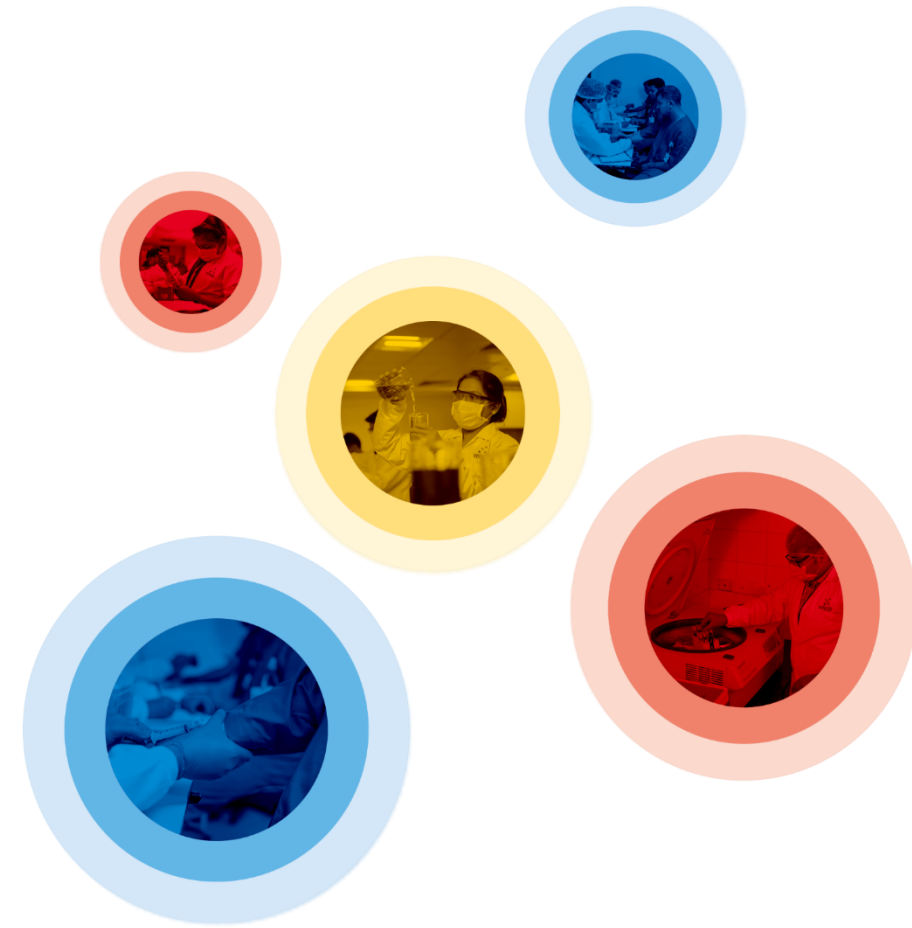




Global Clinical Development Partner



Providing Quality Bioanalytical Services



veeda clinical research®

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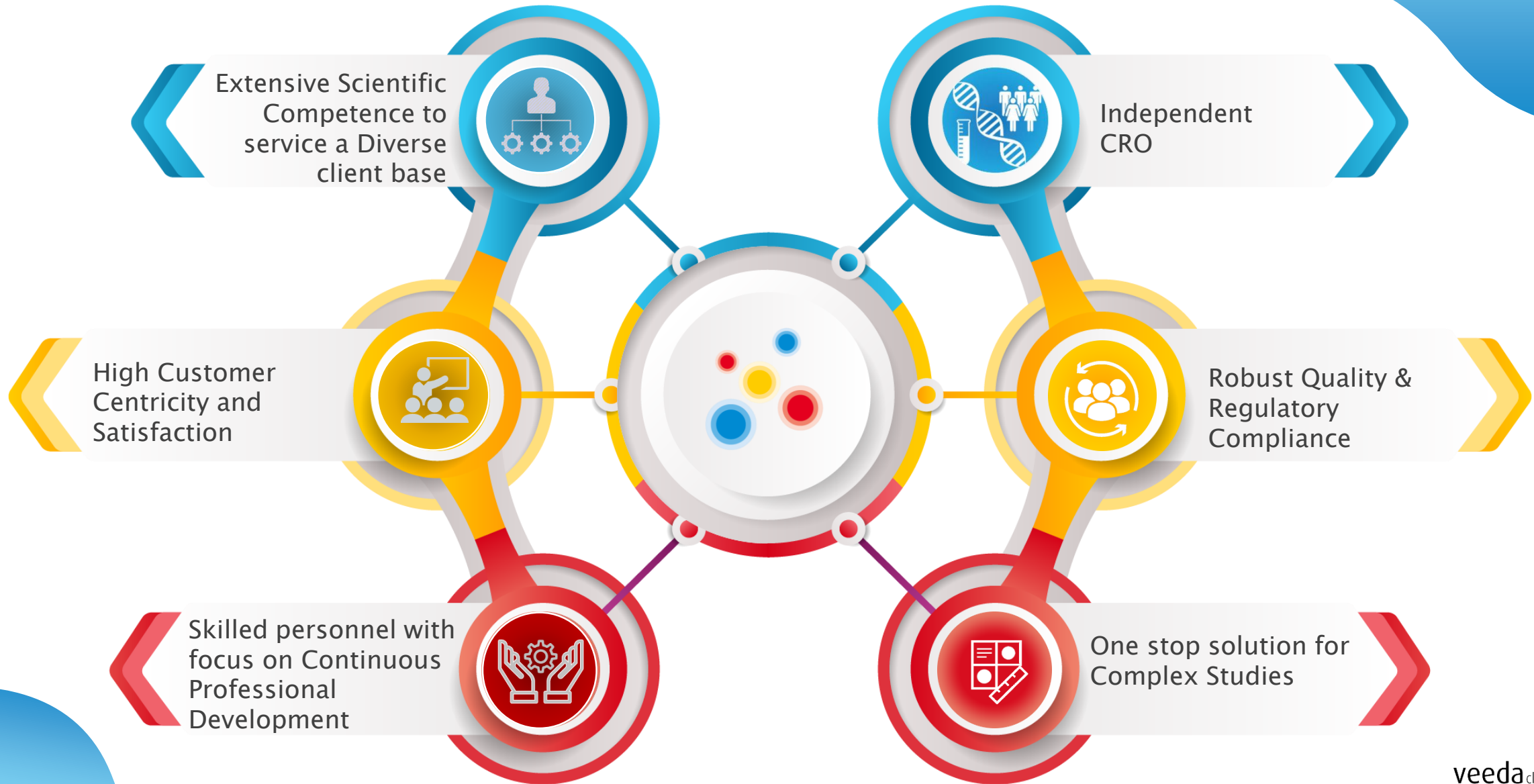
 Large Molecules

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The Veeda Advantage





MISSION & VISION

To strive for Excellence in Quality and Endeavour to become the Partner of choice for our Sponsors and our Stakeholders



