

Leading Pharma Engineering & Compliance Solutions

Integrated engineering, validation and digital compliance solutions for pharmaceutical and life sciences industries

ENGINEERING • COMMISSIONING, QUALIFICATION, AND VALIDATION
• DIGITAL COMPLIANCE



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ABOUT US

Engineering & Compliance, Trusted Globally

Since 2016, Incepbio has grown into a trusted engineering and compliance partner for the pharmaceutical, biotechnology, cell and gene therapy, medical device, CDMO, and other regulated life sciences industries. Our experienced team brings together engineering, validation, and compliance expertise to support complex regulated manufacturing environments.

Powered by  — our continuous compliance partnership — and  — our digital validation platform — we provide integrated engineering, validation, and Global Compliance Support

WHY CHOOSE US

Engineering & Compliance, Trusted Globally

- Engineering & Validation under one roof
- Regulatory-first – FDA, EU GMP, WHO GMP, PIC/S, GAMP 5
- Audit-Ready Documentation, Every Time
- Experienced specialists across every discipline
- Technology-driven – powered by **inceptone**™
- End-to-end, design to ongoing partnership



06

Global
Certifications

03

Countries

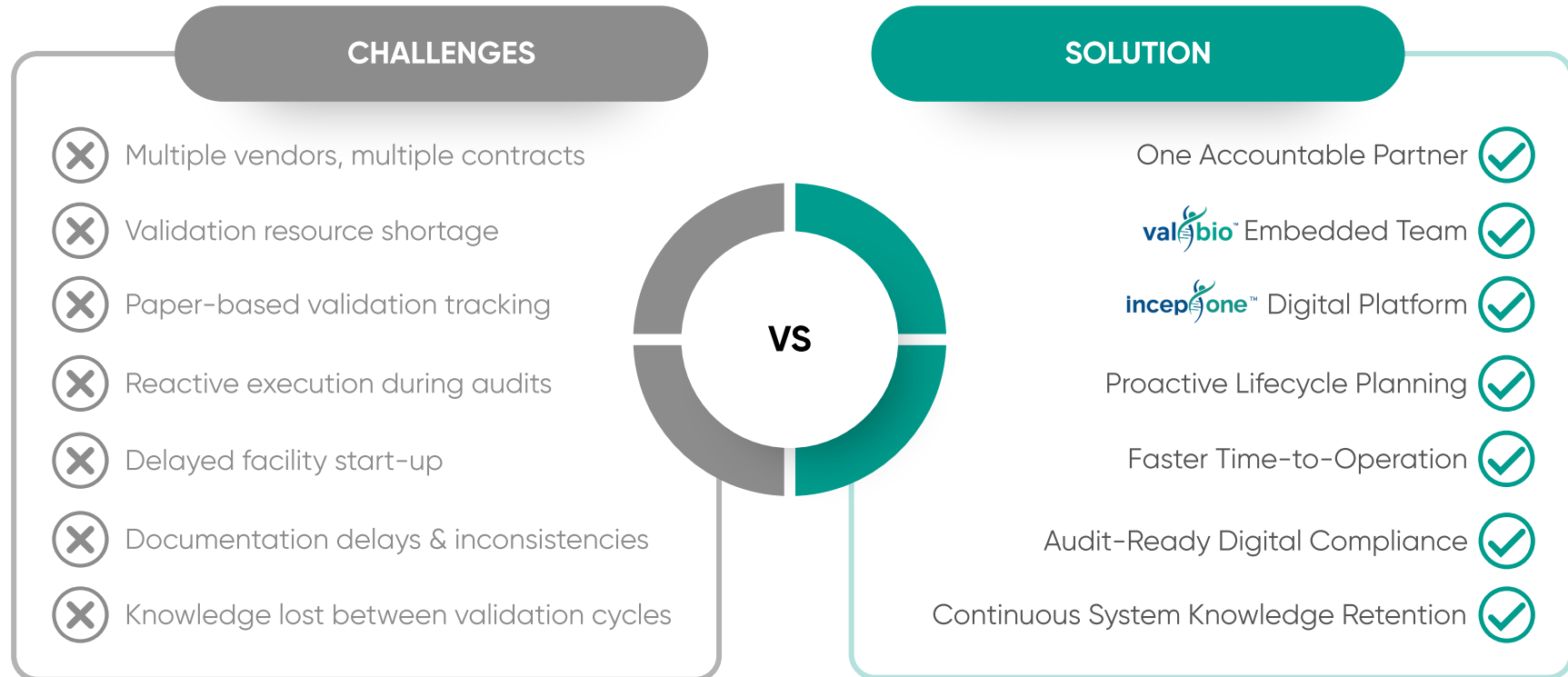
100+

Global
Clients

WHY PARTNER WITH INCEPBIO

Built To Stay. Built To Deliver

One integrated partner for engineering and compliance – powered by **inceptionone™** digital capabilities and **valbio™** embedded expertise.



