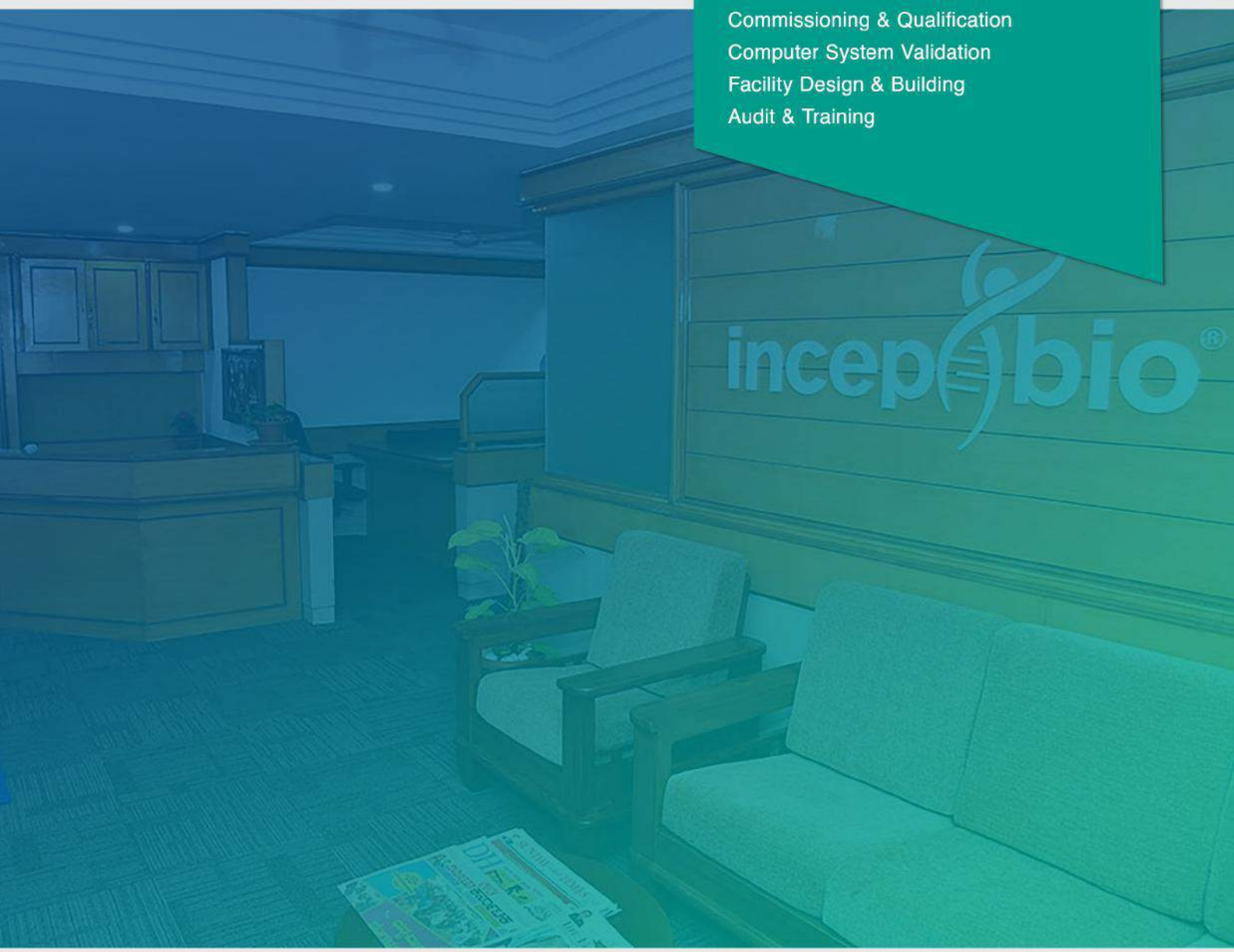
COMPLIANCE MADE EASY FOR YOU

Validation & Calibration
Commissioning & Qualification
Computer System Validation
Facility Design & Building
Audit & Training



incepbio®

About INCEPBIO

Our Mantra

Quality Life Every Day

Our Vision

To Assure a Productive Human Life

Our Core Values

Be Caring
Be Empathetic
Be Responsible

HI THERE!
IN CASE YOU ARE CURIOUS WE STARTED IN
2016

INCEPBIO was built with a purpose to help you **ACHIEVE YOUR VISION** in providing quality and safe products to all the patients across the globe

