

Bio Scientific Research Laboratories (I) Pvt. Ltd.

Your one stop solution partner

Preamble



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Introduction

Bioavailability & Bioequivalence studies commenced in 2012

Spread over about 27000 sq. ft. in Thane, Maharashtra (India)

Provide a range of research services

Bioavailability & Bioequivalence

In strict compliance with GLP, GCP and other applicable regulatory guideline

DCG(I) Approved BA/BE Facility

ISP Chile Approved Facility

Ministry of Health (MOH) IRAQ Approved Facility

NPRA Malaysia Approved Facility

Our dossiers are accepted and approved by FDA-Philippines, BPOM-Indonesia & PPB Kenya

Our Vision & Mission



Our vision is to be a leading CRO & a significant global player by providing high quality, affordable and innovative ideas. To capture the growing business and expand its professional services to the regional area.



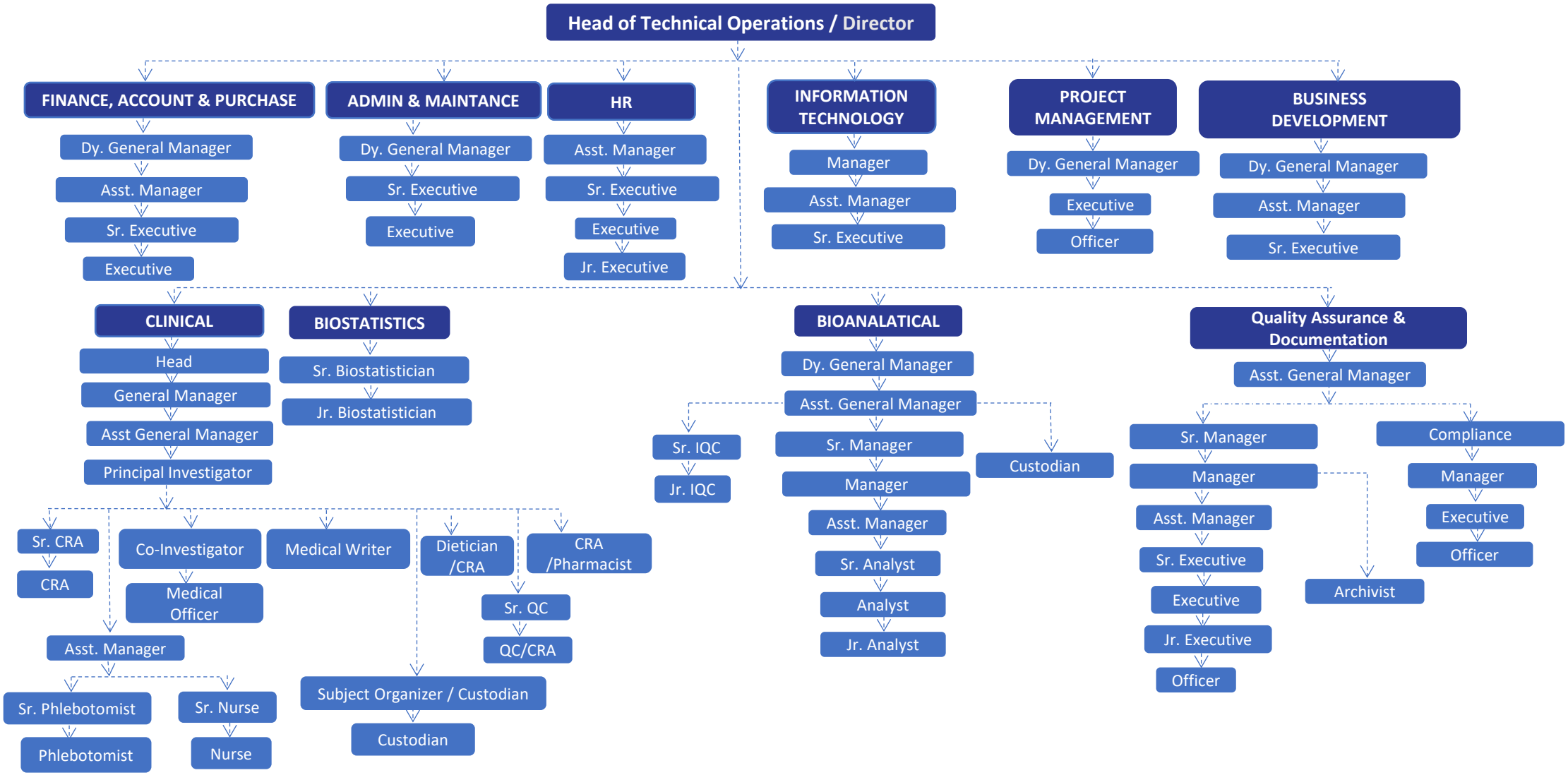
Our mission is to help pharmaceutical industry world-wide in getting efficient, accelerated and time-bound services.