OUR INTEGRATED ECOSYSTEM

Complete Engineering & Compliance – Under One Roof

From concept planning to continuous operational compliance – we cover every stage of the facility lifecycle.



1

Plan

Facility Engineering
Process Utilities
Compliance Strategy



2

Build

Turnkey Projects
Cleanroom Infrastructure
HVAC & Utilities



3

Qualify

CQV (Commissioning, Qualification & Validation)
Cleanroom & Thermal Validation
Smoke Studies
Calibration



4

Sustain

CSA / CSV Support
Automation & Integration
Periodic Requalification
Digital Audit Readiness

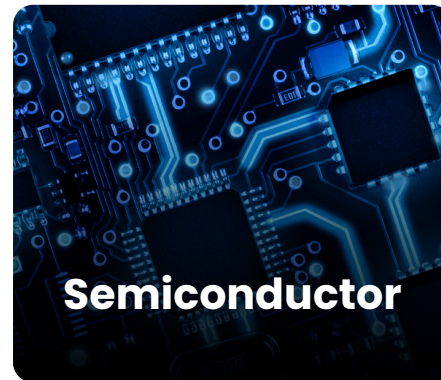
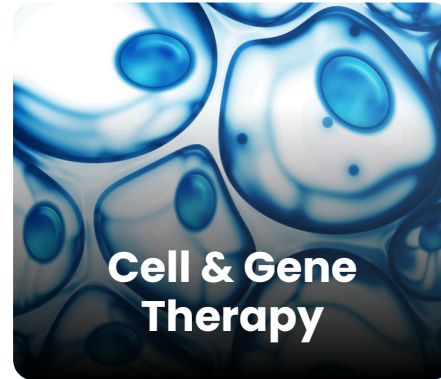
Global Standards We Align With

US FDA · EU GMP · WHO GMP · PIC/S · ISO 14644 · 21 CFR Part 11 · GAMP® 5 · ALCOA++

INDUSTRIES WE SERVE

Supporting Regulated & Mission-Critical Industries

Wherever compliance and operational excellence are essential – our expertise fits.



VALBIO YOUR EXTENDED COMPLIANCE TEAM

Beyond Vendor – Based Validation

Traditional validation runs on periodic vendor visits. **valbio™** makes it an integrated capability with in your facility – an extension of your Engineering & QA teams, powered by **inception™**

Cleanroom Validation

- Airflow Visualization (Smoke Studies)
- HEPA Filter Integrity Testing
- Air Velocity & Volumetric Flow
- Pressure Cascade & Recovery Testing

Thermal Validation

- Autoclave & SIP Systems
- Lyophilizer & Depyrogenation Tunnels
- Cold Rooms, Freezers & Incubators
- Warehouse Temperature Mapping

Equipment Qualification & Compliance Support

- DQ, IQ, OQ, PQ & Periodic Requalification
- Protocol Development & Reports
- Risk Assessments
- Audit Support & Documentation

Environmental Monitoring

- Viable & Non-Viable Particle Counts
- Compressed Air & Gas Testing
- Water System (WFI) Validation
- Cleanroom Contamination Control

Calibration Services

- Thermal & Mechanical Calibration
- Process Instrument Calibration
- Preventive Maintenance (PM) Support
- NABL – Traceable Certification

WHY CLIENTS CHOOSE INCEPBIO

Supporting Regulated & Mission-Critical Industries

Wherever compliance and operational excellence are essential – our expertise fits.

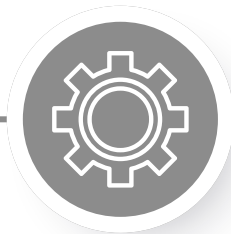
REGULATORY EXPERTISE

FDA, EU GMP, WHO GMP, PIC/S aligned



GMP ENGINEERING

Facility & infrastructure delivery



VALIDATION EXCELLENCE

CQV (Commissioning, Qualification, and Validation) , cleanroom, thermal, calibration



