ISHA'S GMP™
CONSULTANCY PVT. LTD.
Ensuring Global GMP Compliance™®

GLOBAL cGMP & REGULATORY CONSULTANCY

Concept to compliance. Design to delivery.

Turnkey pharma projects • Engineering • QMS • Audits • Training

www.ishasgmp.com







Your integrated life-sciences project partner

Built around engineering discipline, regulatory understanding and executable quality systems.

We bridge the gap between facility design, practical operations and international regulatory expectations.

Turnkey implementation

From feasibility and URS to commissioning, qualification and handover.

GxP quality & compliance

GMP gap assessments, QMS implementation, vendor audits and readiness.

Cross-sector expertise

Pharmaceuticals, biotechnology, medical devices, cosmetics, foods and nutraceuticals.



TURNKEY ENGINEERING

From concept to commissioning



GMP & REGULATORY

Quality systems and inspection readiness



INDUSTRY COVERAGE

Pharma, biotech, devices and more

POSITIONING

A full-service GxP ecosystem

Facility & master planning



Greenfield, brownfield and capacity expansion design.

Turnkey project management



Scope definition, engineering, vendor coordination and execution.

Cleanroom & HVAC solutions



Classification, air systems, utilities and contamination control.

Qualification & validation



DQ, IQ, OQ, PQ, process and utility validation support.

Quality systems & audits



Risk-based QMS, CAPA, data integrity, GMP and gap reviews.

Regulatory & certification



Licensing, documentation, filings and management-system certifications.

Training & capability building



Role-specific GxP training, workshops and mock audits.

Development & transfer



Formulation, analytical development and technology transfer.

Innovation & R&D support



DSIR and associated research documentation support.

INDUSTRY FOCUS

Sector-specific experience. One delivery model.

Engagements are aligned with product risks, production flows, regulatory scope and client operating realities.

Pharmaceuticals



API / formulations / oral solids / injectables

Biotechnology



Bioprocess & research facilities

Medical devices



Device manufacturing & ISO 13485 pathways

Cosmetics



Personal care / topical products / filling

Food & nutraceuticals



Processing / supplements / food-safety systems

Herbal / AYUSH



Botanical processing / herbal products

Engineering, quality and regulatory frameworks

Framework selection and certification scope are tailored to applicable local requirements and target markets.

GMP & GxP	WHO-GMP • revised Schedule M • GDP • GLP • Good Documentation Practices
Quality management	ISO 9001 • ISO 13485 • risk management • supplier quality
Food safety	HACCP • ISO 22000 • FSSC 22000 • BRCGS • Halal / Kosher
Indian approvals	CDSCO / State FDA • medical devices • cosmetic licensing • testing laboratories
Laboratories & R&D	NABL systems • DSIR recognition • method / equipment readiness
International expectations	USFDA • EU GMP • MHRA • PIC/S • TGA and other market-specific requirements

Turnkey plant setup & modernization

Facility development is treated as an integrated technical, commercial and compliance programme.



SITE / INSTITUTIONAL ENGAGEMENT

Concept-to-handover accountability

Integrated engineering and GMP design decisions help reduce costly redesign and readiness gaps.

01 **Feasibility & concept**

Capacity, process flows, design basis, costing and schedule.

02 **Design & tendering**

Layouts, specifications, BoQ, engineering and vendor evaluation.

03 **Execution & supervision**

Civil, cleanroom, process equipment, HVAC and utilities coordination.

04 **Qualification & readiness**

Commissioning, DQ/IQ/OQ/PQ, SOPs and operational handover.

A structured path from user needs to validated operation

01 URS & capacity → 02 Concept / FEED → 03 Design review & DQ → 04 Specifications / BoQ → 05 Vendor evaluation

06 Procurement / FAT → 07 Installation / SAT → 08 Commissioning → 09 IQ / OQ / PQ → 10 Handover / training

Concept & front-end engineering

Facility URS

User needs, product range, capacity assumptions and design basis.

Feasibility & budgets

CAPEX estimates, resources, schedules and utility assumptions.

Process schematics

Block diagrams for manufacturing and water / gas systems.

Zoning strategy

Area classification, cleanroom grades and pressure cascade.

People & material flows

Segregation, logistics, access and contamination control.