Humility



Openness



Honesty and Integrity



Excellence



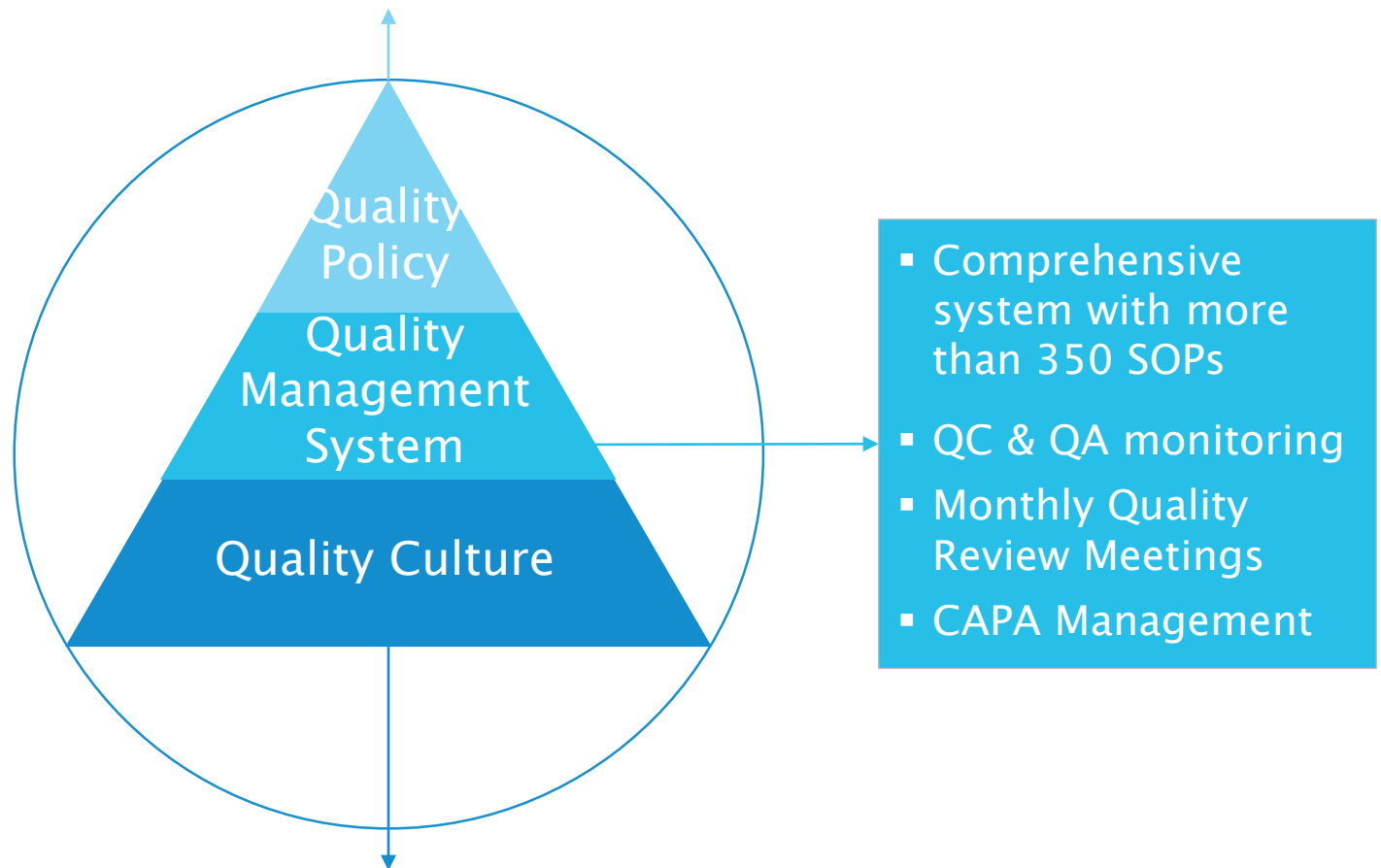
Innovation



Nurturing Individual Growth

Quality Structure

“Veeda’s management is committed to continuous improvement in the effectiveness of our Quality culture, to providing quality research solutions that meet sponsor and regulatory requirements and to protecting the rights, safety and



Focus on implementing policies & nurturing individual behavior to sustain our culture of quality



Balanced Score Cards (BSC) for augmenting corporate strategy



Quantifiable Performance Metrics for all departments



Individual KPI's & KRA's linked to BSC



Continuous process improvement

Regulatory Credentials



*FDA : 17 AUDITS FOR PATIENT BASED STUDIES
16 AUDITS FOR HEALTHY SUBJECTS STUDIES



BIOANALYTICAL INFRASTRUCTURE



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Storage Capacity

- 46 LC-MS/MS machines
 - Insignia – 33
 - Vedant – 13
 - API 5500/4000/3200/3000/2000
 - Shimadzu 8060/8050/8040
 - Quattro Premier
- 2 ICP-OES
- Watson LIMS



Plasma Sample:

45 Deep freezers with capacity to store 11,25,000 samples at -80 C°



IP Storage:

- 3 Walking type stability chambers with overall capacity to store 34000 Ltr for retention at room temperature

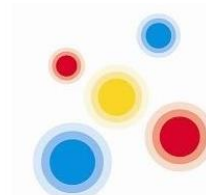
- 4 Humidity chambers with overall capacity of 3200 Ltr