DIGITAL COMPLIANCE

Powered by

inceptionone™





valbio™

Your Continuous Compliance Partner

 **Biocon** *Biologics*

Biocon India | Malaysia

 **Dr.Reddy's**

Dr. Reddy's Laboratories

 **neoAnthem**

Anthem Life Sciences

 **Anthem**
BioSciences

Anthem Biosciences

valbio™



Annual Validation
Planning & Execution



Assist Documentation
Preparation, Review &
Support



Routine
Requalification
Activities



Investigation & CAPA
Support



Environmental
Monitoring



Vendor Management
& Audit Coordination

KEY BENEFITS



No Full-Time Hiring
Required



Flexible Compliance
Support



Continuous Training
Programs

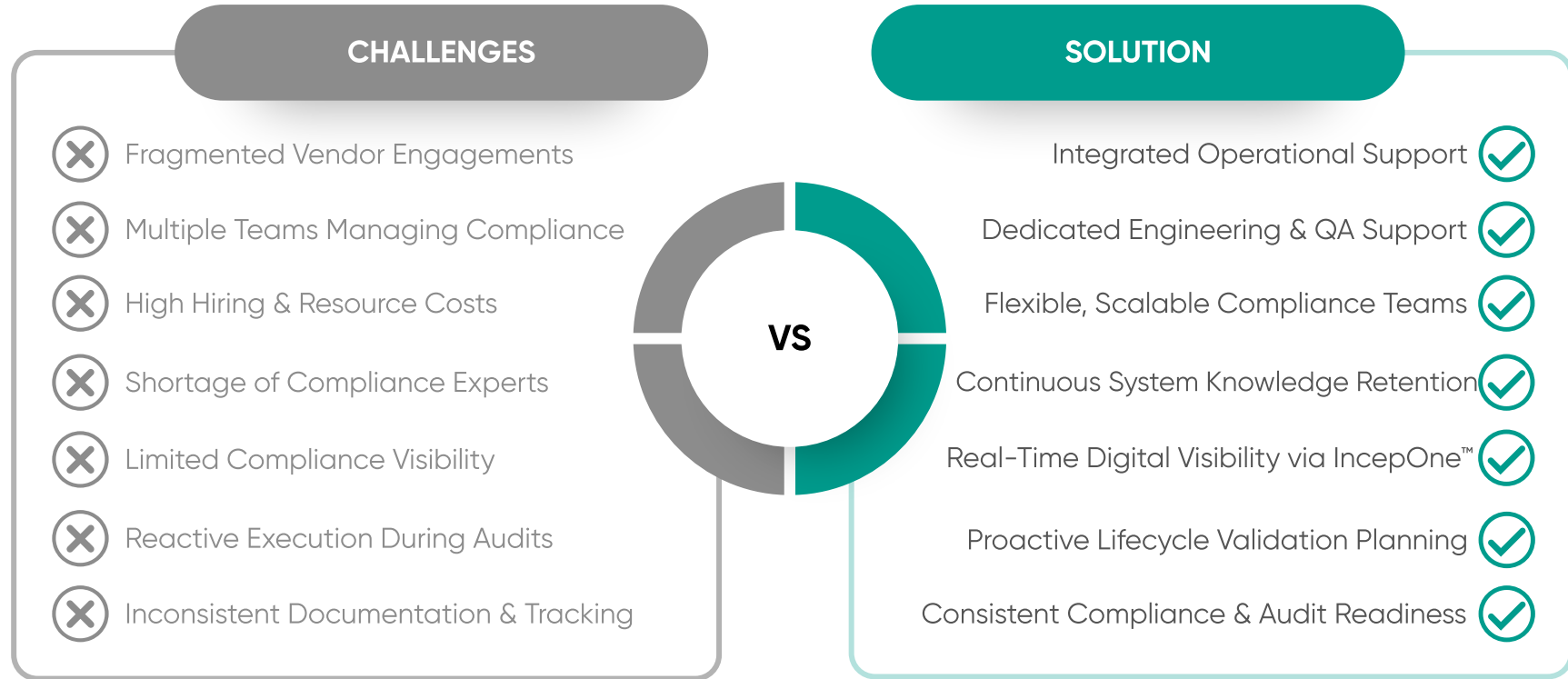


Reliable Project
Delivery

INDUSTRY CHALLENGES

Your Extended Compliance Team

Dedicated expertise without full-time hiring





Paperless Validation



Centralised
Validation Data
Management



Validation Tracking



Designed for
21 CFR Part 11
Compliance



Complete Document
Control & E-Signatures



Real-Time
Dashboards &
Insights

KEY BENEFITS



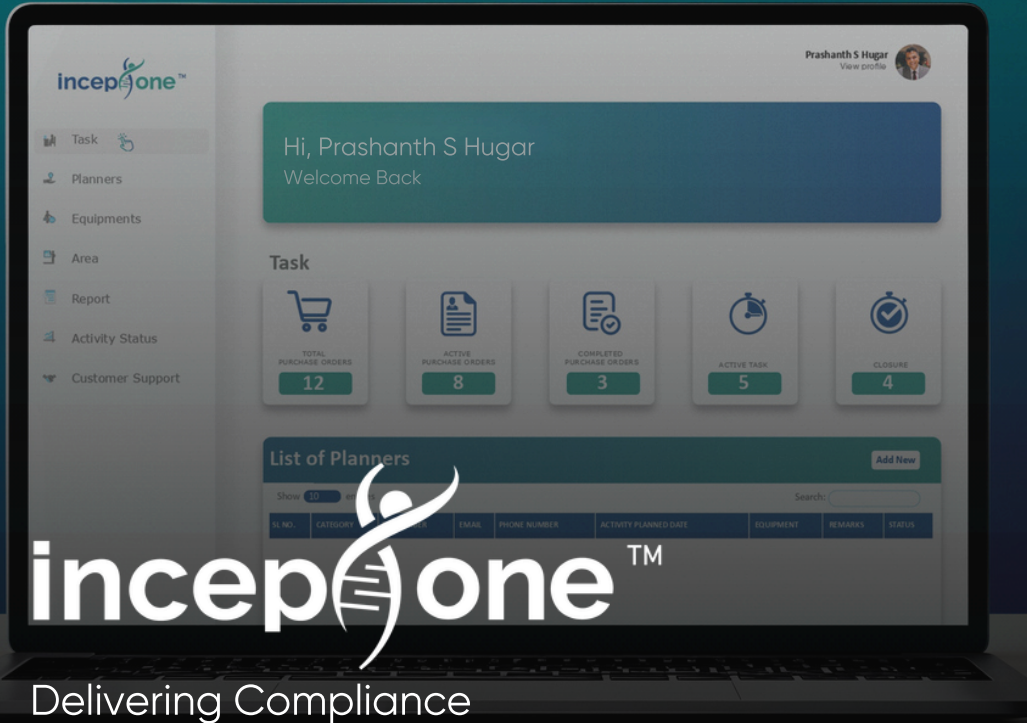
Audit-Ready
Documentation



Real-Time
Visibility



Centralized
Compliance



INDUSTRY CHALLENGES

Compliance Without Visibility Creates Delays

One connected, paperless validation platform.

INDUSTRY CHALLENGES

- 01 Paper-Based Validation
- 02 Data Integrity Gaps
- 03 Limited Project Visibility
- 04 Time-Consuming Audit Preparation

VS

INCEPONE SOLUTION

- 01 Paperless Validation Platform
- 02 21 CFR Part 11-Compliant Electronic Records
- 03 Live Dashboards & Analytics
- 04 Audit-Ready Reports



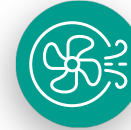
ENGINEERING & TURNKEY

From Concept to Handover

ENGINEERING & TURNKEY



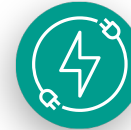
Cleanrooms &
Controlled
