



BioSRL

Your one stop solution partner



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BioSRL Profile

BA / BE

Quality Assurance

Infrastructure

IT Security

Archival

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Introduction



Bioavailability and Bioequivalence studies commenced in 2012.



Located in Thane, Maharashtra (India), our facility spans approximately 27,000 square feet.



Providing a range of research services :

Bioavailability & Bioequivalence | **Pharma-Analytical**



In strict compliance with GLP, GCP and other applicable regulatory guidelines.



DCG(I) Approved BA/BE Facility | **ISP Chile Approved Facility** | **Ministry of Health (MOH) Iraq Approved Facility** | **Maharashtra FDA Approved Analytical Facility** | **ISO/IEC 17025:2017 certified**



Our dossiers are also accepted and approved by FDA-Philippines.



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.



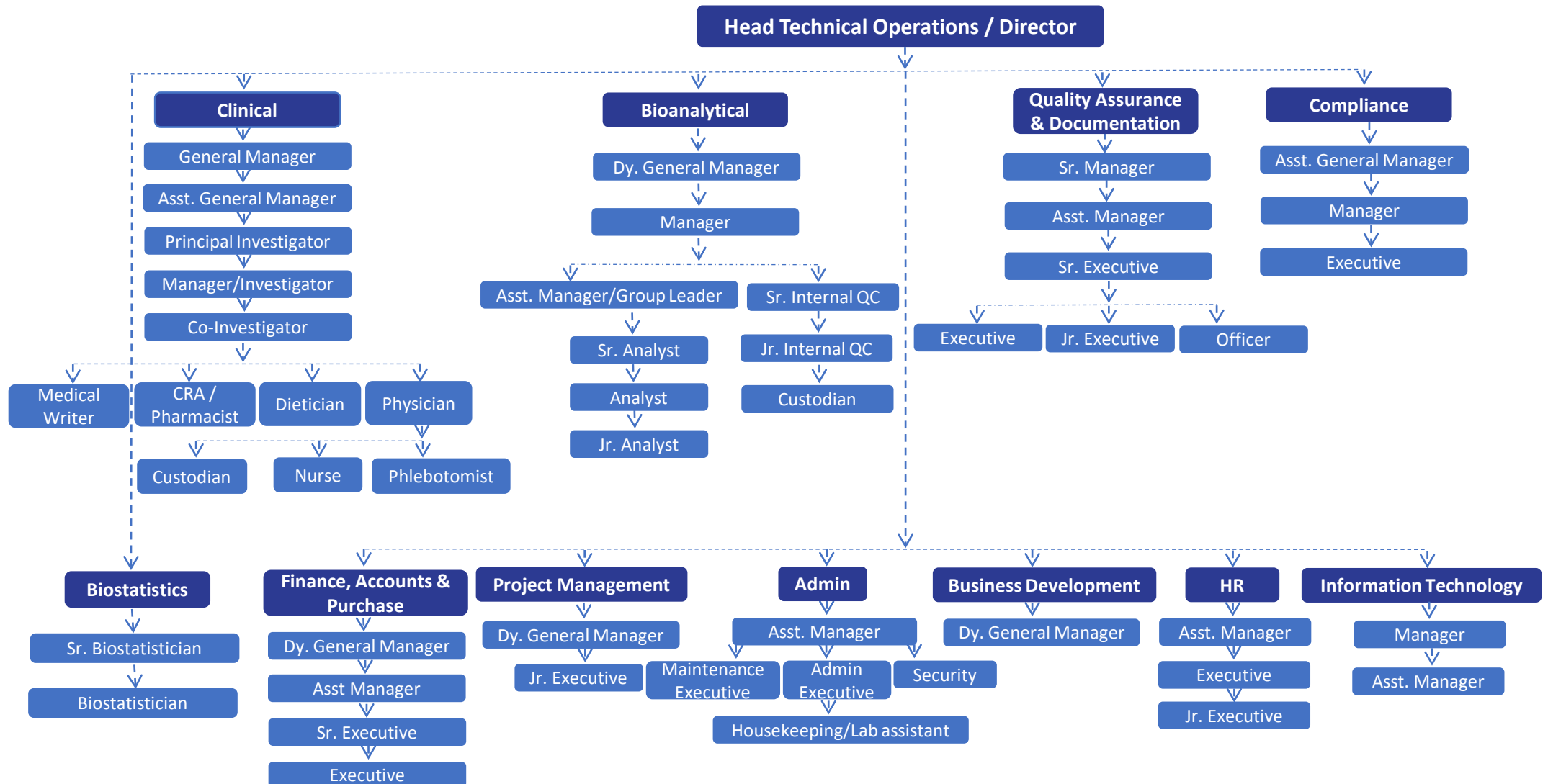
Our mission is to help pharmaceutical industry world-wide in getting efficient, accelerated and time-bound services.