- 4 Pharmaceutical refrigerators having storage capacity of 3550 Ltr at 2-8 C°



Archival: Capacity to archive approximately 51000 files

BIOANALYTICAL CAPABILITIES

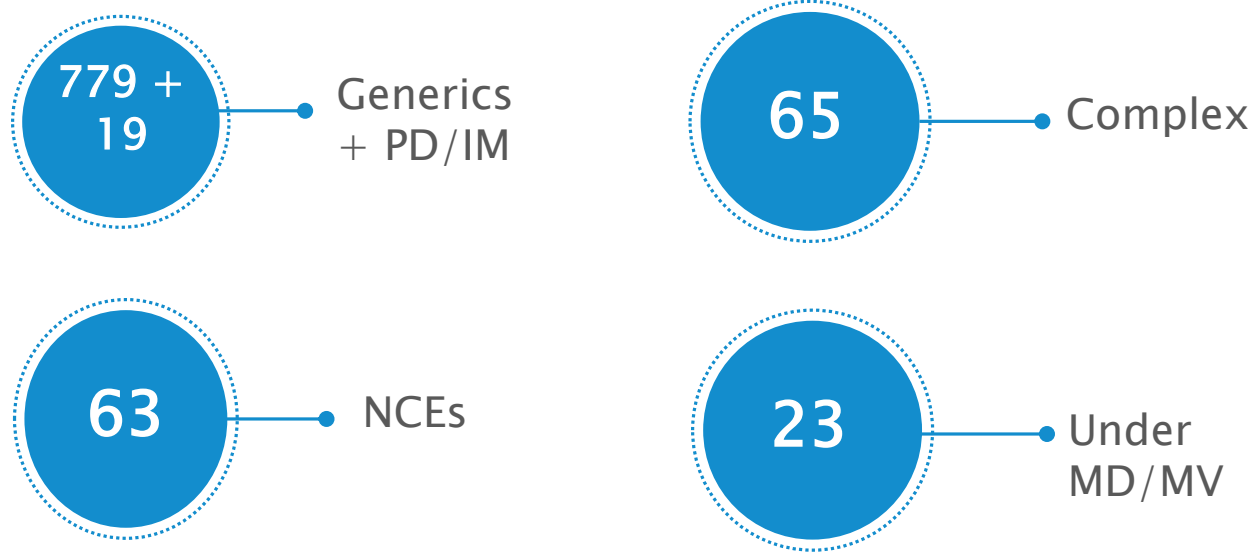


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Bioanalytical Capabilities

Types of Methods

Total available Bioanalytical methods are more than 920



Experience

- No. of studies done- >3000 (BA/BE)
- BR only study- >500 Studies
- ISR- %- >98%

State of the art

- Capability to develop methods with lowest quantification level- up to 0.1 pg
- Methods developed for:
 - Endogenous molecules
 - Hormones
 - Steroids
 - Inhalation formulation
 - Elemental Bioanalysis
 - Immunogenicity
 - Large molecules/ECLIA/ELISA
- Multiple analysis in single injection
- Central labs for Phase II / Phase III studies
- Tissue distribution studies

BIOANALYTICAL SERVICES – HIGHLIGHTS



Bioanalytical Services (Complex Molecules)

Amino Acids Analysis:

Separation of 20 amino acids.

Simultaneous analysis of 20 amino acids after derivatizing with AccQ Tag ultra-reagent kit and then detected on LCMSMS. All 20 amino acids have been separated chromatographically.

Calibration range of all amino acids has been adjusted such that all endogenous amino acids from human plasma are quantified.

1

Peptides (small molecules) by LCMSMS:
Desmopressin; Leuprolide; Octreotide

2



4

Endogenous Compounds:

Estrone (Unconjugated) +Estradiol (Unconjugated); Isotretinoin; Levothyroxine

3

Enantiomers (Chiral Methods):

R-trans & S-trans Tranylcypromine; R & S Lercanidipine; R-SSS & S-RRR Nebivolol

Bioanalytical Services (Complex Molecules)

Elemental Analysis (By ICP-OES):

Total iron and Transferrin Bound Iron; Potassium; Lithium.

For Transferrin bound iron the serum samples are filtered through SPE cartridges to remove free and formulation bound iron while the filtrate contains TBI which is further analyzed by ICP OES..

5

Liposomal Formulation :

Doxorubicin; Amphotericin Challenges faced are the leaching of free from Liposomal formulations during sample handling, sample shipment and storage. Bursting of Liposomes during Thawing of samples.

To overcome the challenges stabilizing buffer is added to all samples and storage of samples at -78 C with controlled temperature shipments. Thawing and Processing at Controlled temperature during analysis.