Environments



HVAC Systems



Electrical &
Automation



Process Utilities



BMS & EMS



Process
Infrastructure

7-Step Delivery Lifecycle



Integrated Engineering, Construction & Commissioning, Qualification, and Validation Support

INDUSTRY CHALLENGES

One Partner. End-to-End Delivery. From feasibility to compliant handover

One Partner. End-To-End Delivery. From feasibility to compliant handover

INDUSTRY CHALLENGES

- ❌ Multiple Contractor Coordination
- ❌ Design & Regulatory Gaps
- ❌ EPC / HVAC Integration Issues
- ❌ Documentation & Approval Delays

VS

INCEPbio's SOLUTION

- ✅ Single-Source Turnkey Delivery
- ✅ GMP-Compliant Design & Execution
- ✅ Integrated EPC & CQV Management
- ✅ Complete Validation Handover

CQV Services

From Qualification to Compliance

CQV SERVICES



Design Qualification
Design Review & Risk
Assessment



Commissioning
FAT / SAT &
Functional Testing



Equipment
Qualification
URS / DQ / IQ / OQ
/ PQ



Utility & Facility
Qualification
HVAC · PW / WFI ·
Cleanrooms



Process & Cleaning
Validation
PPQ · Cleaning · SIP /
CIP



Computer System
Validation
GxP Systems & Data
Integrity

Deliverables



Validation
Master Plan



Protocols &
Reports



Traceability
Matrix

INDUSTRY CHALLENGE

Commissioning, Qualification & Validation

Multidisciplinary CQV, done right the first time.

INDUSTRY CHALLENGES



Shortage of Skilled
CQV Resources



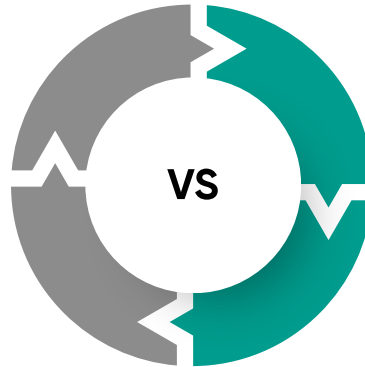
Engineering &
Validation Gaps



Inconsistent Risk-
Based Execution



Qualification
Traceability Gaps



INCEPBIO'S SOLUTION

Dedicated MultiDisciplinary
CQV Teams



Engineering &
Validation Expertise



QbD & Risk-Based
Approach



End-to-End Traceability





CSA & CSV Services

Validating Systems. Ensuring Compliance.