Quality Policy

- BioSRL pursuits of Quality Service and customer satisfaction are based on the adherence to GCP, GLP and other national & international regulatory norms in addition to providing reliable, consistent, traceable and timely test results.
- We commit to meet set timelines and keep knowledge updated and abreast with the most recent and innovative concepts in quality and management systems are the hall marks of our Quality Service.
- We follow good professional practice by use of appropriate tests, methods, standard reference materials, calibrated equipment, trained personnel, maintenance of confidentiality and integrity.
- The management provides necessary resources, which include imparting of training to all concerned employees to aware of the Quality Management System and implement the Quality Policy and Procedures in their work.
- Our continuous training and competency evaluation at various levels of work, to attain quality objectives & implement quality policies and procedures which are reviewed periodically, is in lieu with fostering the professional development of our employees.



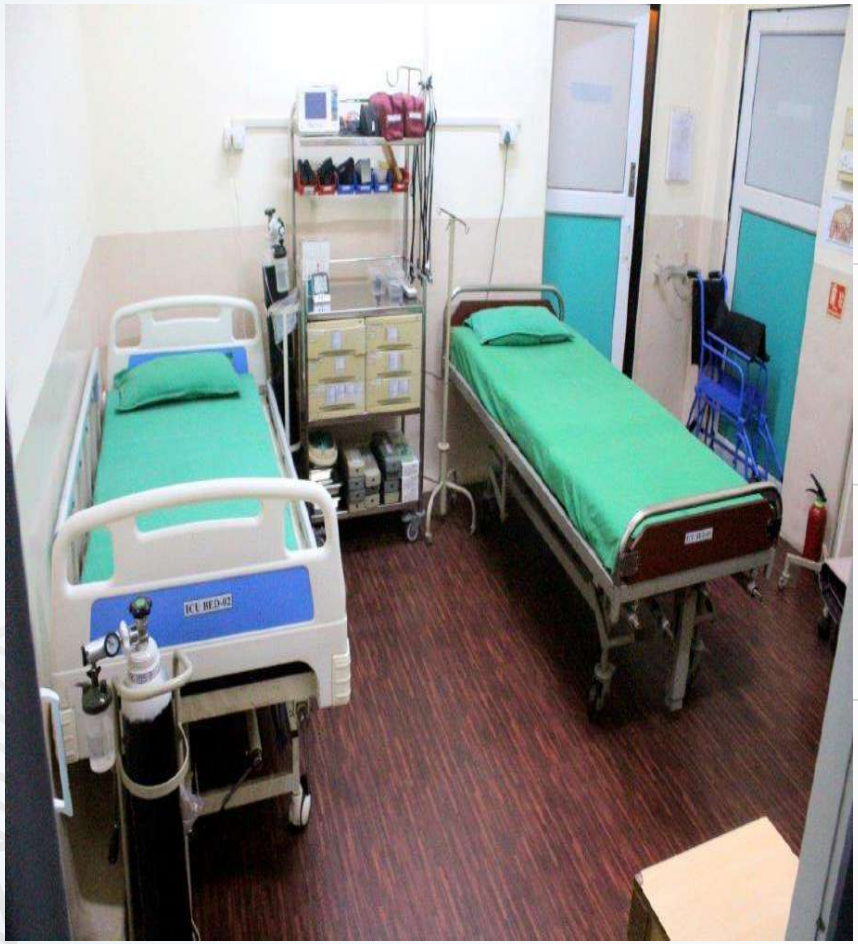
Corporate Organogram



Key Personnel

Employee	Designation	Qualification	Experience	Department
Dr. S. Lakshminarayana	Director/ HTO	M.Sc., Ph.D.	30 Years	NAP
Dr. Sasikumar Menon	Technical Advisor	M.Sc., Ph.D.	33 Years	NAP
Dr. S. Vijay Kumar	Head	MBBS	32 Years	Clinical
Dr. Harminder Dua	Principal Investigator	M.D. (Pharmacology)	24 Years	Clinical
Dr. Avinash Wanjarwadkar	Co-Principal Investigator	MBBS	20 Years	Clinical
Mr. Vikas Khabale	Assistant General Manager	B.Pharm., M.B.A.	20 Years	Clinical
Mr. Niteshkumar Jha	Sr. Biostatistician	M.Sc. Statistics	4.5 Years	Biostatistics
Mr. Suresh Tak	Assistant General Manager	M.Sc.	19 Years	QA & Documentation
Mr. Jayesh Shirke	Assistant General Manager	B.Sc.	18 Years	Bio-Analytical
Mr. Ganesh Kusuma	Manager	B.Sc.	15 Years	IT
Mr. Santosh Rane	Deputy General Manager	B.Com., PGDT	25 Years	Finance, Admin & HR

BA/BE Profile



Studies conducted
550+

Volunteers database
15,000+

Male 14,000+ | **Female** 600+

Beds
92 + 03 (ICU)

