BIONEEDS

Partners in creating a healthier tomorrow

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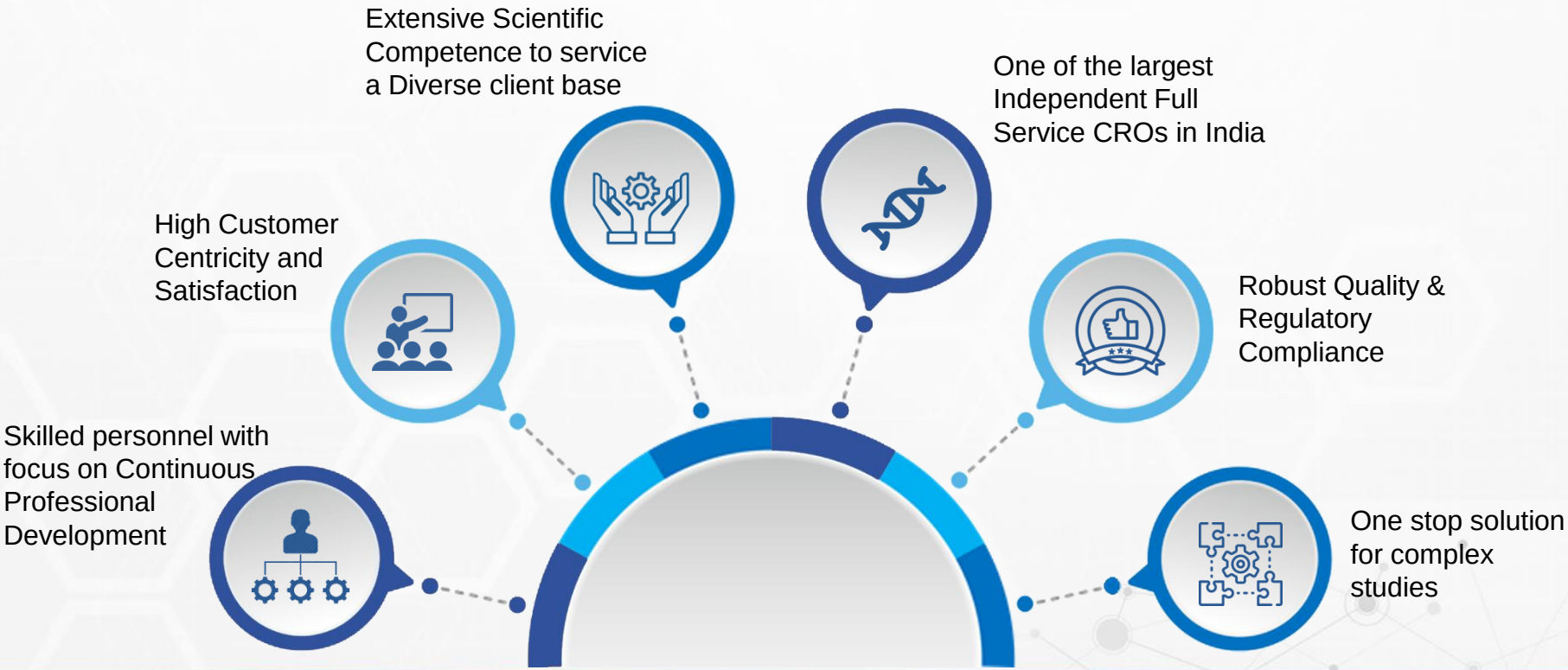
Corporate Overview