Site & production layouts

Plant, laboratory, warehouse and dispensing layouts.



GMP facility design



Concept planning & URS

Basic engineering package

Technical design basis

Room conditions, utilities, equipment criteria and automation.

P&ID / utility systems

AHU, chilled / hot water, purified water and compressed air.

Production layouts

Equipment arrangements and personnel / material movement.

Building services

Partitions, ceilings, electrical and low-current distribution.

Environmental control

Supply / return / exhaust ducting and pressure cascades.

Safety & monitoring

Fire systems, controls, interlocks and safety planning.



Cleanroom & controlled areas



Process & utility engineering

Detailed engineering & tender documentation

Architectural details

Wall and ceiling details, sections and interfaces.

Process & piping

Pipe routing, P&IDs, valves, instruments and tie-ins.

Electrical engineering

Power, panels, loads, cabling and cable-tray drawings.

HVAC calculations

Air flow, cleanroom loads, equipment specifications and controls.

Utilities & clean media

Water systems, nitrogen, clean/black utilities and CIP piping.

Documentation control

Equipment lists, IO lists, design reports and updated schedules.



Equipment and utility integration



Technical installation and commissioning

Cleanrooms, HVAC & critical utilities

Environmental control is designed around product exposure, process risk and facility requirements.

Air cleanliness

Cleanroom zoning, filtration selection, airflow, ACH strategy.

Pressure management

Pressure cascades, airlocks, interlocks and monitoring.

Thermal & humidity

Heat loads, temperature / RH control and stability.

Critical utilities

Purified water, compressed air, gases, steam and CIP.

Monitoring & controls

BMS/EMS strategy, alarms, trending and qualification.

CONTROLLED ENVIRONMENT MODEL



Filtration • Airflow • Pressure • Monitoring

Commissioning, qualification & validation

Documented evidence connects design intent with actual operating performance.

DQ



Design Qualification

Design meets the URS and regulatory intent.

IQ



Installation Qualification

Installed systems match approved specifications.

OQ



Operational Qualification

Functions and controls operate as intended.

PQ



Performance Qualification

Performance is demonstrated under defined conditions.

Beyond qualification

Protocols, checklists, FAT/SAT support, validation reports, training and final operational readiness.

GMP systems, inspection readiness & audits

Gap assessment

Evaluate site, systems, documentation and critical control gaps.

CAPA management

Root cause analysis, corrective actions and effectiveness checks.

QMS implementation

Policies, SOPs, controls, quality records and management review.

Supplier qualification

Vendor assessment, audits, quality agreements and oversight.

Data integrity

ALCOA+ principles, documentation control and audit trails.

Mock inspections

Inspection simulation, readiness review and remediation.

Management systems, certifications & licensing

Practical support spans applicability assessment, documentation, implementation and audit preparation.

GMP / Regulatory

WHO-GMP, Schedule M, manufacturing controls and readiness.

ISO / QMS

ISO 9001, ISO 13485, quality system implementation.

Food / safety

ISO 22000, HACCP, FSSC 22000, BRCGS.

Testing laboratories

NABL documentation, method / equipment readiness and State FDA.

R&D / recognition

DSIR applications, R&D infrastructure and records.

Product-related licensing

Medical-device, cosmetic and related approvals as applicable.

From R&D to manufacturing support

Technical assistance complements the facility and GMP implementation scope.

Analytical development



Specifications, methods and laboratory systems.

Formulation development



Product / process development and scale-up.

Technology transfer



Documentation, process understanding and site readiness.

Dossier & DMF



Product registration and technical file organization.

Investigation support



Deviations, OOS, CAPA and risk-based problem solving.

Contract manufacturing



Outsourcing evaluation, quality oversight and due diligence.

Technical training that strengthens everyday compliance

Instructor-led sessions, practical cases, quizzes and operationally useful training materials.



ACTUAL TRAINING / PROFESSIONAL ACTIVITY



GMP / revised Schedule M

Fundamentals, audit readiness and practical compliance.

GDP & Good Documentation Practices

Record accuracy, traceability and regulatory observations.

CAPA / risk management

Investigations, FMEA, risk controls and effectiveness.

Data integrity / QMS

ALCOA+, document lifecycle and process ownership.