LC-MS/MS
06

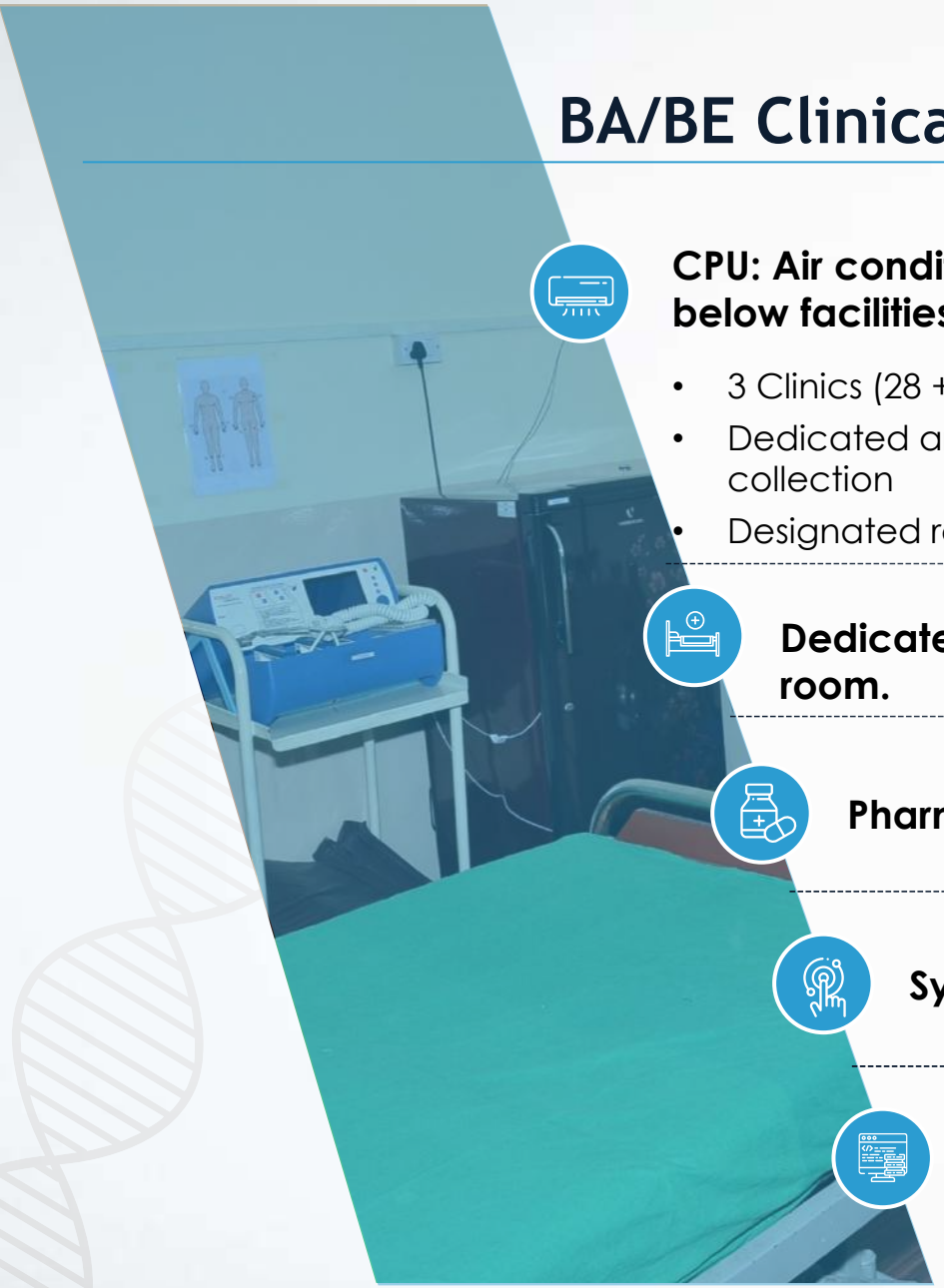
Validated bioanalytical methods
200+

Medical Doctors
On Roll 02 | **Contractual** 05

Pharmacist
04

Number of Employees
120+

BA/BE Clinical Facility



CPU: Air conditioned 92 bedded housing area with below facilities:

- 3 Clinics (28 + 28 + 36 beds each)
- Dedicated area for dosing and sample collection
- Designated room for Sample processing
- 3-bedded Intensive Care Unit (ICU)
- Investigators cabin
- Pantry

Dedicated screening area featuring an Audio/Visual consent room.

Pharmacy with access control measures in place.

Synchronized digital clocks installed throughout the facility.

Centralized data logger system for monitoring temperature, humidity of storage cabinets and deep freezers.

Housing Area



CPU-I (28 Beds)



CPU-II (28 Beds)



CPU-III (36 Beds)

Intensive Care Unit (ICU)

01

- Two-bedded fully equipped Intensive Care Unit (ICU).
- Qualified and trained medical and para-medical professionals.
- Dedicated team for handling emergencies.
- Designed to serve both **CPU I and CPU II.**





02

- One-bedded fully equipped Intensive Care Unit (ICU).
- Qualified and trained medical and para-medical professionals.
- Dedicated team for handling emergencies.
- Tailored to meet the critical care needs of **CPU III.**

Pharmacy

- State-of-the-art access-controlled room.
- 6 Humidity Chambers dedicated to the secure storage of investigational products.



Pharmacy

- Laminar Air Flow (LAF) system to ensure a clean, particle-free working environment by providing uniform, HEPA-filtered airflow over the workspace.



Bioanalytical Services

State of the art Bioanalytical Laboratory equipped with LC-MS/MS that provide the flexibility to develop and execute analysis in wide range of sensitivities (up to pg/mL level).





- **6 AB Sciex LC-MS/MS Systems, Triple Quad – API 5500 with analyst software.**
- **LC-MS/MS Method development, method validation & sample analysis.**
- **Parent & metabolites simultaneous analysis.**
- **Chiral & endogenous drug analysis.**
- **Quantitative analysis of biological samples using FTIR spectroscopy.**

Sample Storage Room

Bio Analytical

- 3 Deep Freezer (-20°C).
- 2 Ultra-Low Temperature Freezer (-70°C).



Clinical

- 2 Deep Freezer (-20°C).
- 4 Ultra-Low Temperature Freezer (-70°C).