Our Global Foot Print

Serving clients across these geographies

Veeda's Team Presence

Veeda Group Advantage



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

Evolution

Privately owned, board managed company

2004 — Founded at Shivalik with 37 Employees

2006 — First regulatory inspection from ANVISA

2007 — First regulatory inspection from WHO, US FDA & UK MHRA

2010 — New Facility at Insignia

2015 — New Facility at Vedant

2018
- New Facility at Skylar Exclusively for Screening
- CX Partners join

2019 — New Facility at Mehsana, Total number of Employees 970

2021
- New Phase 1 Facility at Vedant
- Biosimilar JV with Somru BioScience

Corporate Outlook

- Focus on Organic and Inorganic growth strategies to enhance service capabilities
- Financial Stability based on prudent management & Private Equity sponsorship
- Operational Stability based on experienced professional management and strong quality culture
- Ongoing investments in technology to enhance operating efficiencies and compliance management

Our Values


Humility
Innovation
Accountability
Integrity
Excellence
Collaboration
Nurturing Individual Growth

Quality Framework

"Our 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 well being of the study volunteers"

- Comprehensive system with more than 350 SOPs
- QC & QA monitoring
- Monthly Quality Review Meetings
- CAPA Management

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

- 93 successful regulatory audits till date
- 12 successful regulatory audits in the last year.

US FDA	→	45*	ANSM	→	1
MHRA	→	4	AGES	→	5*
ANVISA	→	8	MCC	→	1
WHO	→	6	DCGI	→	19
NPRA Malaysia	→	5			

*FDA : 23 AUDITS FOR PATIENT BASED STUDIES
22 AUDITS FOR HEALTHY SUBJECTS STUDIES

AGES : 2 AUDIT FOR PATIENT BASED STUDIES
3 AUDITS FOR HEALTHY SUBJECTS STUDIES

Bioanalytical Research

Infrastructure

Scale and Range

- **54 LC-MS/MS** machines
  - Insignia (31), Vedant (16) and Satyamev(07)
  - API 6500/5500/4000/4500/3200/3000/2000
  - Shimadzu 8060/8050/8040
  - Quattro Premier
- **2 ICP-OES**
- **Watson LIMS**
- **BSL-2 Laboratory**

Storage Capacity

Plasma Sample:

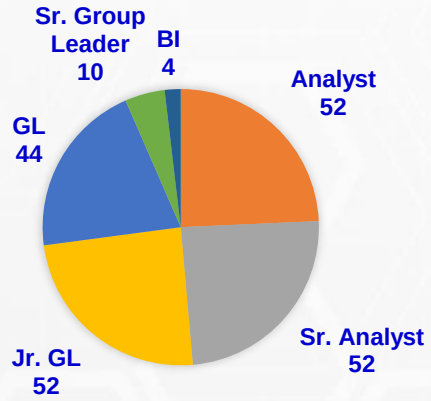
- 41 Deep freezers of -80˚C (1 M samples capacity) and 12 Deep freezers of -20˚C (0.15 M samples capacity)
- 01 Cold Room -20C (0.3 M samples capacity)

IP Storage:

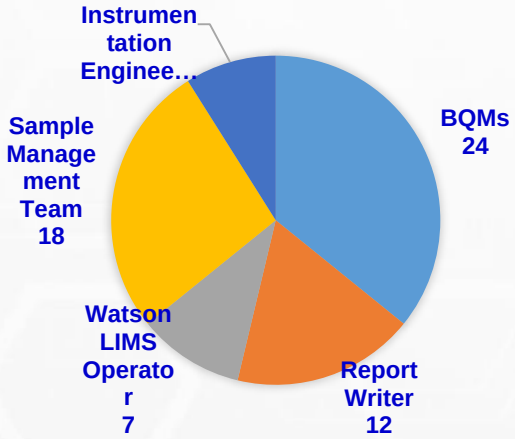
- 6 Walking type stability chambers with overall capacity to store 74,000 Ltr for retention at room temperature
- 5 Humidity chambers with overall capacity of 4,200 Ltr
- 4 Pharmaceutical refrigerators having storage capacity of 11,350 Ltr at 2-8 ℃