CSA & CSV SERVICES



Validation Planning
CSA / CSV Strategy



Data Integrity
ALCOA++
Assessment



Requirements
Traceability
URS & RTM
Management



Audit Trail
Compliance
Assessment &
Verification



System Validation
GxP System



System Integration
Interface Validation

Standards

GAMP® 5

21 CFR Part 11

EU GMP Annex 11

INDUSTRY CHALLENGES

Systems Must Be Validated, Not Just Installed

GAMP 5-aligned validation for every digital system.

INDUSTRY CHALLENGES

- ✗ Poor Validation Planning
- ✗ Data Integrity Risks
- ✗ Audit Trail Deficiencies
- ✗ Complex System Integration

vs

- CSA / CSV Strategy & Planning ✓
- Data Integrity Assessment (ALCOA++) ✓
- Complete Requirements Traceability ✓
- Validated System Integration ✓

INCEPBIO'S SOLUTION



Smoke Study

Visualizing Airflow. Ensuring Compliance.

SMOKE STUDY



Aseptic Filling Line
Airflow



Material & Personnel
Flow



UDAF, RABS &
Isolator Studies



Turbulence & Dead-
Zone Identification



HVAC Airflow Pattern
Assessment



4K Multi-Angle
Recording

Standards

Regulatory

EMA
US FDA

GMP Standards

EU GMP Annex 1

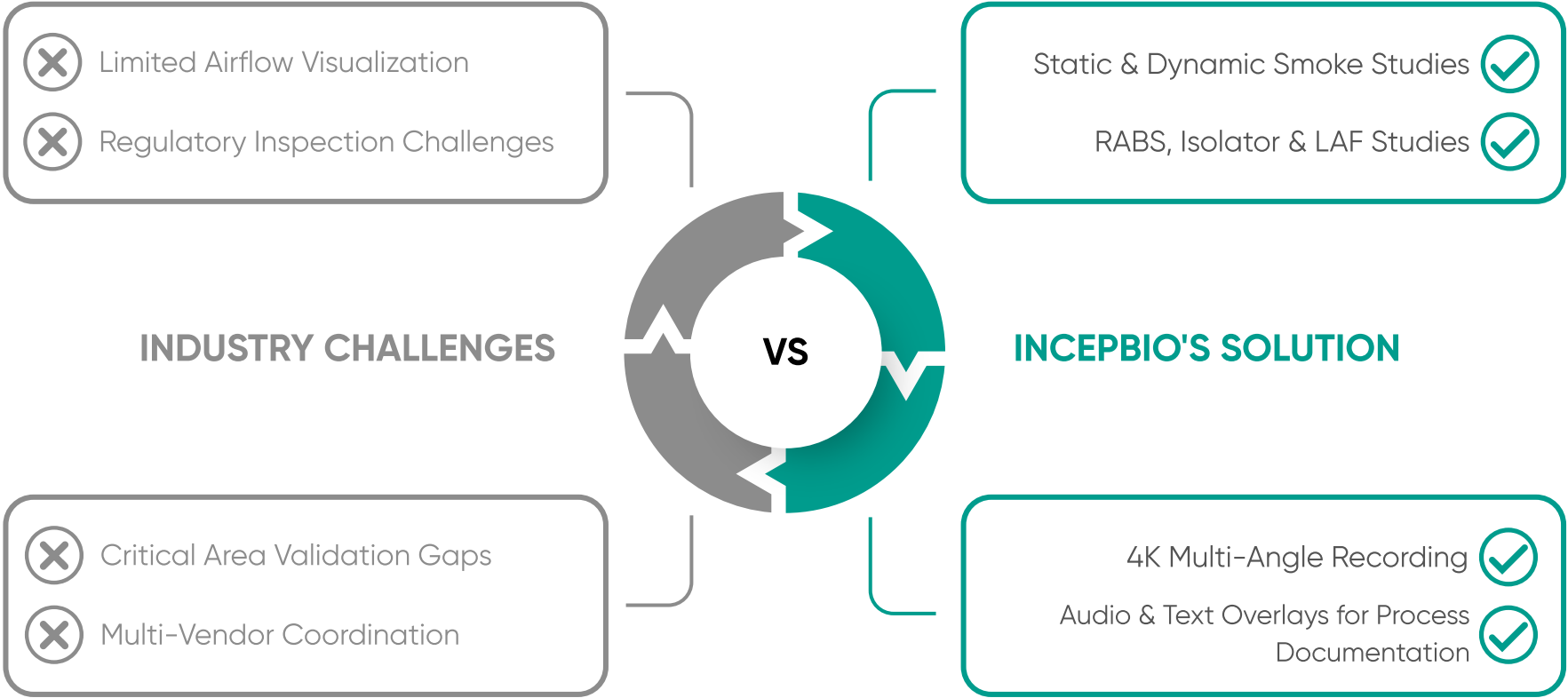
International Standards

ISO 14644
EN 1822

INDUSTRY CHALLENGES

Airflow You Can See. Compliance You Can Prove.

