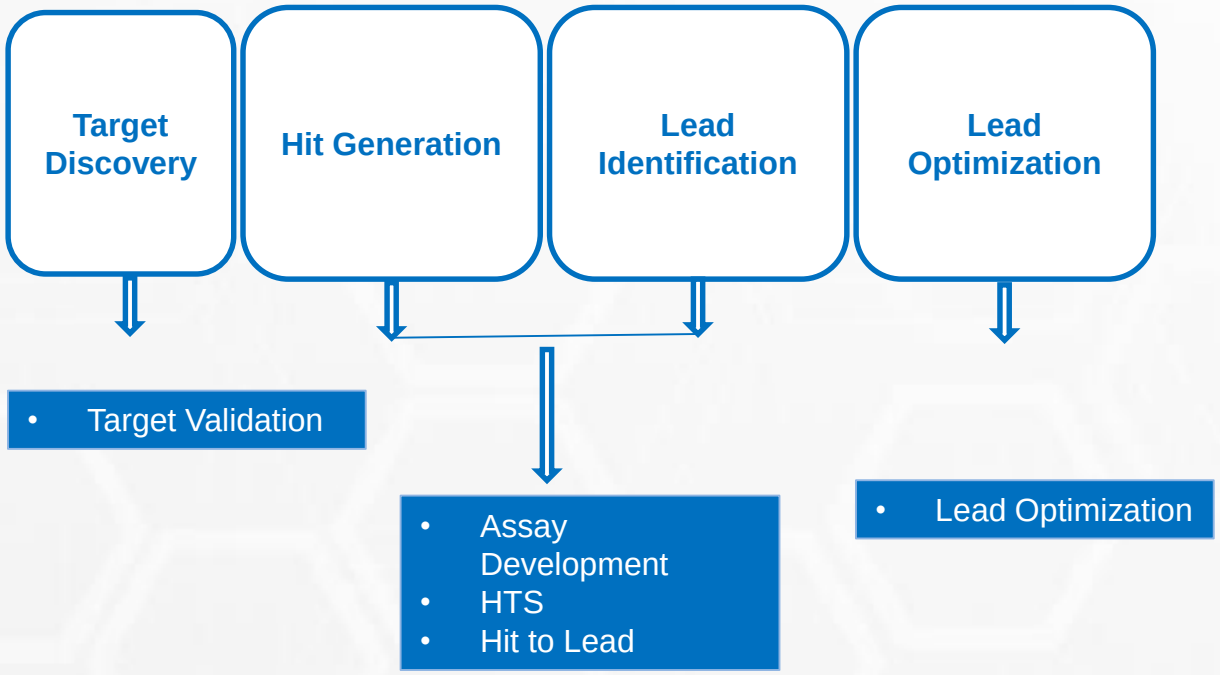
qPCR
(ABI 7500)

*Under the Expansion Plan

# Discovery Biology
# Assay Biology

Partners in creating a healthier tomorrow

# Assay Biology: Screening & Functional Characterization Solutions




## Assay development and Functional characterization solutions:

**Biochemical assays:**

Activity/Binding Assays: Kinases, Proteases, phosphatases, transporters, hERG for cardiac liability, Nuclear Hormone Receptors, PROTAC ternary complex assays, E3, VHL ligase binding assays for PROTACs,
Primary Screening, Profiling screening services for small molecule drug discovery…
Measurement modes: FI, FP, HTRF/TRF, SPR, AlphaScreen®, LANCE®

**Cellular assays:**

Target Binding Assays, Target Phosphorylation assays, cAMP assays, IP1/IP3 assays, Target degradation assays, proliferation and viability assays, Apoptosis assays, Reporter gene assays, Biomaker assays.
Measurement modes: Luminescence, HTRF/TRF, AlphaScreen®, LANCE/DELPHIA®, Flow cytometry, Multiplex, Elispot and other technologies.

