



Table Of Contents

- Corporate Overview
- Bioanalytical Research
 - Infrastructure
 - Bioanalytical Team
 - New chemical entity (NCEs) supports
 - Validated Assay Library
 - Complex Assay Summary
 - Digitalisation- LES & Watson LIMS
- Central Bioanalytical Lab
- Recognitions

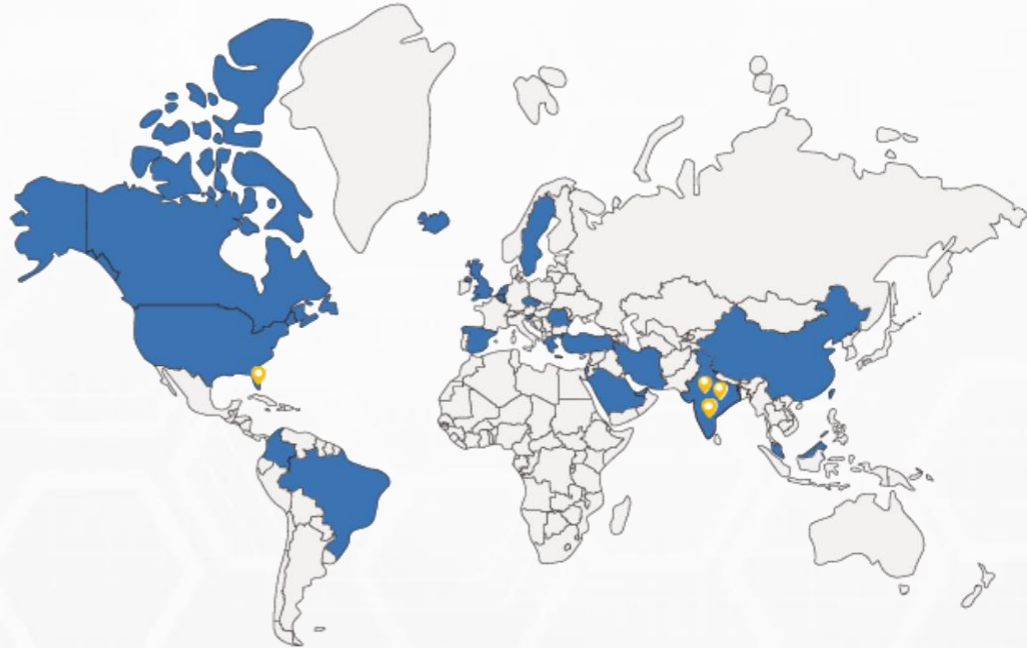





Corporate Overview



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

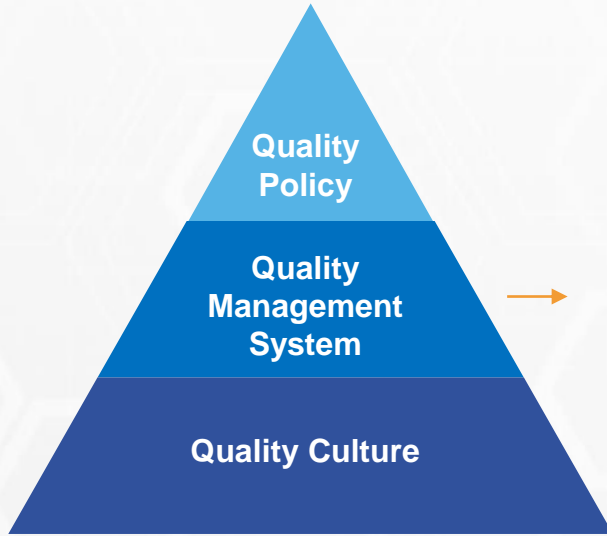
Collaboration

Nurturing Individual Growth

Partners in creating a healthier tomorrow

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”



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

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



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

- 98 successful regulatory audits till date
- 15 successful regulatory audits in the last year.

US FDA → 49*

ANSM → 1

MHRA → 4

AGES → 5*

ANVISA → 8

MCC → 1

WHO → 6

DCGI → 19

NPRA
Malaysia → 5

**FDA : 25 AUDITS FOR PATIENT BASED STUDIES
24 AUDITS FOR HEALTHY SUBJECTS STUDIES*

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

Bioanalytical Research



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)

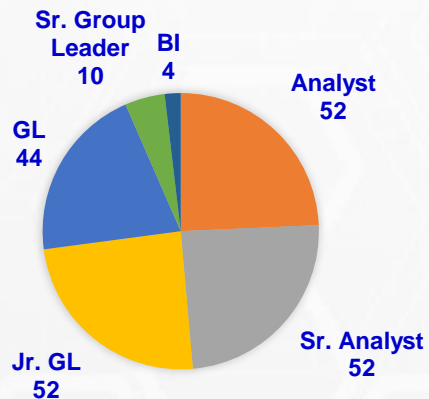


IP Storage:

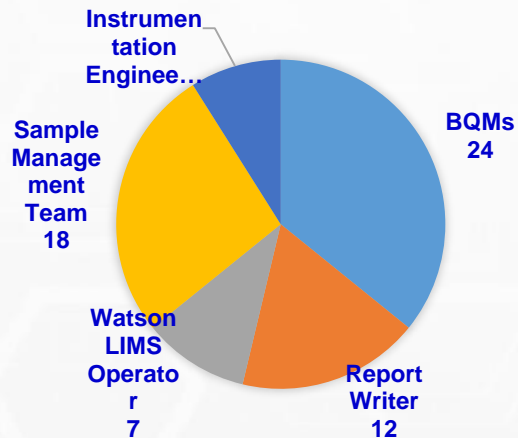
- 6 Walking type stability chambers with overall capacity to store 74,000 Ltr for retention at room temperature
- 5 Humidity chambers with overall capacity of 4,200 Ltr
- 4 Pharmaceutical refrigerators having storage capacity of 11,350 Ltr at 2-8 °C

Bioanalytical Team

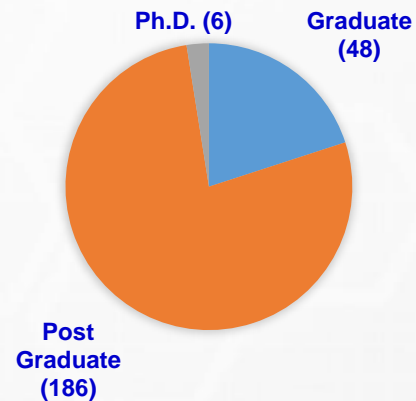
OPERATION TEAM-BRD



SUPPORT STAFF-BRD



QUALIFICATION - BRD EMPLOYEE



New chemical entity (NCEs) supports

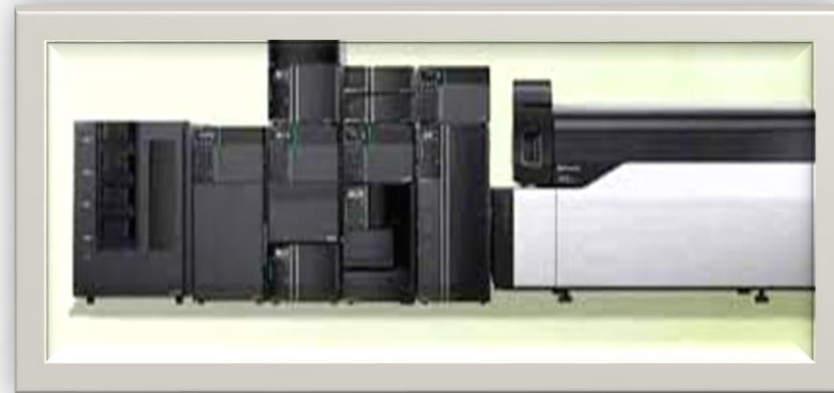


- Phase- 1 molecule development /validation from Preclinical methods.
- Clinical trial samples (FIH) study support and reporting.
- Phase- 2/3 samples and analysis
- Exploratory support for Microsampling, DBS, rare matrix analysis (CSF, Skin)
- PPB and biomarker analysis.
- Specific analytical support 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.
 - **α 1 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



BIONEEDS

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 1221

995 + 20

Generics +
Pharmacodynamics/
Immunogenicity

108

Complex
Generics

98

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, Glycopyrronium, 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	α 1 Acid Glycoprotein (AAG), Coproporphyrin-1
Iron Sucrose/ FCM formulation	Total Iron and Transferriin 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



BIONEEDS

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



Celebrating
19 YEARS
of excellence in Clinical Research

Organization	Award Category
ASSOCHAM I.D.A.	Best Clinical Research Organization - India
Health & Wellness	Clinical Trial Company of the Year
ECONOMIC GROWTH FOUNDATION	Bharat Udhog Ratan Award in Clinical Research

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



Organization	Award Category
PraxisMedia	National Excellence Award
AI Global	Best Pharmaceutical CRO
Health & Safety Awards	Best Clinical Research- India
Health & Safety Awards	Best Clinical Research- India
Mark of Excellence	Mark of Excellence
FROST & SULLIVAN	Indian Clinical Research company of the year

Organization	Award Category
Green Quality Excellence	Best Quality Clinical Research Organization in India
PHARMACEUTICAL RESEARCH INSTITUTE	Best Quality Clinical Research Organization in India
Indian Clinical Research company of the year	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

Partners in creating
a healthier tomorrow