Static & Dynamic Airflow Visualisation for Aseptic Areas.



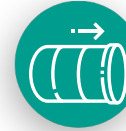
Thermal Validation

Ensuring Temperature. Assuring Compliance.

THERMAL VALIDATION



Autoclaves & Dry Heat Sterilizers Heat Distribution, Bowie-Dick & Leak Testing



Depyrogenation Tunnels & Vacuum Tray Dryers Heat Distribution & Temperature Mapping



Stability Chambers & Cold Rooms Temperature & Humidity Mapping, MKT Calculations



Deep Freezers, Incubators & Lyophilizers Temperature Mapping & Validation



Warehouse & Cryogenic Mapping Temperature Mapping & Transport Validation



F₀ & MKT Calculations Thermal Validation & Process Lethality Assessment

Deliverables



Thermal Mapping Reports



Trend Graphs & Statistics



Compliance Documentation

INDUSTRY CHALLENGES

Temperature Deviations Can Compromise Batches

High-accuracy thermal mapping across every asset.

INDUSTRY CHALLENGES

- ✗ Sterilization Process Variability
- ✗ Temperature Control Challenges
- ✗ Cold Storage Validation Gaps
- ✗ Worst-Case Location Identification

VS

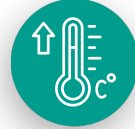
- Sterilization & Autoclave Validation ✓
- Precision Temperature Mapping ✓
- Cold Room & Stability Mapping ✓
- Audit-Ready Validation Reports ✓

INCEPBIO'S SOLUTION

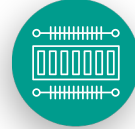
Thermal Calibration

Ensuring Accuracy. Maintaining Compliance.

THERMAL CALIBRATION



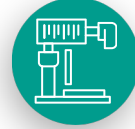
Temperature Calibration



RTD, Thermocouple & Sensor Cal.



Data Logger & Monitoring Systems



Critical Instrument Calibration



On-Site & In-House Calibration



Periodic Calibration Programs

Deliverables



Calibration Certificates



Traceability Documents



Compliance Reports

INDUSTRY CHALLENGES

Calibration Drift Undermines Every Result

Traceable calibration for every temperature device.

INDUSTRY CHALLENGES

- 01 Temperature Measurement Drift
- 02 Sensor Calibration Inaccuracies
- 03 Calibration Documentation Gaps
- 04 GMP Compliance Challenges

VS

INCEPBIO'S SOLUTION

- NABL-Traceable Calibration 01
- RTD & Thermocouple Calibration 02
- Calibration Certificates & Records 03
- On-Site Calibration Support 04



Mechanical Calibration

Ensuring Precision. Maintaining Compliance.