We have a combined experience of **35+** years in the Pharmaceutical industry

Dynamic and versatile Teams

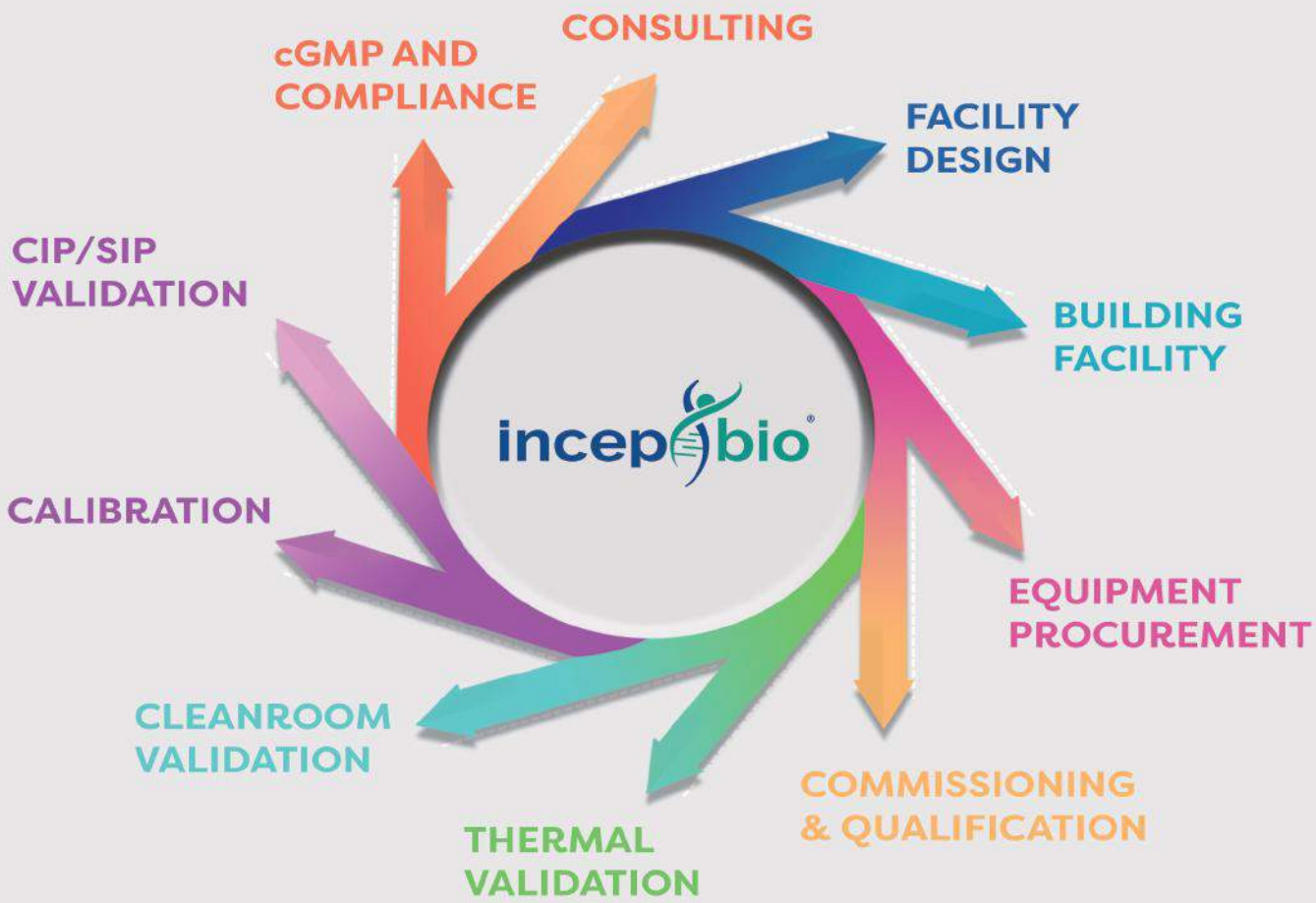
We have solved problems of more than **100** clients