Formats: classroom • workshop • mock audit • on-the-job coaching

Transparent, milestone-led consultancy delivery

Clearly defined responsibilities and review checkpoints help clients maintain control of scope and quality.

01



DISCOVER

Site walkdown
Current-state review

02



DESIGN

Design basis
Risk & resource plan

03



DELIVER

Execution support
Document controls

04



VERIFY

Qualification
Mock audit

05



HAND OVER

Action closure
Training & transition

Typical outputs: approved scope • drawing register • CAPA tracker • milestone reviews • final readiness pack

Quality, people & professional collaboration



Industry engagement



Professional networking



Collaborative team activity

Training, learning & technical exchange

Selected photographs from ISHA'S GMP's original company gallery and project profile.



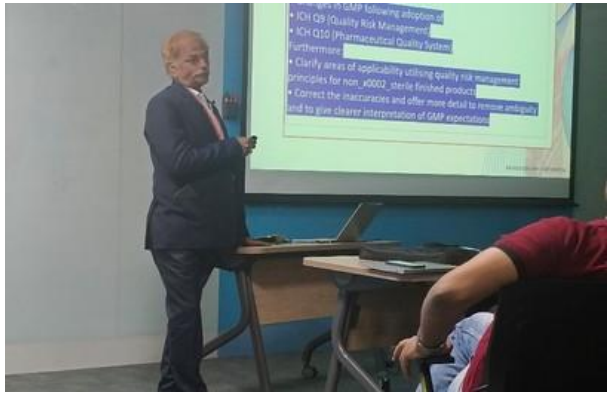
Technical presentation



GxP learning session



Training and discussion



Knowledge-sharing session

Illustrative examples of the breadth of assignments; full reference lists follow in the appendix.

Karnataka Antibiotics & Pharmaceuticals

Conceptual detailed project report

Indira IVF Hospital

Vendor audit / FDA licensing consultancy

Coromandel International

Bioproduct turnkey project

DFE Pharma

Excipients GMP gap assessment

Anabond Stedman

GMP / GDP / GLP training

C.L. Baid Metha College of Pharmacy

Testing lab / NABL / DSIR support

Incisee Rotomatic

R&D / DSIR project

Manali Petrochemicals

WHO-GMP gap assessment

Project experience spanning India and overseas markets

The reference portfolio includes assignments in Asia, the Middle East, Africa, Europe and North America.

INDIA	Domestic assignments & multi-sector facility support	
MIDDLE EAST	Saudi Arabia • UAE • Yemen • Iraq region	
AFRICA	Nigeria • Ghana • Ethiopia • Uganda • Congo	
ASIA PACIFIC	Malaysia • Sri Lanka • Nepal • Pakistan	
EUROPE / NORTH AMERICA	Ireland • Slovakia • United States	

Project experience spanning India and overseas markets

Designed for proposal discussions, due diligence and technical capability reviews.

61

Major executed-project entries

Categorized under API, beta-lactam, oral, sterile, cosmetics, food and herbal plant projects.

49

Domestic assignment entries

Client-specific scope descriptions in the source profile.

17

Overseas assignment entries

Examples across Saudi Arabia, the UAE, Africa, South Asia and elsewhere.



Manufacturing & projects



Domestic engagements



International reach

API & Chemical Plants • 1/2

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
1	MENEZES CHEMICALS LTD. GOA	1.7	2004
2	BENZO CHEM INDUSTRIES PVT. LTD. AMBERNATH, THANE	0.7	2006
3	FERMENTA, KULLU	2	2006
4	SANDOZ LTD. MAHAD, MAHARASHTRA	1	2010
5	NGL FINE-CHEM LTD. NAVI MUMBAI	6	2011

API & Chemical Plants • 2/2

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
6	OC SPECIALITIES PVT. LTD. SOLAPUR	6	2013
7	ROASARRI BIOTECH LTD. SILVASA, INDIA	6	2011
8	THE HIMALAYA DRUG COMPANY DEHRADUN, INDIA	5.83	2010
9	LACTOSE (INDIA) LTD. VADODARA, GUJARAT, INDIA	4	2012-2013

Beta-Lactam Projects • 1/1

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
1	KHADELWAL LAB, RUDRAPUR	2	2005
2	CORAL LABS LTD. DHERADUN	3.1	2006
3	UTTARANCHAL BIOTECH LTD, RUDRAPUR	2.9	2009
4	BIOPHARMA INDUSTRY YEMEN	4.71	2009
5	MILAN LABORATORIES PVT LTD	2.9	2014