Bioanalytical Team

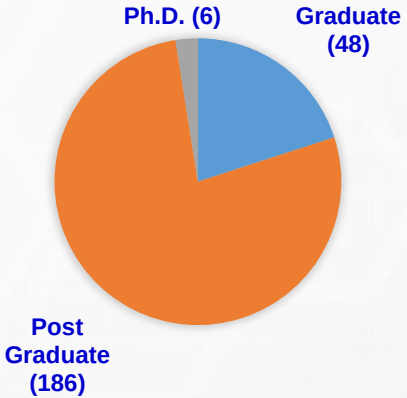
OPERATION TEAM-BRD



SUPPORT STAFF-BRD



QUALIFICATION - BRD EMPLOYEE



New chemical entity (NCEs) supports

- Phase- 1 molecule development /validation from Preclinical methods.
- Clinical trial samples (FIH) study support and reporting.
- Phase- 2/3 samples and analysis
- Exploratory support for Microsampling, DBS, rare matrix analysis (CSF, Skin)
- PPB and biomarker analysis.
- Specific analytical support for SFC, Oligonucleotide etc.
- LIMS, report as per client specific requirement.
- Governance structure for science, process and quality oversight, steering committee for quarterly review of progress.

New chemical entity (NCEs) supports

Supercritical fluid chromatography (SFC) coupled with MS/MS

- Supercritical fluid chromatography (SFC) is a form of normal phase chromatography that uses a supercritical fluid such as carbon dioxide as the mobile phase.
- Useful technique for separation of Chiral molecules, thermally liable compound, separation of drug metabolites and reduce overall run time of chromatography assay.
- **Currently working on complex Drug and Metabolite enantiomers separation for New Chemical entity in FIH programme**

New chemical entity (NCEs) supports

Inductively Coupled Plasma Optical Emission spectroscopy (ICP-OES)

- ICP-OES is an analytical technique used to determine how much of certain elements are in a sample. The ICP-OES principle uses the fact that atoms and ions can absorb energy to move electrons from the ground state to an excited state.
- Assay for following elements has been validated by ICP-OES and also conducted studies for regulatory submission.

  - **Total iron and Transferrin Bound Iron (from Iron Sucrose)**
  - Potassium (from Potassium Chloride)
  - Lithium (from Lithium Carbonate)
  - Magnesium (from Magnesium glycerophosphate)
  - Zinc (from Zinc Acetate)

New chemical entity (NCEs) supports

Biomarker Assay by HPLC-UV and LC-MS/MS

- Biomarkers are distinctive biological characteristics which can be discovered and measured in parts of the body like the blood, serum or tissue. They may be a sign of normal or diseased processes in the body.
- Assay for following elements biomarker has been fully validated and also conducted studies to support Clinical programme.

    - **α1 Acid Glycoprotein (AAG) :** Analyzed by HPLC-UV, used AAG free beagle plasma to construct calibration curve and QCs in real matrix
    - **Coproporphyrin-1:** Analyzed by LC-MS/MS, used charcoal stripping method to construct Calibration curve and QCs in real matrix

New chemical entity (NCEs) supports

Micro-sampling Assay

- Microsampling is a procedure for capturing and analysing minute samples of blood for analysis. The samples require no more than 10-20 µL (microliters) of blood volume. A conventional sample drawn by venipuncture may consist of sample volumes of up to 10 ml, as much as 500 to 1,000 times the size of micro samples.
- Analysis of patients samples for one of NCE programme has been performed by collecting samples **with Capillary and TAP device**. Method was validated partially and used exploratory estimation of patients samples.
- **Planning to start work on Tasso M-20 micro-sampling devices and also with Dry blood spot (DBS) for one NCE programme**

Experience

Capabilities

Total available Bioanalytical methods are more than 1205

986 + 20 Generics + Pharmacodynamics/ Immunogenicity

104 Complex Generics

95 NCEs

Salient Features

- Average processing capacity of 1,00,000 samples per month
- Central Bioanalytical Laboratory for global Phase II/ Phase III trials

Types of Methods

- Capability to develop methods with lowest quantification level- up to 0.1 pg
- Methods developed for:
  - Endogenous molecules
  - Amino Acids (Multiple analysis in single injection)
  - Hormones
  - Steroids
  - Inhalation formulation
  - Elemental Bioanalysis (Other matrix- Urine)
  - Immunogenicity
  - Large molecules/ECLIA/ELISA
  - Chiral and Liposomal
- Tissue distribution studies.