Biostatistics

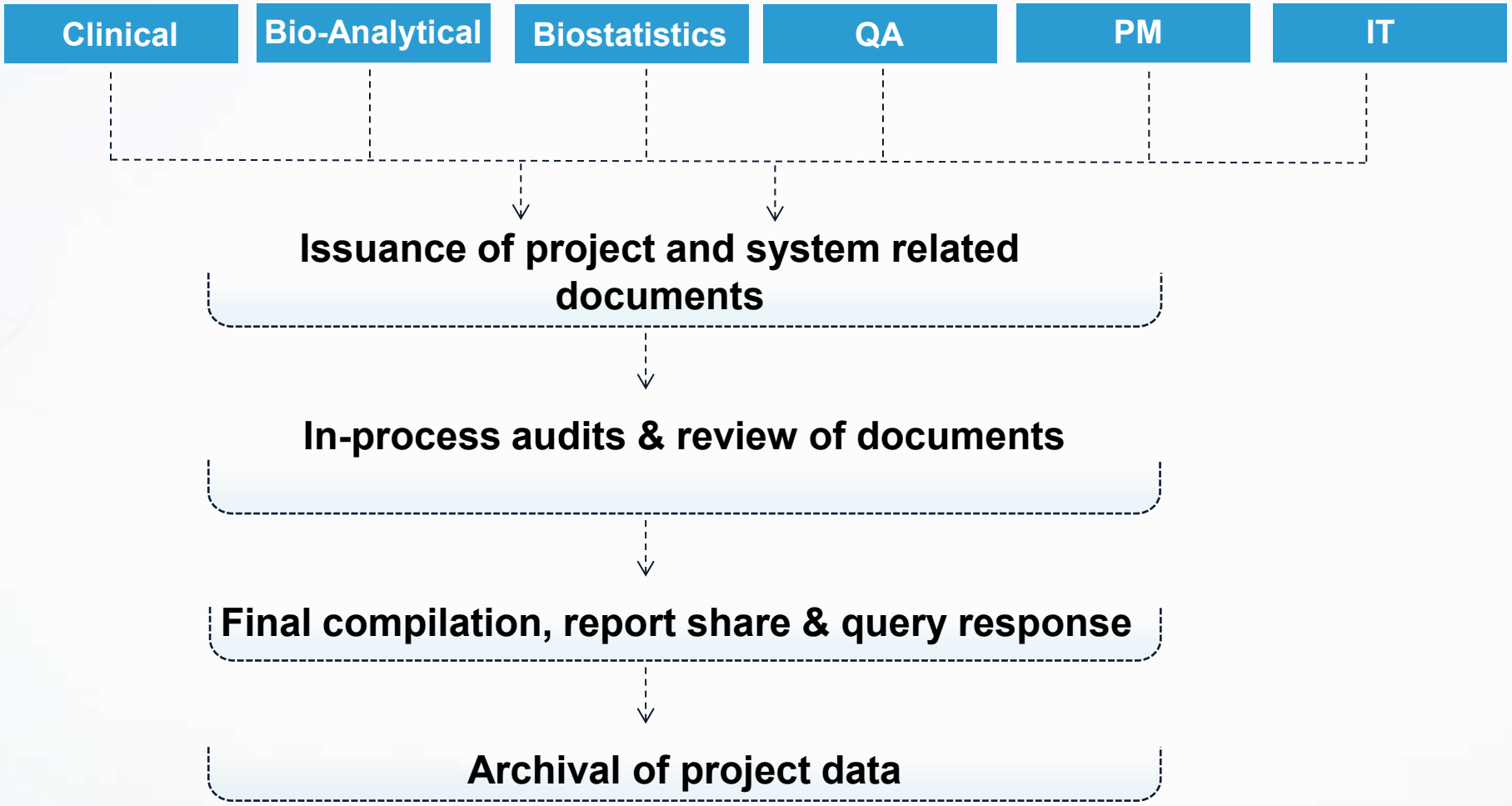


Quality Assurance

Independent QA and Documentation department



QA Department Process Flowchart



Archival



01

Access-Controlled area for temporary archival of project data and supporting documents.

02

Separate storage for electronic data & study documents.

03

Offsite archival for records and document storage.