ISO 9001:2015 Certified

We are the only company to provide End to End integrated services focused on DESIGN, CONSULTATION & EXECUTION

Our Portfolio of

Services



Our UNIQUE Selling Proposition

The Power of a Full Scale Service Provider

Managing multiple vendors for multiple services is a biggest challenge. Plus it is a tedious process to get a vendor on board for regular services.

This is where our business stands out from others. We provide all services from facility design, building design, equipment procurement, commissioning classification, thermal validation, cleanroom validation, calibration, CIP/SIP validation till compliance serving all the areas in this industry.

We excel in helping you with all your problems with a single point of contact with lesser headache.

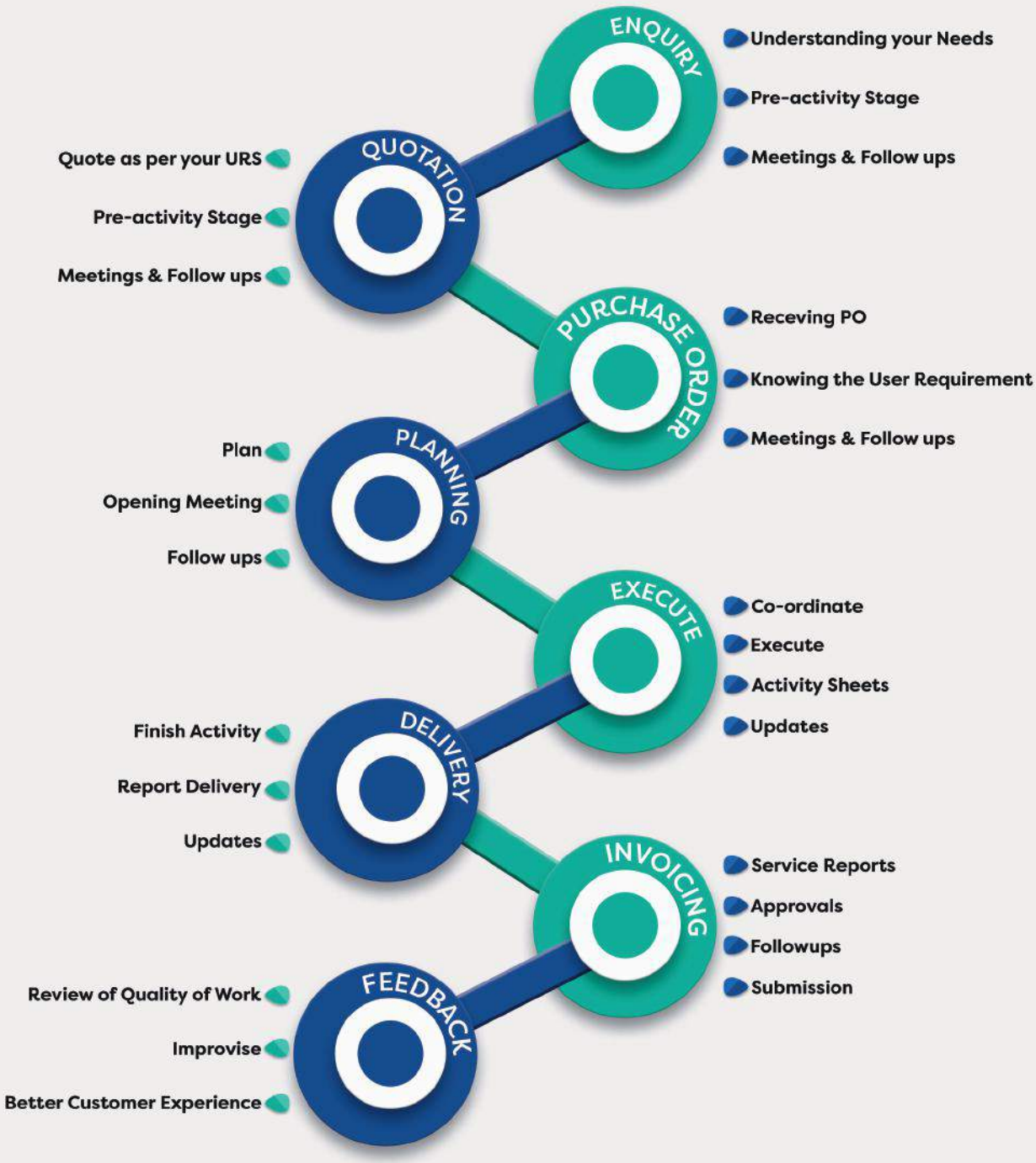
We are not only saving costs for our clients but also saving time and valuable effort from going waste.