MECHANICAL CALIBRATION



Pressure Calibration



Mass & Dimensional Calibration



Flow Meter Calibration



Speed & Sound Level Calibration



On-Site Mechanical Calibration



Periodic Calibration Programs

Deliverables



Calibration Certificates



Traceability Documents

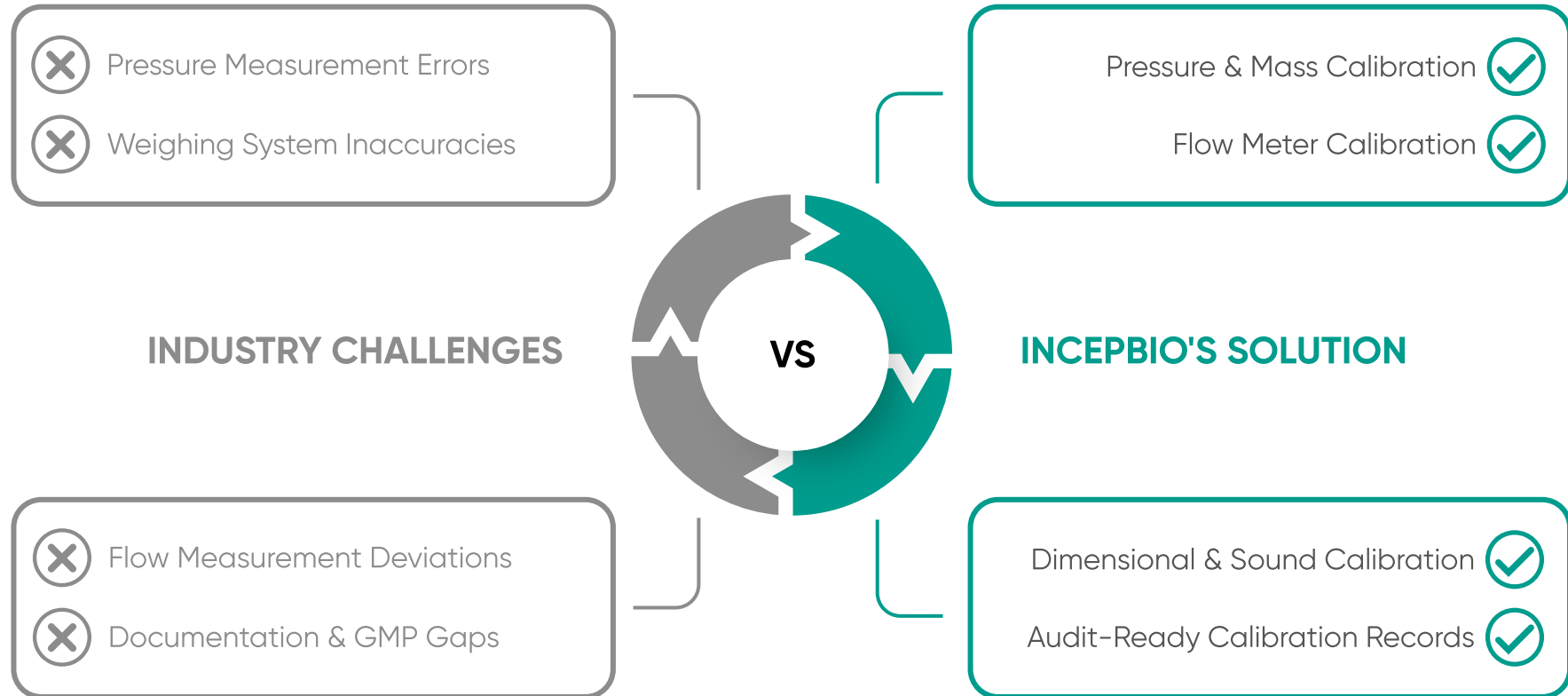


Audit-Ready Records

INDUSTRY CHALLENGES

Accuracy Across Pressure, Mass & Flow

Multi-parameter calibration, fully traceable.

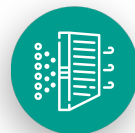




Cleanroom Validation

Ensuring Controlled Environments. Assuring Compliance.

CLEANROOM VALIDATION



HEPA Filter Integrity Testing



Airflow & HVAC Verification



Particle Counting & Classification



Differential Pressure Mapping



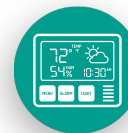
Smoke Study Support



Regulatory Inspection Support



Pressure Balancing



Temperature & Humidity Monitoring

Equipment



Particle Counters



Aerosol Photometers



DEHS Generators

INDUSTRY CHALLENGES

Contamination Risks Don't Give Second Chances

Certified HEPA, airflow & classification testing.

INDUSTRY CHALLENGES



HEPA Filter Integrity Failures



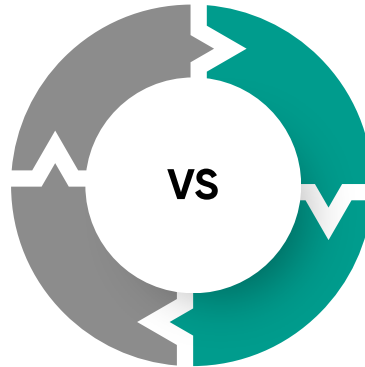
Airflow & HVAC Performance Issues



Cleanroom Classification Deviations



Documentation & Compliance Gaps



INCEPBIO'S SOLUTION

Certified HEPA Filter Testing



Airflow & HVAC Verification



ISO 14644 Particle Classification



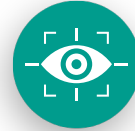
Audit-Ready Validation Documentation



Microbial Monitoring

Monitoring Microbes. Maintaining Compliance.

MICROBIAL MONITORING



Active Air Monitoring
Viable Microbial
Monitoring



Passive Air Monitoring
Settle Plate Monitoring



Surface & Personnel
Monitoring
Contact Plates &
Swab Testing



Environmental
Monitoring
Cleanroom Microbial
Assessment



Trend Analysis
Microbial Data
Trending & Evaluation



Alert & Action Limits
Excursion Assessment
& CAPA Support

Deliverables



Monitoring Maps &
Sampling Locations



Trend Analysis
Graphs



Alert / Action
Limit Evaluation

INDUSTRY CHALLENGES

What You Can't Detect Can Impact Safety

Environmental monitoring with trend-based insight.

INDUSTRY CHALLENGES

- ✗ Hidden Microbial Contamination
- ✗ Inadequate Air Monitoring
- ✗ Surface Contamination Risks
- ✗ Delayed Microbial Investigations

VS

INCEPBIO'S SOLUTION

- ✓ Risk-Based Environmental Monitoring
- ✓ Active & Passive Air Monitoring
- ✓ Surface & Personnel Monitoring
- ✓ Trend Analysis, Alert/Action Limits & CAPA

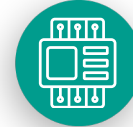
Pharma Automation

Automating Processes. Ensuring Compliance.