Oral Drug Dosage Plants • 1/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
1	ABBOTT INDIA LTD. GOA, INDIA	2	2003
2	ELVINA PHARMACEUTICALS LTD. GOA, INDIA	3	2005
3	KHANDELWAL LAB. RUDRAPUR	2.33	2005
4	JOCUND INDIA LTD HARIDWAR, INDIA	3.16	2006
5	CORAL LABS LTD DEHRADUN	4	2006

Oral Drug Dosage Plants • 2/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
6	MANKIND PHARMA LTD	3	2007
7	CHI AT NIGERIA	6	2007
8	WALLACE LTD. BADDI, INDIA	4.5	2007
9	BIOPHARMA INDUSTRIES YEMEN	4.71	2009
10	LEXAND LABORATORIES PVT. LTD. MUMBAI	4	2009

Oral Drug Dosage Plants • 3/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
11	MILAN LABORATORIES PVT. LTD. MUMBAI	3.66	2012
12	PREMIER NUTRICARE PVT. LTD. DEHRADUN, INDIA	2.18	2012
13	ERIS LIFESCIENCES PVT. LTD. GUWAHATI	8	2013
14	ZIM LABORATORIES LTD. NAGPUR. INDIA	5	2014
15	HARMAN FINOCHEM LIMITED AURANGABAD. INDIA	10	2014

Oral Drug Dosage Plants • 4/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
16	PROCTER & GAMBLE GUJARAT, INDIA	10	2023

Cosmetic Plants • 1/1

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
1	THE HIMALAYA DRUG COMPANY DEHRADUN, INDIA	5.63	2010
2	MORISION INDUSTRIAL PL NIGERIA	6	2007
3	PREMIER NUTRICARE PVT LTD DEHRADUN, INDIA	2.18	2012
4	UNICHEM LIQUID INDUSTRIES LTD. GHANA	3	2014
5	BEKAS CHEMICALS PLC ETHIOPIA	3.5	2018

Food Plants • 1/1

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
1	ABBOTT INDIA LTD. GOA	2	2003
2	FERMENTA BIOTECH LTD. KULLU. INDIA	2	2007
3	LACTOSE (INDIA) PVT LTD. VADODARA. GUJARAT	3.6	2007
4	RUCHI SOYA INDUSTRIES LTD. ROORKEE . INDIA	3.5	2009

Herbal Plants • 1/1

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
1	THE HIMALAYA DRUG COMPANY DEHRADUN, INDIA	5.63	2008
2	HERBION PAKISTAN (PVT) LTD PAKISTAN	7	2010
3	BAIDYANATH AYURVED. MADHYA PRADESH	2.5	2014
4	UNIJULES LIFESCIENCE LTD	3.5	2017

Sterile Plants • 1/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
1	INTERVET PVT. LTD. PUNE, INDIA.	3	2004
2	SAMRUDHA PHARMACEUTICALS PVT.LTD MUMBAI. INDIA	2.2	2006
3	SAMRUDHA PHARMACEUTICALS PVT.LTD MUMBAI. INDIA	3.5	2006
4	MANKIND PHARMA LTD POUNTA SAHIB, INDIA	4	2007
5	BIOPHARMA INDUSTRIES, YEMEN.	4.71	2007

Sterile Plants • 2/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
6	NEON LAB LTD, MUMBAI. INDIA	2	2009
7	LIFESPAN BIOTECH PVT LTD BHOPAL. INDIA	6.5	2009
8	UTTRANCHAL BIOTECH LTD RUDRAPUR. INDIA	3	2010
9	JOCUND INDIA LTD HARIDHWAR. INDIA	4	2010
10	KHANDELWAL LAB RUDRAPUR, INDIA.	3	2010

Sterile Plants • 3/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
11	DHANA PHARMA NIGERIA	2.2	2011
12	AKRITI PHARMACEUTICALS PVT.LTD PUNE. INDIA	3.5	2013
13	CIRON DRUGS AND PHARMACEUTICALS PVT. LTD. MUMBAI, INDIA	4	2013
14	AURO PHARMACEUTICALS PVT. LTD. CONGO.	4.71	2014
15	MAGNUS PHARMA, PVT. LTD. NEPAL	2	2016