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 (V.01)



Key Personnel

Employee	Designation	Qualification	Experience	Department
Dr. S. Lakshminarayana	Director/ HTO	M.Sc., Ph.D.	23 Years	NAP
Dr. Sasikumar Menon	Technical Advisor	M.Sc., Ph.D.	33 Years	NAP
Dr. Harminder Dua	Principal Investigator	M.D. (Pharmacology)	24 Years	Clinical
Dr. Sachin Rajput	General Manager	M.B.B.S., DGO, MD	10 Years	Clinical
Mr. Vikas Khabale	Assistant General Manager	B.Pharm., M.B.A.	18 Years	Clinical
Dr. Anand Ashtekar	Manager (Investigator)	M.B.B.S.	08 Years	Clinical
Mr. Mansingh Rajput	Deputy General Manager	M.Sc.	20 Years	Bio-Analytical
Dr. Kanchan Gandhi	Manager	M.Sc., Ph.D.	12 Years	Bio-Analytical
Mr. Pritam Lonandkar	Sr. Manager	M.Sc.	16 Years	QA & Documentation
Mr. Jayesh Shirke	Assistant General Manager	B.Sc.	16 Years	Pharma-Analytical & Compliance
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
450+

Volunteers database
11,500+

Beds
92 + 03 (ICU)

LC-MS/MS
07

Validated bioanalytical methods
200+

Medical Doctors
05

Ph.D. and Postgraduates
60+

Pharmacist
08

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 & Sample Storage Room

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



Pharmacy



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



Sample
Storage Room



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).



- **7 AB Sciex LC-MS/MS Systems, Triple Quad – API 4500 & API 5500 with analyst software 1.7.3.**
- **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.**

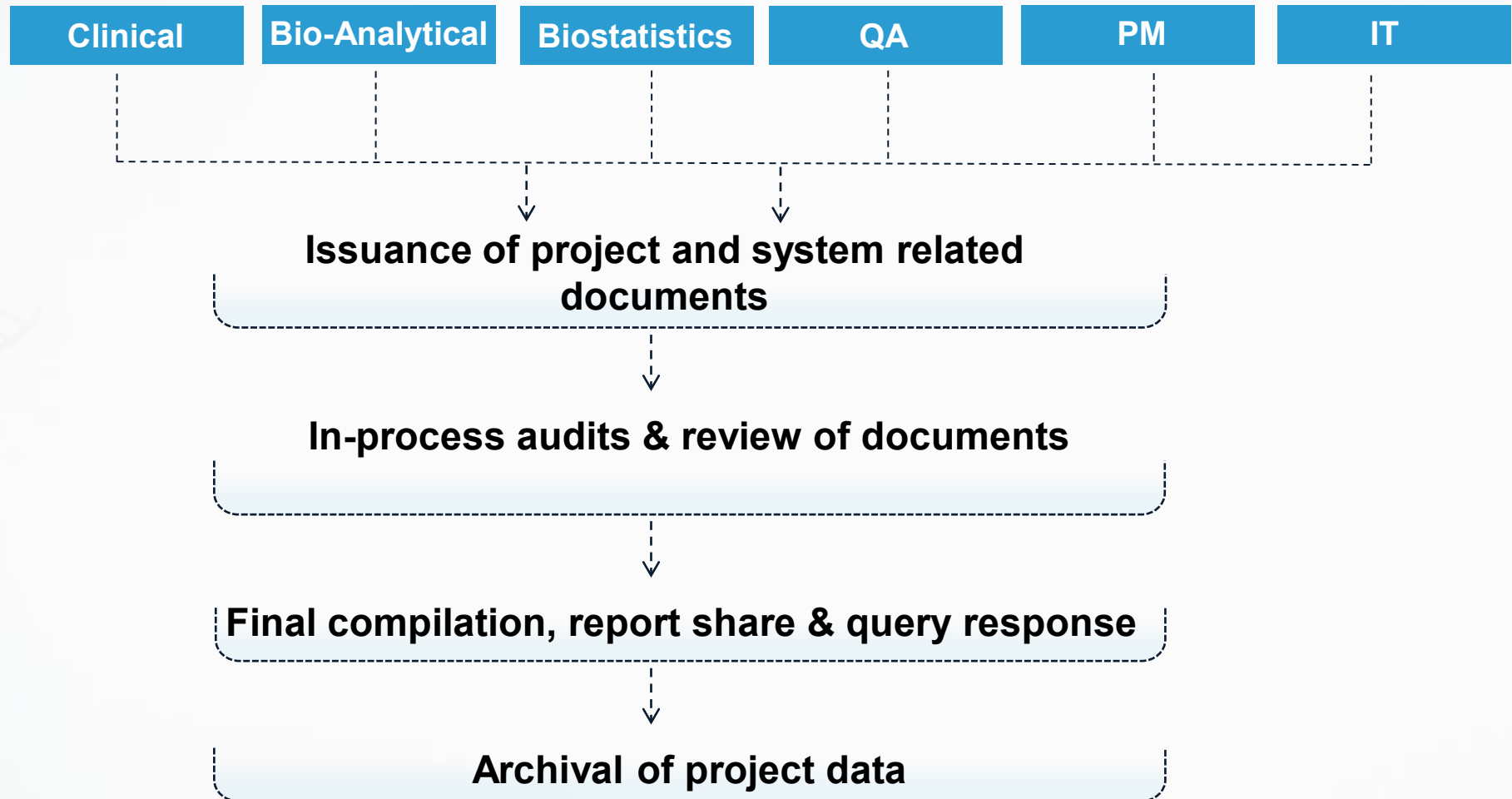




Independent and centralised QA and Documentation department



QA Department Process Flowchart





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.