**SPR Biacore assays:**

SPR: Biacore binding studies, Association and dissociation kinetics.

**Flow cytometry:** Receptor Binding, Immunogenicity, Immune Cell Profiling. Reporter Gene Assays.

# Discovery Biology: Technology

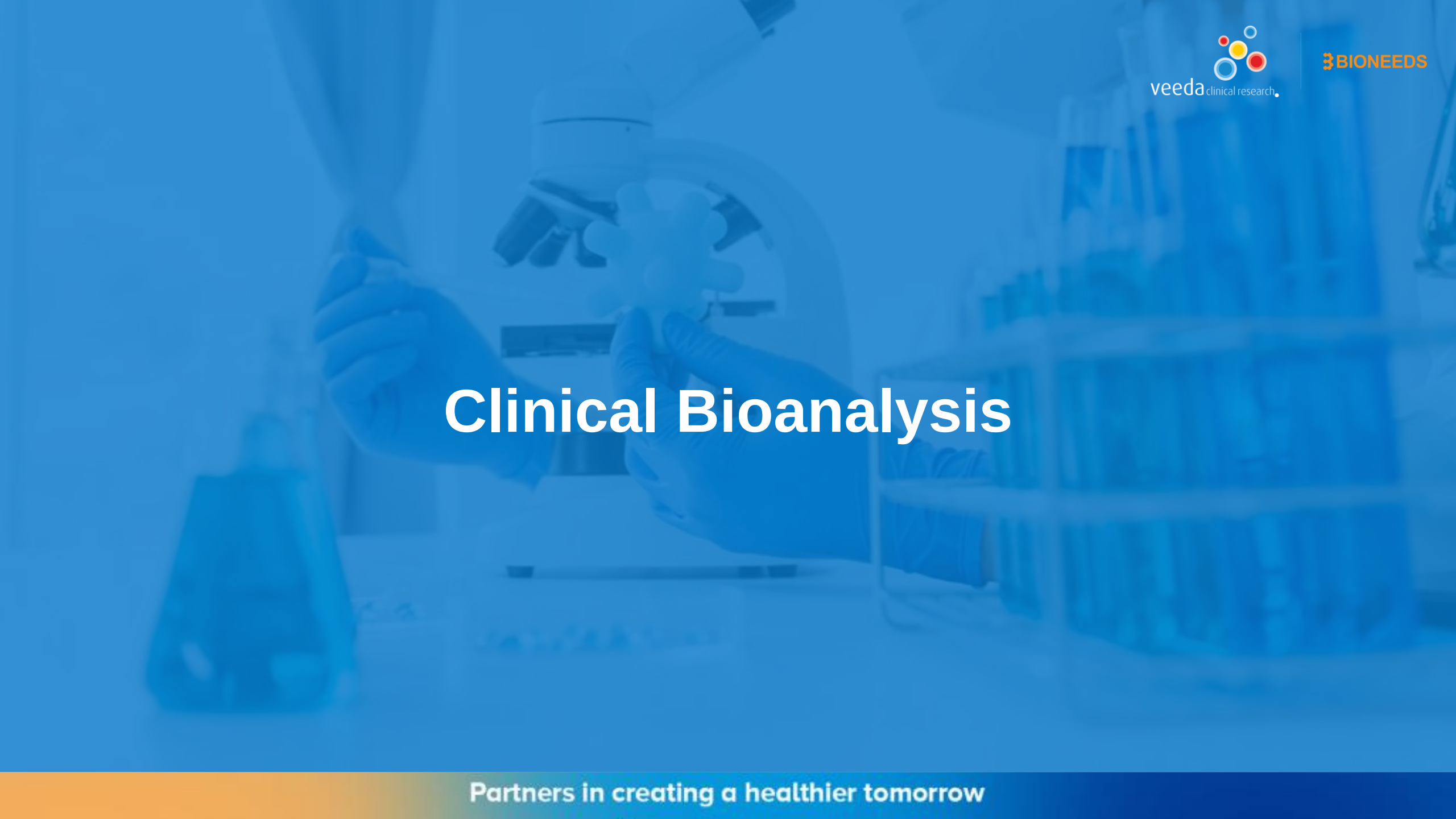
Tecan SPARK

SPR Biacore 1S+

96-well Plate Washer

Integra Robotic Platform


Luminex Intelliflex