Sterile Plants • 4/4

	CLIENT / LOCATION	PROJECT COST (USD M)	YEAR
16	AWAMEDICA ERBIL, KURDIATAN	6.5	2017
17	MAGNUS PHARMA, PVT. LTD. NEPAL	3	2016
18	EVEREST PARENTERAL PVT. LTD. NEPAL	4	2018

India assignments • 1/17

01 **Indian Institute of Integrative medicines Jammu (IIIM), subsidiary of central scientific…**

SECTOR: Tablet, Capsule, Liquid oral, Herbal extract

SERVICES: Addition, alteration, renovation work in existing premises which is modified as a pharmaceutical facility. Plant layout, civil /…

02 **Simfa labs Pvt. Lts Indore**

SECTOR: Veterinary Liquid Oral, Powder, Tablet

SERVICES: Plant layout, civil / electrical / HVAC / utilities and equipment URS

03 **Acme Generics, Baddi**

SECTOR: Tablet, Capsule, Liquid Oral, Herbal extract

SERVICES: Compliance and Training, readiness for EU GMP audit in terms of Quality and Manufacturing systems.

India assignments • 2/17

Client, application/sector and consultancy scope from the original company profile.

04

Immacule Life Sciences, Baddi

SECTOR: Manufacturer of Liquid and Lyophilized Injections

SERVICES: Project management for sterile liquids and lyophilized injections for regulated markets.

05

Sterile – Gene Life Sciences, Pondicherry

SECTOR: Manufacturer of Liquid and Lyophilized Injections, Tablets, Capsule, Softgel (General, Hormone, Cephalosporin &…

SERVICES: Plant layout, civil / electrical / HVAC / utilities and equipment URS & GMP compliance, Documentation work.

06

Hindustan Phosphate Pvt. Ltd. Pithumpur

SECTOR: Biotechnology project

SERVICES: Plant layout, civil / electrical / HVAC / utilities and equipment URS

India assignments • 3/17

07

Swift Formulations Indore

SECTOR: Liquid oral

SERVICES: Plant layout, civil / electrical / HVAC / utilities and equipment URS

08

Vinkem Pharma, Chennai

SECTOR: Generic Oncology Injectable (Lyophilized) liquid & Vial

SERVICES: Preparation of plant layout & plant engineering design for Civil, electrical, HVAC, Utilities, machine URS, etc for injectable section.…

09

Mediclone Biotech Private Limited, Chennai

SECTOR: Oncology Injectable (Lyophilized) liquid & Vial

SERVICES: Preparation of plant layout & plant engineering design for Civil, electrical, HVAC, Utilities, machine URS, etc for injectable section.…

India assignments • 4/17

10 **ACCORD LIFE SPEC PVT LTD, Chennai**

SECTOR: Oncology Injectable (Lyophilized) liquid & Vial

SERVICES: Preparation of plant layout & plant engineering design for Civil, electrical, HVAC, Utilities, machine URS, etc for injectable section….

11 **Sanctus Drugs & Pharmaceuticals Pvt. Ltd. Pithumpur**

SECTOR: IV Fluids

SERVICES: Addition & alteration work for compliance as per cGMP.

12 **Sagar Rubber Products Pvt. Ltd. Mehsana Guj.**

SECTOR: Rubber Stoppers (Pharma Packaging Material)

SERVICES: Plant layout design as per WHO GMP requirement.

India assignments • 5/17

13 **Symbiotic Laboratories, Indore**

SECTOR: Hormone API's

SERVICES: GMP compliance, Documentation work.

14 **Sumit Laboratories, Vapi**

SECTOR: Bulk Drug (API's)

SERVICES: Plant layout design, GMP compliance, Documentation work.

15 **Impress Chemicals Pvt. Ltd. Pithumpur**

SECTOR: Bulk Drugs (Triprolidine Hydrochloride)

SERVICES: Plant layout design.

India assignments • 6/17

16 **Advance Enzymes Technologies Ltd. Pithumpur**

SECTOR: Bulk Drugs (Enzymes Products)

SERVICES: GMP compliance, Documentation work.