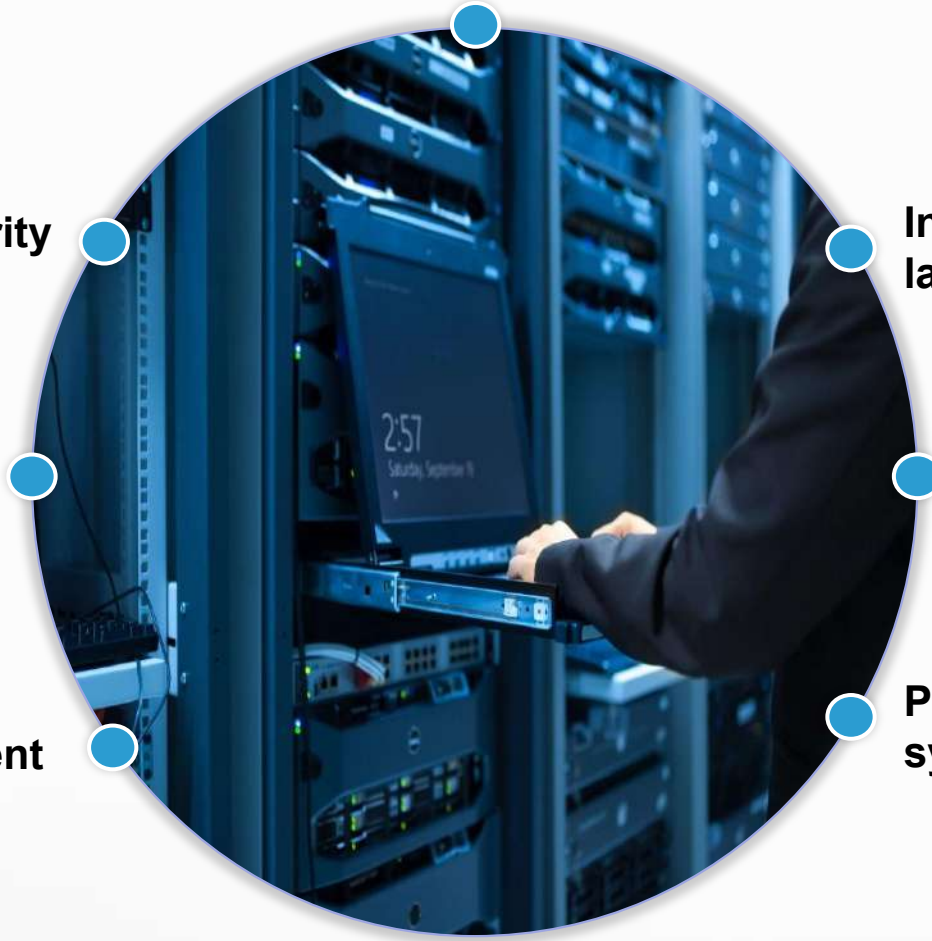
Information Technology

IT Governance & Support

IT Security

Independent & dedicated laboratory network systems

Data Backup, Data Restore & Data Verification



Highly secure door access control systems

Software Management

Password based user authentication systems

List of Computerized Systems

Sr. No	Software Name	Version
01	Analyst	1.7.3
02	SAS (Statistical Analysis System)	9.4
03	ThermoScientific Smart-Vue	2.2.4.5
04	VIMS (Volunteer Information Management System)	1.0.1
05	Sentinel (Volunteer Cross Participation and Verification System)	3.0.01
06	MAC 2000 ECG Analysis System	1.1
07	Agilent MicroLab	5.6

SOP Strength

All activities performed in BioSRL are strictly SOP driven and as per the applicable regulatory guidelines

Department	Clinical	Bio-analytical	QA & DOC	Biostatistics	IT	Purchase, Admin & HR	PM	Total SOPs
SOP's	59	55	25	08	11	17	01	176

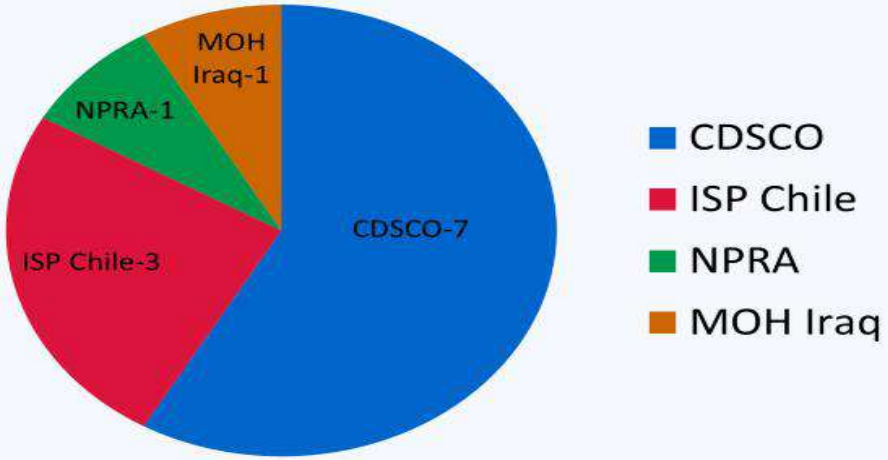
Collaborations

Vendor	Details	Remarks
Multi-Specialty Hospital	Meditech Hospital	At a distance of about 4 km from the organization
Pathological Laboratory	1. Suburban Diagnostic 2. Intense Diagnostics 3. Vilife Diagnostics	1. NABL/CAP certified 2. ISO 15189:2012 / NABL certified 3. ISO 15189:2012 / NABL certified
Offsite Archival	Iron Mountain	ISO 9001: 2015 / ISO/IEC 27001: 2013
Ambulance	Om Sai Ambulance Services	Fully equipped Cardiac ambulance
Blank Plasma	1. Darpan Diagnostic Research Centre 2. Precision Labs	1. ISO 9001: 2015 2. ISO 9001: 2015
Biowaste Management	Touch n' Glow	Authorized by MPCB
Calibration Services	1. Thermolab Testing Services 2. Criticam Medical System LLP	1. ISO/IEC 17025:2017 2. NABL 126