We are what you would call a complete package. We solve all your challenges while following all international and national industry standards. Our team does so by carrying a combined experience of 35+ years in Pharma industry.

We unleash all our industry experience on your problems

Make the Right CHOICE

OUR UNIQUE Process



WHY YOU CAN TRUST OUR SERVICES

Customer - Centricity
You are at the centre of everything we do

Instant Raw Data Submission
4X faster than all other competitors. Quicker than Dominos.

End to End Integrated Services
All Services under one roof. We are your Amazon Prime.

Strong Credibility
35+ years of Combined experience in Pharmaceutical industry.

21CFR Part11 Compliant
Show the data with confidence to auditors

Quality of Reports
Clear, Concise & Comprehensive reports. Not like the ones in old government offices.

Audited Facility/System
Audited, Appreciated & Approved by clients like you.

Online Documentation
We work as if there is no tommorow

Peace of Mind Assured
Sleep Peacefully with Lesser Supervision

Immediate Support on Short Notice
As Easy as booking a UBER cab

Strong Technical Support
Stronger than Ambuja cement

Clientele

Himalaya HERBAL HEALTHCARE

Shilpa

Stelis Biopharma

Anthem BioSciences

SUN PHARMA

HLL Lifecare Limited (A Government of India Enterprise)

Syngene

BLUE STAR

Cipla

PASTEUR INSTITUTE OF INDIA COONOOR 1907

VIATRIS

Biocon

MERCK

gsk

RINAC

immuneel

99.7%

Satisfied Clients

> We don't just build facilities for you
> We build you as a **BRAND**

Facility Design

We have the best engineering services up our sleeves, thus providing you with robust facility solutions based on sustainable solutions, like:

- Integrating concepts and design of cGMP facilities
- Flexible cleanroom solutions
- Optimization of flows and logistics
- HVAC and Containment
- Seamless quality and cGMP compliance
- Concepts and design of laboratory facilities focusing on lean operations

Pharmaceutical facility design with a focus on

- Fast implementation
- High flexibility
- Regulatory compliance
- Affordable pricing

Our Comprehensive SERVICES

Building Facilities for you

We understand the nuances and details that deliver successful projects in the life sciences industry.

During our many years of experience, our staff have gained an intimate understanding of the laws and regulations that accompany the construction of pharmaceutical facilities and environments in today's life science industry.
Our professionals provide services on projects that involve:

- Clean rooms
- Laboratories
- Secondary manufacturing
- Packaging
- Launch facilities
- Biological areas

at a level of detail that corresponds to achieving owner-stated visions and goals by precise coordination of project schedules and tasks. We leave no project or detail unattended when working with owners and stakeholders who are vested in providing these sensitive and complex environments.

We are your GENIE-OUS

> We BUY it for you, We TEST it for you and We QUALIFY it for you

Equipment Procurement

Some dreams require the best equipment and we are the ones that help you achieve that dream. Pick any equipment and we shall procure it for you.