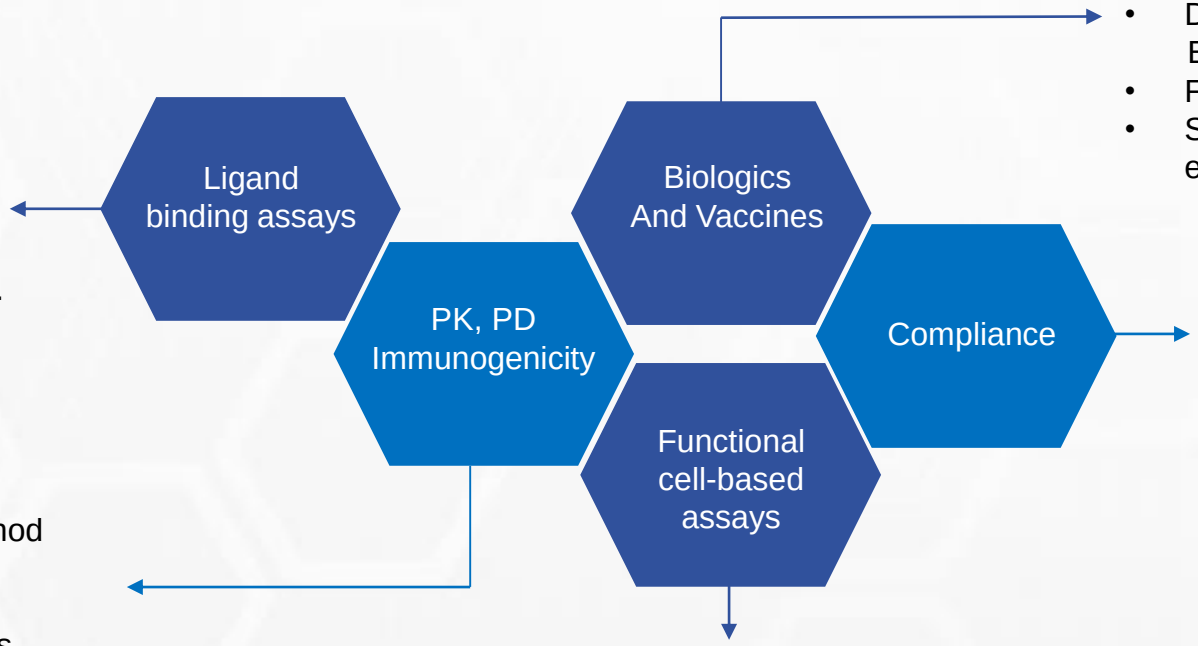
# Clinical Bioanalysis

Partners in creating a healthier tomorrow

# Large molecule bioanalytical – GCLP Compliant laboratory

## Immunoassays for PK, PD, Immunogenicity and Biomarkers

- Ligand binding assays for PK, PD and Immunogenicity
- Multiplex Assays
- mAbs, bi specifics, fusion proteins, proteins and conjugated proteins etc.