Complex Assay Summary

Types of Assay	Molecule Name
Endogenous Molecules	Levothyroxine, Hydrocortisone, Isotretinoin Estrone (total), Estrone (Unconjugated) +Estradiol (Unconjugated), Trans and Cis –Phytonadione (Geometric isomers), Free Thiamine
Amino Acid	Separation of 20 amino acids and their quantification, Amino Acid with NCE
Inhalation formulation	Tiotropium, Budesonide, Formoterol, Ipratropium, Glycopyronium, beclomethasone dipropionate
Liposomal formulation	Doxorubicin and Amphotericin (Free and liposome encapsulated estimation)
Protein bound drug	Paclitaxel and Docetaxel (Unbound and total Drug estimation): Ultrafiltration
Small peptide	Desmopressin, Leuprolide, Octreotide
Large Molecule	Insulin Aspart, Insulin Glargine with M1 and M2
Biomarker	α1 Acid Glycoprotein (AAG), Coproporphyrin-1
Iron Sucrose/ FCM formulation	Total Iron and Transferrien Bound Iron
Exploratory support	Tissue distribution, skin, contact lens, fecal, CSF

Central Bioanalytical Lab

Central Bioanalytical Lab Services

Dedicated team for Central Lab Services

- Project Manager
- Sample management team (BRD custodians)
- Kits & Logistics coordinator
- Analytical Team (PK analysis – based on projects)
- Watson Team

Central Bioanalytical Lab Experience

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 Pharmaceutical company

- Type of studies : NCE (Multisite)
- Total studies : More than 40 studies ongoing (from Multisites globally, 20000 samples per year)
- Services provided: Sample management, method development, method validation and analysis of NCEs
- Sample receipt to analysis within 5 days
- Sponsor specific reports with e-CTD
- More than 64 methods developed and validated for NCEs
- Exploratory studies, e.g. skin tissues , plasma protein binding experiment, chiral impurity estimation in the sample

Digitization – LES & Watson LIMS

ELN/LES:

- Development server is ready and installation completed
- Training and Workshops sessions for Phase 1 completed.
- Configuration will be completed by 10 Feb 2023 for Phase-1
- Tentative Date for Phase 1 to be completed and Go-Live: 01 May 2023

Watson LIMS 7.7:

- Installation (IQ) Completed.
- FS Document, OQ Plan, and OQ Scripts finalised
- OQ ongoing. Tentative completion date: Apr 2023
- Tentative Date for Go-Live: Jul 2023

Recognitions

Recognitions

veeda clinical research

BIONEEDS

Celebrating
19 YEARS
of excellence in Clinical Research

Organization	Award Category
ASSOCHAM INDIA	Best Clinical Research Organization - India
Health & Wellness	Clinical Trial Company of the Year
ECONOMIC GROWTH FOUNDATION	Bharat Udhyog Ratan Award in Clinical Research

Organization	Award Category
BioSpectrum	Top CLRO Company
Praxis Media	Best Quality Clinical Research Services in India

2004 → 2017 → 2018 → 2019 → 2020 → 2022

Organization	Award Category
Praxis Media	National Excellence Award
AI Global	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research- India
	Best Clinical Research- India
	Mark of Excellence
FROST & SULLIVAN	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

Organization	Award Category
SHIMADZU Excellence in Science & SPINCO BRINGING TECHNOLOGY. ENABLING SCIENCE.	MS Excellence in BABE Services, Largest Indian CRO

THANK YOU

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

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a healthier tomorrow