- Autoclave
- Incubators
- Hot air oven
- Heating block
- Freezer & ultra-deep freezer
- Walk-in and reach-in cold room
- Walk-in and reach-in stability chamber
- Biosafety cabinet/Laminar air flow cabinet
- Dry heat sterilizer
- Fume Hood Cabinet
- Humidity Chamber
- And many more...

Commissioning & Qualification

We also provide onsite/offsite C&Q services for Bio-Pharmaceuticals, Vaccines, Oral Solid Dosage, Fill/Finish, Parenteral, Medical Device and Nutraceutical facilities.

Global Regulatory Guidelines WE FOLLOW

World Health Organization

FDA USDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MHRA
Regulating Medicines and Medical Devices

Our Services Include:

- Equipment Requalification
- Protocol Development, Execution and Reports for DQ, IQ, OQ & PQ
- Commissioning & Qualification Project Management
- Computer System Validation (CSV)
- Cleaning Validation
- SIP and CIP Validation
- GAP Analysis
- Document Management
- Factory Acceptance Testing / Site Acceptance
- Master Planning (Commissioning, Qualification and Validation)
- Risk-based approaches (ASTM E2500, ICH -Q 9 principles)

Whether you are looking to add new equipment, optimize an existing process, improve cleaning cycle outcomes or automate an existing manual CIP process. We can provide our team of experts that will help you achieve it.

21 CFR Part 11 Compliant Data loggers

100%
21 CFR Part 11 Compliant

500+
Wireless data loggers

3500+
Positive customer reviews

10+
Wired data loggers

26+
Validation Engineers

5003+
Temperature mapping studies

11+
Document Reviewers

5023+
Temperature and relative humidity mapping studies

12071+
Autoclave Cycles

Thermal Validation

Serving Clients since 2016

Pharmaceutical industry
Biopharmaceutical industry
Cosmetic industry
Medical Device industry
Cold Chain industry
Food and Beverage industry
Dairy and Meat Processing industry

We offer temperature and relative humidity mapping services of all the controlled environments in accordance with National and International regulatory standards.

We Validate instruments & equipment over a range of

-196°C to 300°C & 20% to 95% RH

Autoclave
Cooling incubator
CO2 incubator
BOD incubator
Hot air oven
Heating block
Freezer & ultra-deep freezer
Walk-in and reach-in cold room
Walk-in and reach-in stability chamber
Biosafety cabinet/Laminar air flow cabinet
Dry heat sterilizer
Humidity Chamber
Bio Reactor/fermenter
Liquid Nitrogen Dewar
Tunnels
Bung Processor