PHARMA AUTOMATION



Automation Strategy
& System Design



PLC / SCADA / DCS
Programming &
Integration



Manufacturing
Execution
Systems (MES)



HMI & Visualization –
Process Monitoring &
Control



Recipe / Batch Control
Optimization



Data Integration –
ERP / QMS / LIMS

SYSTEMS & PLATFORMS

PLC · HMI · SCADA · DCS · MES · BMS · EMS ·
ERP / QMS

INDUSTRY CHALLENGES

Manual Processes Limit Speed & Control

PLC, SCADA & MES built for GMP.

INDUSTRY CHALLENGES

- 01 Manual Manufacturing Processes
- 02 Data Integrity & Visibility Risks
- 03 Limited Process Control
- 04 Manual Batch Execution

VS

INCEPBIO'S SOLUTION

- 01 Automation Strategy & System Design
- 02 SCADA & Real-Time Monitoring
- 03 PLC & MES Automation
- 04 Electronic Batch Records & Recipe Control

OUR CLIENTS

Trusted by Industry Leaders.



Syngene



onesource



MERCK



KEMWELL
Keeping You Competitive



APOTEX
Canadian-Based
Global Health Company



Equipment Portfolio



Anemometer



Particle Counter



Eupry WiFi Data Logger



Data logger



Temperature Calibration Bath



Microrite



Air Capture Hood



Aerosol Photometer



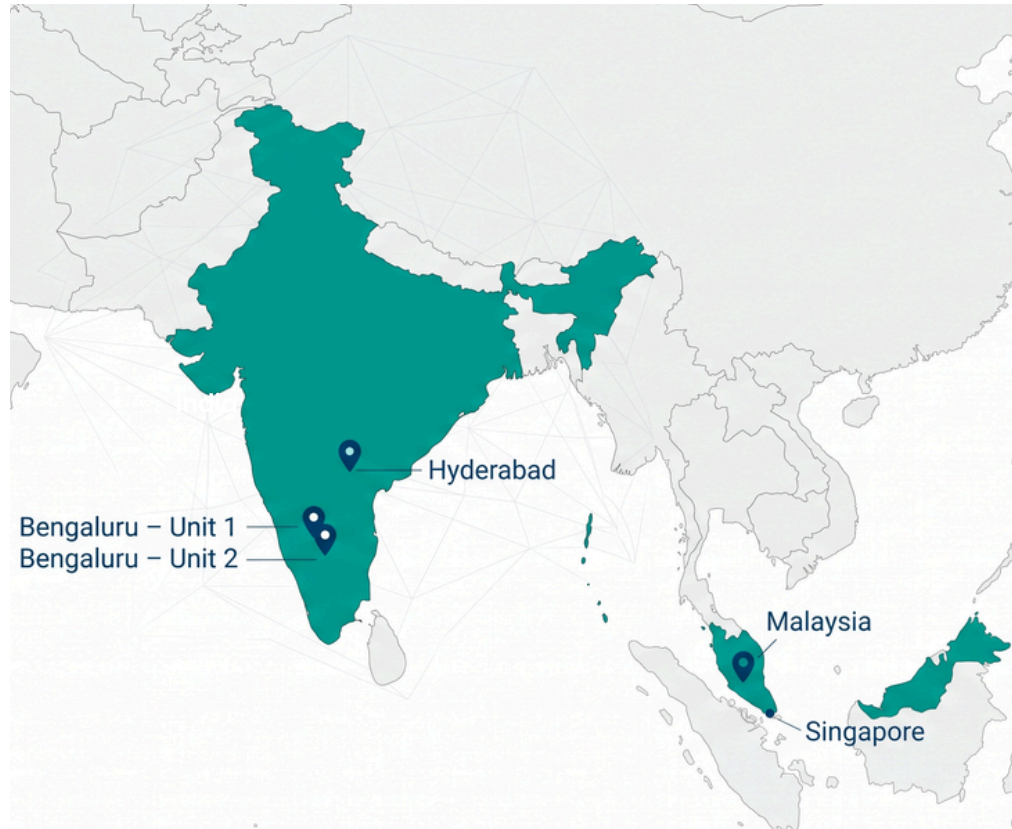
Lux Meter



DEHS Generator

GLOBAL PRESENCE & OFFICES

India · Malaysia · Singapore



Bengaluru Unit 1

No. 24, 22nd Main,
Marenahalli, J P
Nagar 2nd Phase,
Bengaluru

Bengaluru Unit 2

2nd Cross, Yarandahalli,
Bengaluru, Karnataka
560099, Opposite Hotel
Malabar

Hyderabad

12A04, 13th Floor, Manjeera
Trinity Corporate, JNTU-
Hitech City Road, KPHB,
Beside Lulu Mall,
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True Partner
in Progress