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**



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	Total SOPs
 SOP's	60	74	25	8	10	14	191

Collaborations

Vendor	Details	Remarks
Multi-Specialty Hospital	Meditech Hospital	At a distance of about 4 km from the organization
Pathological Laboratory	<ol style="list-style-type: none"> 1. Suburban Diagnostic 2. Intense Diagnostics 	<ol style="list-style-type: none"> 1. NABL/CAP certified 2. 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	<ol style="list-style-type: none"> 1. Darpan Diagnostic Research Centre 2. Vardhman Diagnostic Research Centre 3. Precision Labs 	<ol style="list-style-type: none"> 1. ISO 9001: 2015 2. ISO 9001: 2015 3. ISO 9001: 2015
Biowaste Management	Touch n' Glow	Authorized by MPCB
Calibration Services	<ol style="list-style-type: none"> 1. Thermolab Testing Services 2. Criticam Medical System LLP 	<ol style="list-style-type: none"> 1. ISO/IEC 17025:2017 2. NABL 126

Certifications & Accreditations



Drugs Controller General (India)



ISP Chile



Ministry of Health (MOH) Iraq

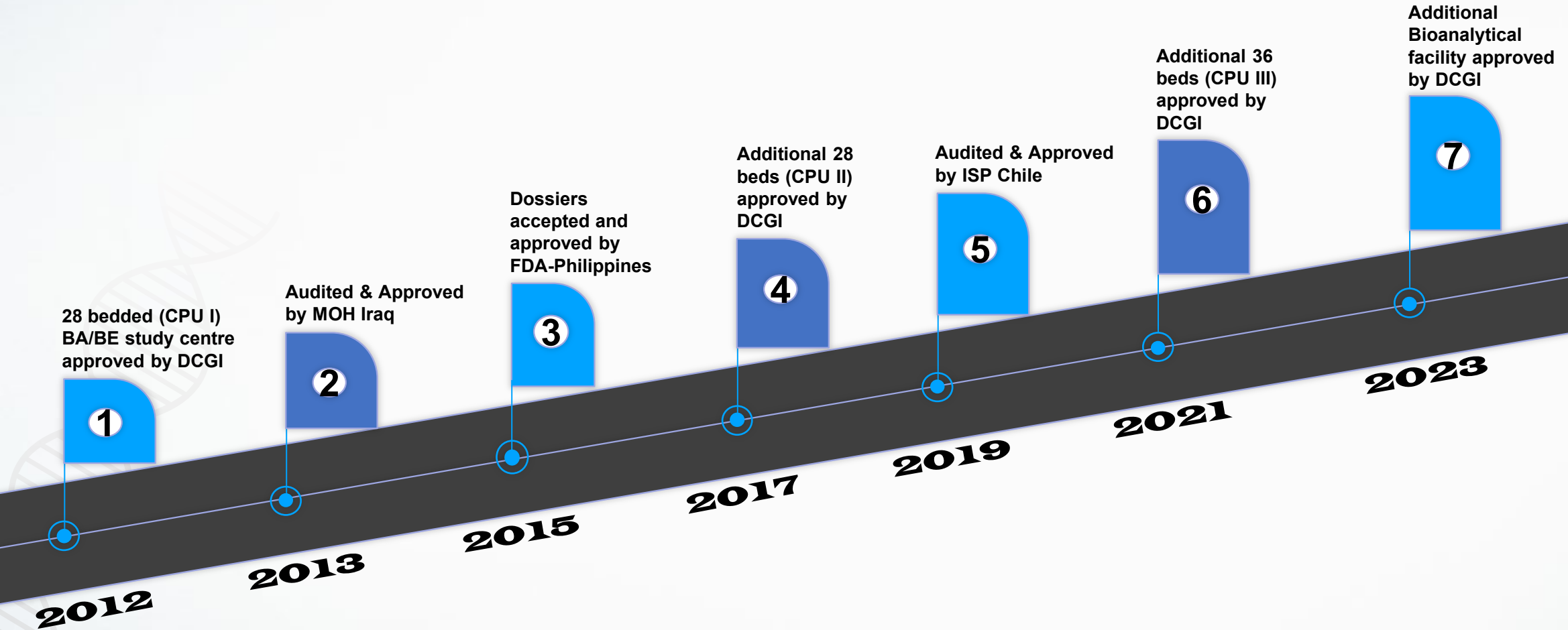


Maharashtra FDA



ISO/IEC 17025:2017

Key Milestones



Thank You



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