WHO TRS 961 Supplements 7 & 8

ISPE Good Practice Guide- Controlled Temperature Mapping and Monitoring

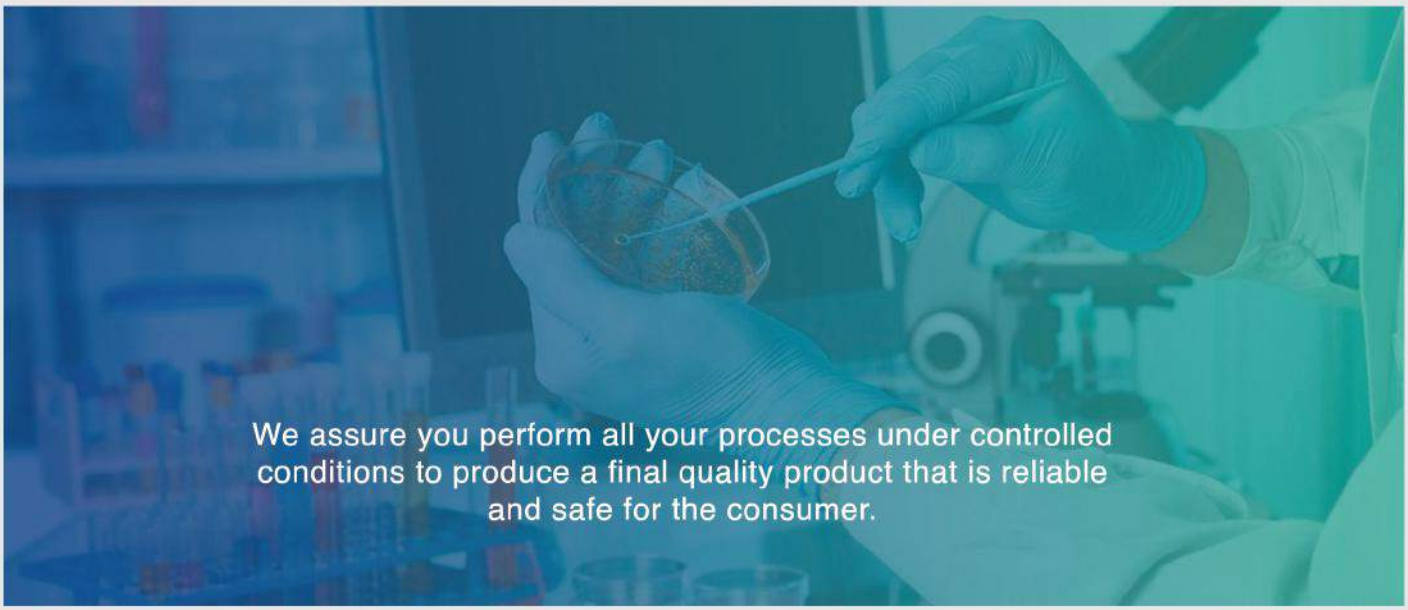
ISO 14644-3

Schedule- M (National Regulatory Body)

BS EN285

PDA Technical Report Series 1 and 3

Clean Spaces Safer Products



WE VALIDATE

Cleanrooms

Sterilizing Tunnels

Dust Collector

Dispensing Booth

Sampling Booth

Isolator

Biosafety Cabinet

Laminar Air Flow

Dynamic Pass Box

Garment cubicles

Air Shower units

Operation Theaters

Fume Hood

We perform cleanroom HVAC validations as per below guidelines

ECGMP

EUG MP

ISO 14644

WHO -TRS-937

WHO -TRS-961

ISO 8573

NABH guidelines for all Operation Theatres

We work with a range of clients from start-up labs to the world's best Pharmaceutical and Biotech companies.

Cleanroom Validation

99%
On Time Delivery

27+
Validation Engineers

4
Set of HVAC

5009+
AHUs Validated

10000+
Compliance reports released

2493+
Equipment Validated

5031+
Validation of Clean Rooms

Cleanroom Services we offer

- Air flow velocity Test
- ACPH Calculations
- Filter Integrity test
- Non-Viable Particle Count Test
- Recovery Test
- Air flow pattern simulation
- Air flow visualizations test
- Air Pressure Balancing
- Containment Test
- Temperature & RH Measurement
- Light Intensity Measurement
- Sound Level Measurement
- Viable particle count studies
- UV Light intensity test
- N_2/ Compressed Air Particle count test

WELCOME!

To the new BENCHMARK OF CALIBRATION

Our facility uses world-class masters
with excellent environmental conditions.

Our calibration service comes with a calibration certificate conforming to

ISO/IEC 17025:2017
NABL Accredited

IncepBio undertakes calibration of temperature & pressure sensors, data loggers, weight boxes and micropipettes adhering to National & International standards ensuring best in class accuracy.

Calibration

EQUIPMENTS THAT WE CALIBRATE

- TEMPERATURE SENSORS
- (RH) HUMIDITY SENSORS
- DATA LOGGERS
- PRESSURE GAUGES
- PARTICLE COUNTERS
- MICROPIPETTES
- WEIGHT BOXES
- WEIGHING BALANCES
- PH METERS
- AND MANY MORE ...