6

8



7

Protein Bound Formulation :
Paclitaxel

Biomarker analysis:
 $\alpha 1$ Acid Glycoprotein by HPLC-UV

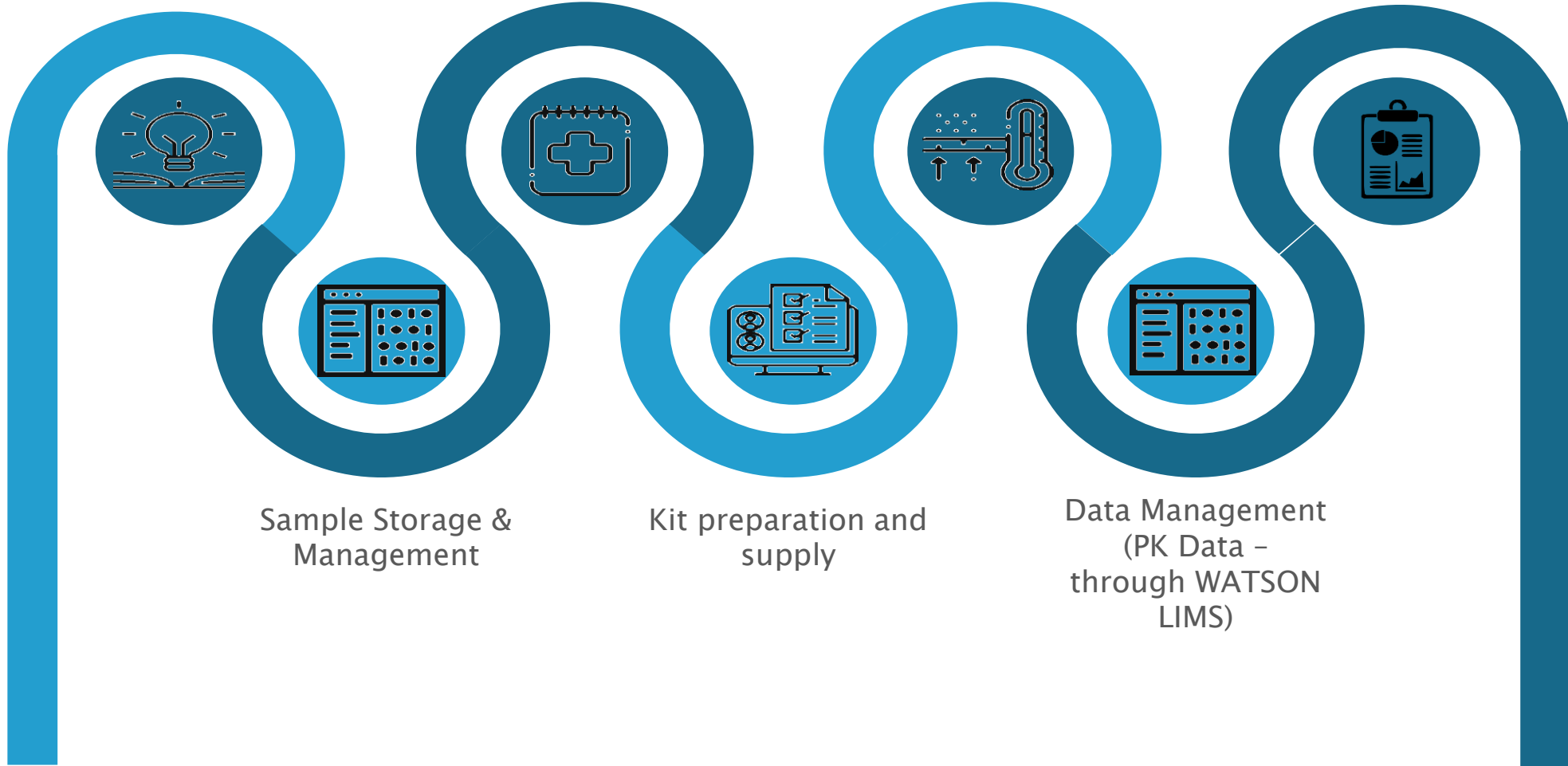
Bioanalytical Services – Central Laboratory

Project Management

Lab Manual Preparation

Analyte Testing

Reports Presentations



Sample Storage & Management

Kit preparation and supply

Data Management (PK Data - through WATSON LIMS)

1.

Multicenter study (which involved more than 35 sites (150 subjects, 10 Analytes).

- ❖ Required screening sample analysis within 10 days from sample collection-.
- ❖ Estimated 10 analytes for this study– Total 4 bio-analytical methods .
- ❖ Provided sample collection kits to all sites– within stipulated time



2.