Regulatory Inspection

Global Regulatory Inspection & Approval Overview

Regulatory Inspection Distribution



Regulatory Inspection Summary

CDSCO (India)
7 Inspections | Valid up to 2031

ISP Chile
3 Inspections | Valid up to 2029

NPRA Malaysia
1 Inspection | Valid up to 2029

MOH Iraq
1 Inspection | Last Approval: Apr 2013

BE Study Dossiers Accepted and Approved by

01 FDA Philippines

02 BPOM Indonesia

03 PPB Kenya

Certifications & Accreditations

Drugs Controller General (India)

NPRA-Malaysia

FDA-Philippines

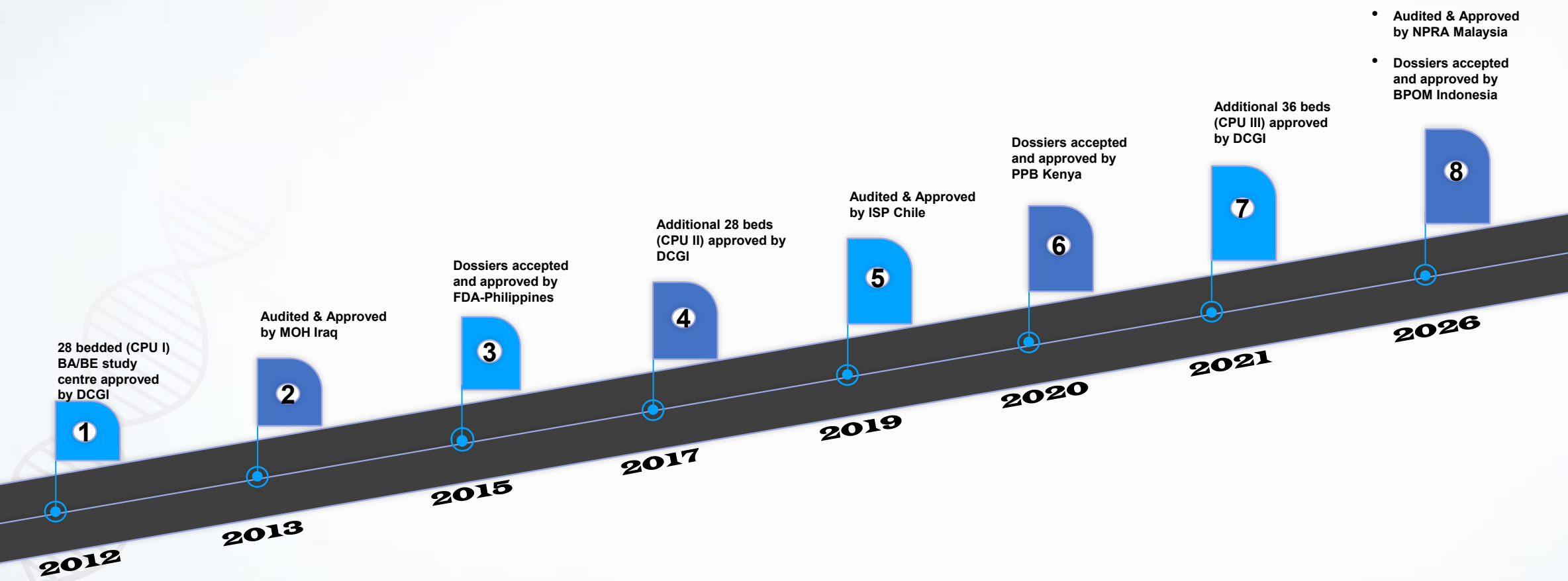
ISP Chile

BPOM-Indonesia

Ministry of Health (MOH) Iraq

PPB-Kenya

Key Milestones





Thank You

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