17 **D.J Laboratories Pvt. Ltd .Pithumpur**

SECTOR: IV Fluids, Injectables

SERVICES: GMP compliance, Documentation work.

18 **Prem Pharmaceuticals Indore**

SECTOR: IV Fluids

SERVICES: GMP compliance, Documentation work.

India assignments • 7/17

19 **Ives Drugs Ltd. Indore**

SECTOR: IV Fluids, Water for Injection (WFI)

SERVICES: GMP compliance, Documentation work.

20 **Vishal Pharmaceuticals Indore**

SECTOR: Liquid Oral, Tablet, Capsule

SERVICES: GMP compliance, Documentation work.

21 **Syndicate Pharma Indore**

SECTOR: Liquid Oral

SERVICES: GMP compliance, Documentation work.

India assignments • 8/17

22 **Arc Pharmaceuticals Indore**

SECTOR: Liquid Oral

SERVICES: GMP compliance, Documentation work.

23 **Zenith Drugs Pvt. Ltd. Indore**

SECTOR: Liquid oral, ointments

SERVICES: GMP compliance, Documentation work

24 **Glister Pharmaceuticals**

SECTOR: Liquid external

SERVICES: GMP compliance, Documentation work

India assignments • 9/17

25 **Sovereign remedies Pvt. Ltd. Indore**

SECTOR: Liquid oral, tablet, ointments

SERVICES: GMP compliance, Documentation work

26 **Gurjar Chemicals Pvt. Ltd Indore**

SECTOR: Bulk Drugs (API's)

SERVICES: Plant layout design

27 **Stickwell Industries Indore**

SECTOR: Adhesive tapes

SERVICES: Plant layout design

India assignments • 10/17

28 **Indo Borax & chemicals Ltd. Pithumpur**

SECTOR: Bulk Drugs (API's)

SERVICES: Plant layout design, GMP compliance

29 **Arihant chemicals Ratlam**

SECTOR: Bulk Drugs (API's)

SERVICES: Plant layout design, GMP Compliance

30 **Rajaram & Brothers Mandsaur**

SECTOR: Bulk Drugs (API's)

SERVICES: Plant layout design, GMP Compliance

India assignments • 11/17

31 **Ordeal Laboratories**

SECTOR: Injectables

SERVICES: GMP compliance

32 **Sovereign Pharma Pvt Ltd, Daman**

SECTOR: Manufacturing of liquid vial, ampoule, PFS. With lyophilized.

SERVICES: Additional line design, machine URS & GMP compliance documentation.

33 **Swiss Garnier life sciences, sikkim**

SECTOR: Manufacturing of Tablets & Capsules

SERVICES: GMP Compliance & Documentation.

India assignments • 12/17

34 **Karnataka Antibiotics & Pharmaceuticals Limited, Bangalore**

SECTOR: Drug Intermediate & Drug Products

SERVICES: Preparation of Detailed Project Report for Conceptual Proposed Drug Intermediate products.

35 **Kerala State Drugs and Pharmaceuticals Ltd., Kalavoor P.O., Alappuzha, Kerala - 688522**

SECTOR: Service Provider

SERVICES: GMP Consultancy for Regulatory Market registration

36 **Indira IVF Hospital**

SECTOR: GMP Consultant (Vendor Audit & FDA license)

SERVICES: Company consultants for vendor Management

India assignments • 13/17

37 **Akums Drugs & Pharmaceuticals Ltd.**

SECTOR: GMP Consultant (Vendor Audit & FDA license)

SERVICES: Company consultants for vendor Management

38 **BDR Pharmaceuticals Internationals Pvt. Ltd.**

SECTOR: GMP Consultant (Vendor Audit & FDA license)

SERVICES: Company consultants for vendor Management

39 **Procter & Gamble**

SECTOR: Husk & Suppressant

SERVICES: Validation, Plant layout design, GMP Service and Training

India assignments • 14/17

40 **Coromandel International Limited, (Bio Product, Division), Thyagavalli, Cuddalore - 608801**