Sponsor– Global Pharma company since 2009

- ❖ Type of studies : NCE – Multisite
- ❖ Total Studies : 144
- ❖ Total Samples: 1,61,613
- ❖ Total Methods: 58
- ❖ Services Provided: Sample Management (receipt, logging in LIMS for reconciliation), method development, method validation and analysis of NCEs .
- ❖ For safety analysis, sample receipt to analysis within 5 days
- ❖ Sponsor specific reports with e-CTD
- ❖ Exploratory studies, e.g. skin tissues , plasma protein binding experiment, chiral impurity estimation in the sample

Biosimilars (PK Assay) by

ELISA :

G-CSF, Insulin Aspart,
Teriparatide (PTH)

PD Assay :

C-Peptide (ELISA), Enoxaparin
(Anti-Xa & Anti-IIa by
Chromogenic method)

Bioanalytical Services Large Molecules

Human Insulin Glargine and Metabolites by LC/MS/MS

Method under final
development stage on
LC/MS/MS (Shimadzu 8060)
(Using multiple charge MRM)

Immunogenicity Assay by

ELISA:

Enoxaparin, PTH

- i. Screening assay
- i. Confirmatory Assay
- ii. Titer Assay

TESTIMONIALS

“ In a highly regulated environment, such as the pharmaceutical industry, where quality is critical and time is precious, having a trustworthy partner is one of the key elements of success. Working with Veeda provides a peace of mind, with respect to consistently and timely delivering quality work. I've worked with Veeda on several projects and plan to continue doing so for the foreseeable future. ”

–Our Esteemed Client from Europe



“ When it comes to choosing your partner for a clinical program, Veeda is the first CRO you can think of. All these years of partnership with Veeda we came across with high qualified personnel, fully-dedicated to our challenging demands. ”

– Our Esteemed Client from Europe



“ It has been a pleasure having Veeda CR as a contract research organization for the conduct of our bio equivalence studies. Being an independent CRO, it is good to see Veeda have a wide range of analytical methods and good clinical experience. Their quality practices, open communication and timely delivery has been a highlight of their work system which enables us stay on top of our project. Looking forward to see the good work continue in the coming years. ”

–Our Esteemed Client from India



TESTIMONIALS

“As a Sponsor in different time zone (USA), I have found Veeda Team to be very responsive in providing timely operational updates to enable our team to make quick decisions ”.

–Our Esteemed Client from USA



“ The excellent project management and support and openness from a experienced, well trained and scientifically oriented team along with quality of the deliverables are some of the reasons that kept us close partners for more than 12 years. Congratulations and keep up with good work Veeda team! ”.

– Our Esteemed Client from Europe

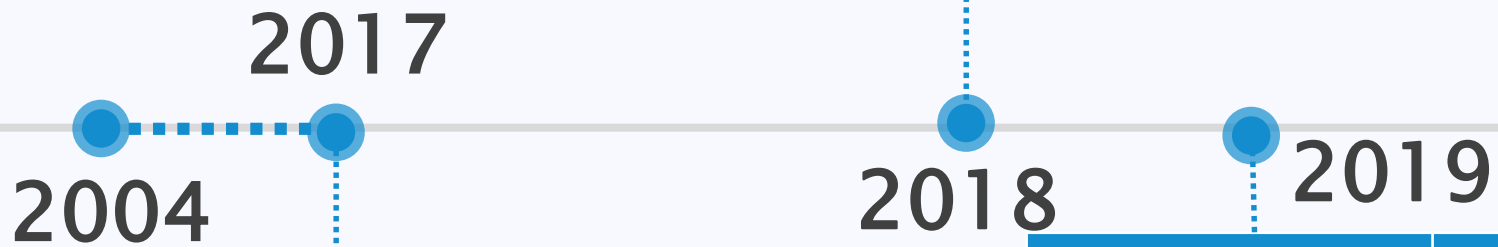


“ Our organization has worked with Veeda for a number of years, and we are continually impressed with the team’s speed of responsiveness to their customers. The Veeda team is available, knowledgeable and always willing to work through any queries we might have. We greatly value Veeda’s customer service, expertise and seamless project management. Congratulations on 15 years of Clinical Excellence! ”

–Our Esteemed Client from USA



ACHIEVEMENTS



Organization	Award Category
	Best Clinical Research Organization – India
	Clinical Trial Company of the Year
	Bharat Udhog Ratan Award in Clinical Research

Organization	Award Category
	National Excellence Award
	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research– India
	Best Clinical Research– India
	Mark of Excellence
	Indian Clinical Research company of the year

Organization	Award Category
	Best Quality Clinical Research Organization in India
	Best Quality Clinical Research Organization in India
	Indian Clinical Research company of the year