- Develop matrix specific methods by ELISA, MSD and Cell based assays
- Fit-for-purpose validations
- Sero protection and seroconversion estimations

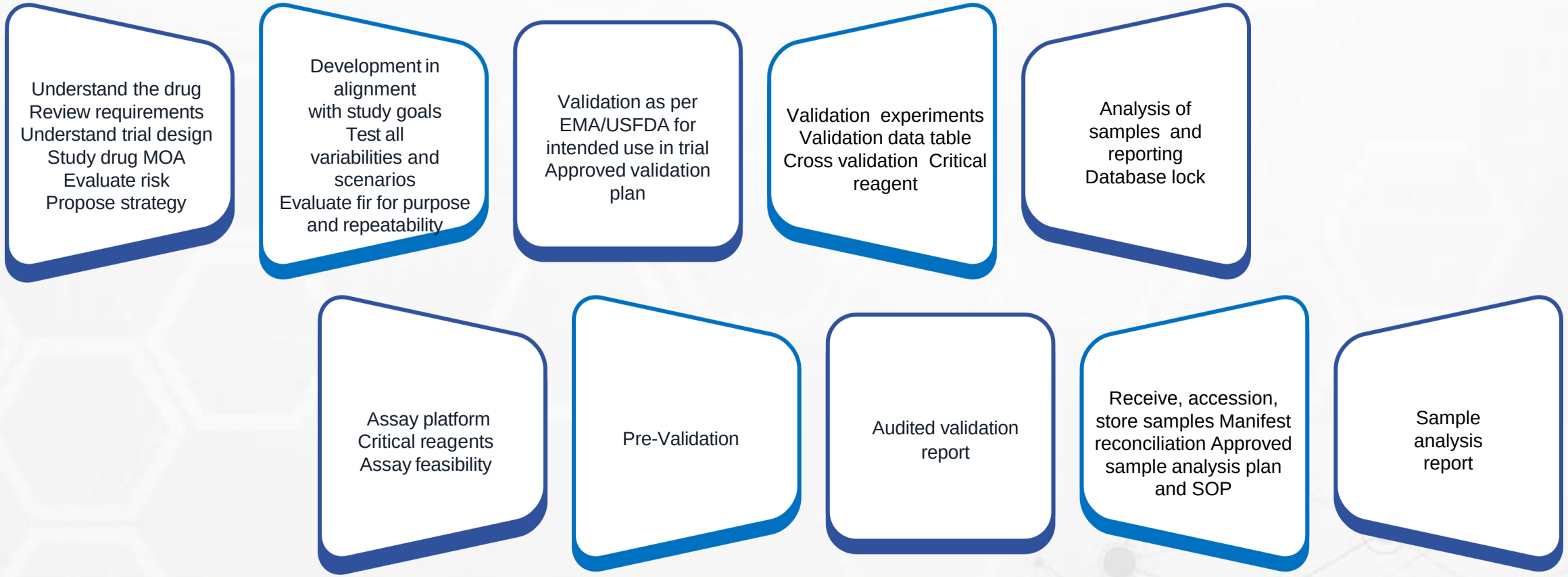
- GCLP, ICH M10 and USFDA guidance adherence in assay development/validation

- Method Transfer, Method
- Development, Method Validation
- Study Sample Analysis

- Invitro Functional neutralizing antibody assays
- Potency assays for biological activity, characterization and comparability

# Regulated Assay Transfer/Development/Validation

The journey of an assay from concept to data is well planned & monitored throughout the assay lifecycle



# Clinical Bioanalytical Services

| | |
|---|---|
| **Pharmacokinetics / Pharmacodynamics Assays** | Primary and secondary clinical endpoints<br>PK parameters – Cmax, Tmax, AUC, t1/2<br>Biosimilar Equivalence – One assay approach<br>Incurred Sample Reanalysis |
| **Higher-Order Structure Characterization** | Tier based approach – Regulatory Acceptance<br>Screening, confirmatory and titer assays<br>Functional Nab Assays - Cell based/competitive ELISA |
| **High-throughput Characterization (ZipChip)** | Cytokine Panel Estimations – Th1/Th2/Th17 Panels<br>Disease targeted biomarker analysis<br>High throughput multiplexing assays |
| **Analytical Services** | Antibody titer and concentration estimations (GMT/GMC)<br>Seroconversion and seropositivity estimations<br>Cell based functional assays – Serum Neutralization Assays/Serum bactericidal Assays |