SERVICES YOU
Must Definitely Try

> **Reduce Costs**
> Increase Effective Compliance

CIP/SIP Validation

We validate Cleaning-In-Place (CIP) and Sterilization-In-Place (SIP) systems for automatic cleaning and disinfecting without major disassembly and assembly work.

Things that makes us different:

- High degree of assurance
- Adhering to current manufacturing practices (cGMP)
- High degree of prevention of possible cross contamination
- Top quality documentation

cGMP and Compliance

At Incepbio, we maintain cGMP compliance throughout our processes by delivering customized compliance services, from problem solving to compliance achievement.

- Quality systems development and support
- cGMP strategy development
- Quality support on optimization, implementation and training
- Audits and quality assurance services
- Root cause analysis and other CAPA support
- Mock inspections/GAP analysis and inspection readiness assessments
- Employee Training

Hire Trained Personnel

Facing downtime due to recruitment problems for short term projects?

We know that employee costs contribute to at least 50% of every company's overhead cost which further decreases the profitability of the company.

So here is Incepbio to solve your problem.

We can help you by providing manpower who are trained as per the pharma industry standards. Not just that, you can hire our trained personnel for as less as 1 day. This will significantly save not just your direct manpower costs, but also the indirect cost like associated HR costs.

> **Hire Trained personnel for as less as 1 day**

Audit Consulting

Being in the patient care industry, pharmaceutical companies are continuously challenged to achieve and maintain regulatory compliance. You need to qualify your vendors, prepare for inspections by regulatory authorities, visit at-risk or under-performing facilities and sites, and verify that staff is adequately trained, following procedures, and producing/maintaining quality data. We at IncepBio in collaboration with the best names in the auditor's community will assess, analyse and help you achieve the highest compliance standards that will help you build a more trustworthy and a compliant brand in the pharma industry.

Few of the services that we can support with are:

- Preparedness/Mock Audits
- Vendor Qualification Audits
- Quality System Audits
- Validation Audits
- Routine Audits
- Route Cause Analysis Audits

Employee Training

Recent audits have highlighted the need of trained employees in the pharmaceutical industry. Employees are the biggest strength of any organization, however only few know how convert them to best assets. Our training programmes for your employees exactly help you do that. Not just that, we know that each employee is unique and has his own learning behaviour. To address this challenge our expert trainers at IncepBio have designed all the training modules customized for your employees that will help in better learning experience, which ultimately increases the overall productivity of each employee.

Consulting

Documentation Consulting

There is a saying in the pharmaceutical industry which goes “If not documented then it’s not done” Documentation is the heart of pharma industry as it is the only evidence to demonstrate and prove to the regulatory bodies about your commitment to quality. In our 30+ years of combined experience in the pharma industry we have realized that having proper documents is the biggest challenge that many pharmaceutical companies face. It is not just about having any documents, but it is about having auditable documents that are approved and agreed by all the national and international regulatory bodies. Our core documentation team at IncepBio has enormous experience in this industry and will help you with preparing all the documents that you need which are compliant to every auditor’s requirement.

Facility Design Consulting

The design of the building plays a critical role in any industry, but with the pharmaceutical industry it plays a much bigger role as it would be used for manufacturing life-saving drugs. The building design must be clearly demarcated into clean and unclean areas to avoid any potential product contamination. Also, there must be designated spaces designed for your material and man movement respectively to avoid cross-contamination. Our core design team at IncepBio has enough experience to help you with designing spaces which are not just spacious but also regulatory compliant.

Transport Validation

Finished medicinal products, investigational medicinal products, bulk product and samples should be transported from manufacturing sites in accordance with the conditions defined in the marketing authorisation, the approved label, product specification file or as justified by the manufacturer.
It is recognised that verification of transportation may be challenging due to the variable factors involved, however, transportation routes should be clearly defined. Seasonal and other variations should also be considered during verification of transport.
A risk assessment should be performed to consider the impact of variables in the transportation process other than those conditions which are continuously controlled or monitored, e.g. delays during transportation, failure of monitoring devices, topping up liquid nitrogen, product susceptibility and any other relevant factors.
Due to the variable conditions expected during transportation, continuous monitoring and recording of any critical environmental conditions to which the product may be subjected should be performed, unless otherwise justified.