## Molecules

- Peptides & Proteins
- Monoclonal Antibodies
- Multi Domain Biologics
- PEGylated and complex molecules
- Cytokines & Biomarkers
- Novel Biologics
- Vaccines

## Instruments

- ELISA (Colorimetric, Fluorescence, Luminescence)
- MSD Quickplex SQ 120
- Sciex 6500+ with Acquity Premier UPLC

# Clinical Bioanalysis: Technology


Synergy H1 Plate Reader

Meso Quickplex SQ 120

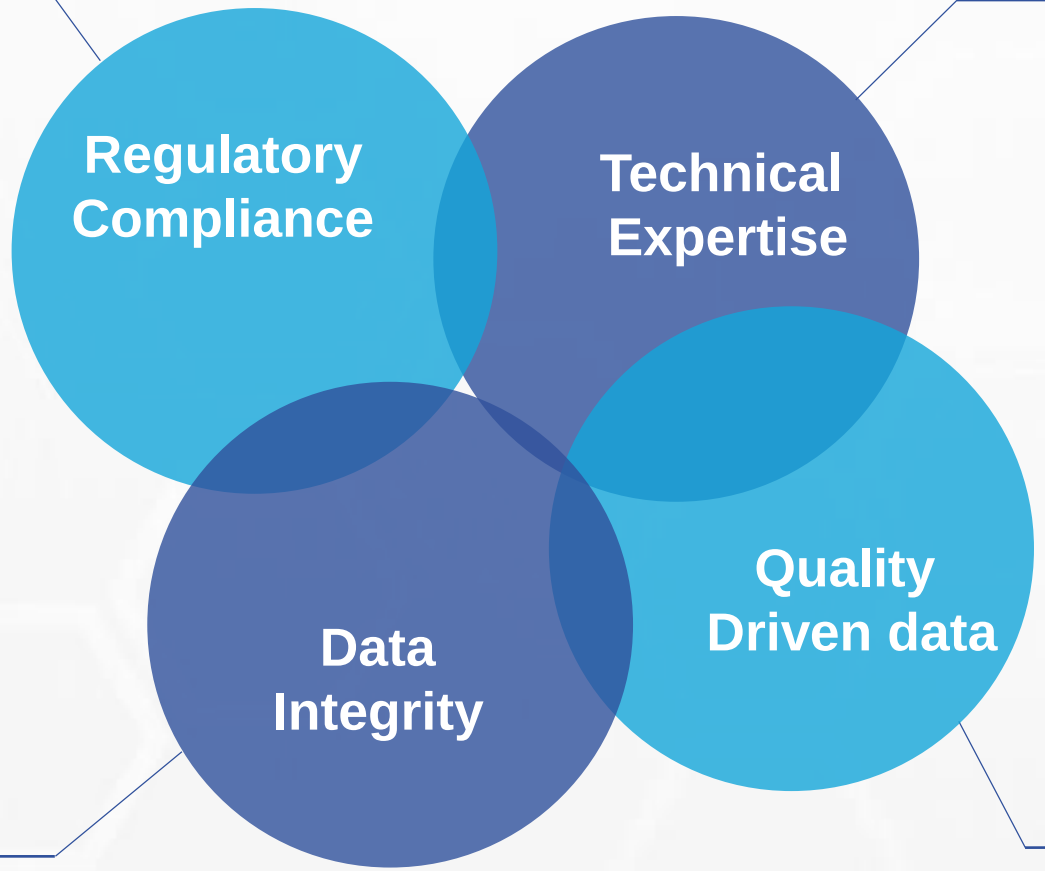
Automated 96-well Plate Washer

Integra Assist Plus Liquid Handler

Sciex 6500+ with Acquity Premier UPLC

# Quality Assurance and Regulatory Compliance

In compliance with internal SOPs, US FDA, EMA & ICH M10 guidelines




Experienced scientists in the field of large molecule bioanalysis

Computerized systems are validated as per 21 CFR part 11 compliance with audit trials (GxP softwares)

This slide is 100% editable. Adapt it to your needs and capture your audience's attention.