We at Incepbio execute and perform validation studies for all kind of transport vehicles.

Endotoxin Challenge Study for DHS & OVENS

Endotoxins are one of the biggest challenges for any pharmaceutical company. The products if contaminated with endotoxins might potentially kill a patient. To avoid this disaster, pharmaceutical companies use DHS (Dry Heat Sterilizers) to depyrogenate the glassware which are the potential source for endotoxins. However, it takes significant time, money and efforts to perform these studies.

We at IncepBio, have an expert team of Microbiologists who can design, develop and perform such studies thus saving a lot of cost, time and efforts of our pharmaceutical clients.

Our Unique Services

Viable Particle Count Tests that we perform

Any newly designed space in a pharmaceutical company must be qualified before the same can be used for routine manufacturing activities.

IncepBio is the only company in India that supports pharmaceutical clients with the unique VPC execution.

We help our pharmaceutical clients by providing end to end support in executing and handing over the qualified facility within specified timelines.

Active sampling

Passive/Settle plate sampling

Surface monitoring

Personnel monitoring

At rest / Static studies

In operation / Dynamic studies

Only Indian Company

to Perform Unique VPC strategy & execution*

Biological Indicator (BI) Enumeration Test

Like endotoxins, microbial contamination pose the biggest threat for any pharmaceutical company. To counter and kill these microbes, an autoclave is used. As a proof of concept, these autoclaves use biological indicators to validate an effective killing of microbes. However, these BIs which are supplied by a third party must be validated for its effectiveness before they are used. We at IncepBio, have an expert team of Microbiologists who can design, develop and perform such studies, thus saving a lot of cost, time and efforts of our pharma clients.

Indoor Air Quality Test

It is not just your products or the patients who use your products who must be protected, it is the ethical responsibility of every company to protect their employees by providing safe and clean spaces. As most of the spaces are closed, air conditioned and unventilated, one of the potential hazards is the quality of indoor air that can have severe long term health impacts on each of its employees. This not only increases the health cost spending but also significantly reduces the productivity of the company. Our expert team of IAQ specialists at IncepBio can help you by periodically checking the quality of the indoor air in all the unventilated spaces. Not just that, we also provide you necessary solutions to counter any potential problems that might arise.

Our Unique Services

Hold Time Study

Manufacturing processes should be shown to be capable of consistently manufacturing pharmaceutical products that are of the required quality and that comply with their specifications. Current manufacturing practices (cGMP) require that arrangements should be made to ensure that the dispensed raw materials and packaging materials, intermediate products, bulk and finished products are stored under appropriate conditions. Storage arrangements should not have deleterious effects on the subsequent processing, stability, safety, efficacy or quality of starting materials, intermediate products and bulk products prior to final packing. Maximum acceptable holding periods should therefore be established to ensure that intermediates and bulk product can be held, pending the next processing step, without producing results outside the acceptance criteria for the quality of the material. Normally, intermediate and bulk products should not be stored beyond the established hold time. The choice of maximum holding period should be supported by relevant data. Studies may extend beyond the chosen maximum but it is not necessary to extend testing to determine the extreme limits at which failure occurs.

Our expert team at Incepbio can design, develop and execute a variety of Hold Time Studies that will help you generate relevant and reliable data.

Our Versatile TEAM

OUR TEAM STRENGTH

FLOOR TEAMS

TRAINING SESSION

REPORT TEAM

ACTIVITY TEAM

OUR PHENOMENAL TEAM IN ACTION

To all our Pharma Clients

We THANK YOU for working on a NOBLE cause.
Your commitment to manufacture Quality &
Safe products is SAVING Millons of LIVES

-Team incepbio®

GET IN TOUCH WITH US

VISIT OUR WEBSITE
www.incepbio.com

FOLLOW US ON SOCIAL MEDIA

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