# Biopharma Team

## Sanjib Banerjee

Chief Operations Officer

Ex: Biological E, Syngene, Aurobindo, Mylan, Dr. Reddy's

### Jagadeesh B

General Manager

Ex: Nektar, Biological E

**Clinical Bioanalysis**

### Naganath M

General Manager

Ex: Lupin,Panacea

**Bioprocess**

### Chandrasekar K

Assoc. Vice President

Ex: Syngene, Jubilant, Advinus

**Clinical Bioanalysis**

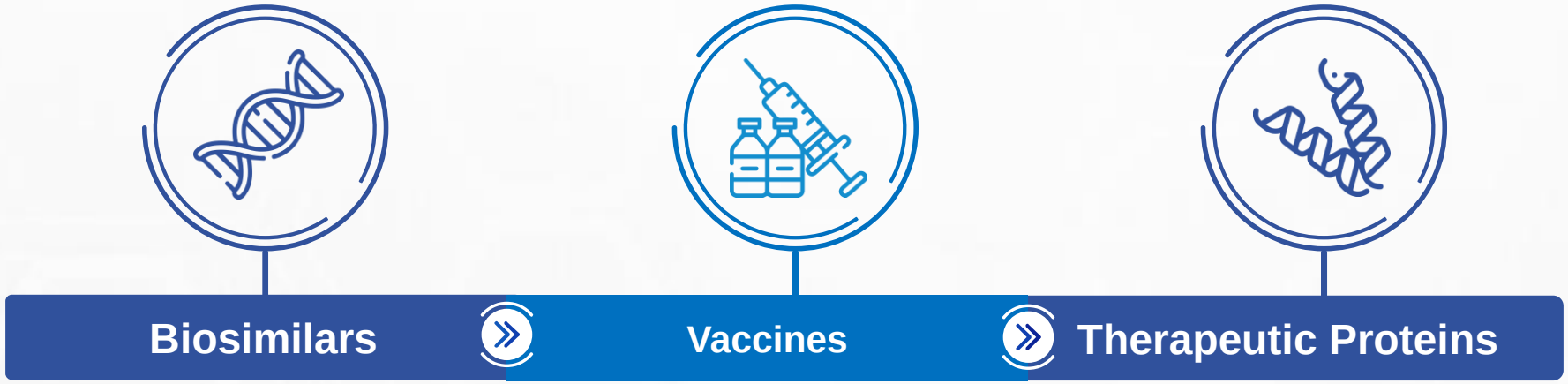
### Rajiv B

Asst. General Manager

Ex: Syngene, DRL, Waters, Biocon Biologics, Novozymes

**Analytics & Characterization**

# Biosimilars/Biologics Development Experience



## Biosimilars

- Denosumab
- Pertuzumab
- Pembrolizumab
- Abatacept
- Adalimumab
- Etanercept
- Infliximab
- Rituximab
- Aflibercept
- Mepolizumab
- Bevacizumab
- Trastuzumab
- Nivolumab

## Vaccines

- PCV
- HPV
- Hepatitis A
- COVID Vaccine
- Typhoid
- Pentavalent
- Hexavalent
- MMR

## Therapeutic Proteins

- Filgrastim (I/III)
- Pegfilgrastim (I)
- Romiplostim (I)
- r-FSH (I/IV)
- Teriparatide (I)
- Erythropoietin (II/III)
- Darbepoetin
- PEG IL-2
- PEG IL-15

# THANK YOU

For any further assistance kindly write to us at **info@veedacr.com**
Visit us at **www.veedacr.com**

Partners in creating
**a healthier tomorrow**