SECTOR: Bio Product

SERVICES: TurnKey Project

41 **DFE Pharma Ltd, Cuddalore**

SECTOR: Excipients Manufacturing

SERVICES: Gap Assessment & GMP Complaince

42 **INCISEE ROTOMATIC PVT LTD**

SECTOR: DSIR

SERVICES: DSIR Project for R & D

India assignments • 15/17

43 **C.L. Baid Metha College of Pharmacy**

SECTOR: CTL – State Drug approval NABL DSIR

SERVICES: End to End Services

44 **Anabond Limited (Anabod Stedman Pvt. Ltd)**

SECTOR: Training

SERVICES: Annual GMP/GDP/GLP Training

45 **East Cost Hopital , Pondicheery**

SECTOR: Nutraceutical Plant Setup

SERVICES: End to End Services

India assignments • 16/17

46 **Manali Petrochemicals Limited (MPL) – Plant II: Sathangadu Village**

SECTOR: Plant for Propylene Glycol I.P. Propylene Glycol B.P. Propylene Glycol U.S.P. Propylene Glycol Ph.Eur.

SERVICES: WHO GMP & Gap Assessment

47 **Rathna Clinic ,Chennai**

SECTOR: Cosmetics Mfg Licece

SERVICES: End to End Services

48 **Primacy Industries Pvt. Ltd**

SECTOR: Cosmetics & Spary

SERVICES: WHO GMP and Revised Schedule M assessment and Implementation

India assignments • 17/17

49

LA ASIATIC, Ranipet

SECTOR: Pain bam and Cosmetics Mfg Section

SERVICES: Plant Design & CDSCO

International assignments • 1/6

01 **Hakeem Pharma, Riyadh, Saudi Arabia**

SECTOR: Liquid Injection, Liquid Oral, Ointment

SERVICES: Concept and detailed engineering: electrical, HVAC, utilities and URS

02 **Omar ban taha alsaggaf Factory for medical products, Jeddah, Saudi Arabia**

SECTOR: Tablet, Capsule, Liquid Oral, Ointment, Dry & Liquid Injection, Powder, Capsules, Laboratory Reagent

SERVICES: Facility layout and civil / HVAC / electrical / utilities design

03 **Al Hobail Pharmaceuticals, Riyadh, Saudi Arabia**

SECTOR: Vial (Lyo) & Ampoules

SERVICES: Preparation of feasibility study report as per SIDF, concept & detailed engineering design for plant

International assignments • 2/6

04

Best Green Lab, Slovakia

SECTOR: Tablet, Capsule, Liquid Oral

SERVICES: Preparation of plant layout & plant engineering design for Civil, Electrical, HVAC, Utilities, machine URS etc.

05

Isolez Biotech AG, Colombo, Sri Lanka

SECTOR: Liquid Injections

SERVICES: Plant layout design

06

Global Pharma, A Sanofi Company, Dubai

SECTOR: Tablet, Capsule, Powder

SERVICES: HVAC redesigning

International assignments • 3/6

07 **Aqaqeer Jazan Industries for Medical Drugs, Jazan, Saudi Arabia**

SECTOR: Tablet, Capsule, Liquid Oral, Ointment; Dry & Liquid Injection, Powder, Capsules

SERVICES: Preparation of Feasibility study report as per SIDF

08 **United Pharmaceuticals**

SECTOR: Tablet, Capsule, Liquid Oral, Ointment; Dry & Liquid Injection, Powder, Capsules

SERVICES: Preparation of Feasibility study report

09 **Symbiotica Speciality Ingredients Sdn. Bhd., Malaysia**

SECTOR: Sterile API

SERVICES: Turkey Project

International assignments • 4/6

10 **GSK – Ireland**

SECTOR: APIs for NDA molecule

SERVICES: Preparation of plant layout & plant engineering design for Civil, Electrical, HVAC, Utilities, machine URS etc.

11 **Pharmacare Leading Manufacturing Company, Jeddah, Saudi Arabia**

SECTOR: Tablet, Capsule, Powder

SERVICES: Preparation of Drug master file in CTD (Common technical documents) formats for product registration with SFDA

13 **Invapharm Ontario, USA**

SECTOR: Nutraceuticals

SERVICES: Preparation of plant layout & plant engineering design for Civil, Electrical, HVAC, Utilities, machine URS etc.

International assignments • 5/6

14 **Doctor Company for Pharmaceutical Industry Jeddah, Saudi Arabia**

SECTOR: Tablet, capsule, Ointment

SERVICES: Preparation of plant layout & plant engineering design for Civil, Electrical, HVAC, Utilities, machine URS etc.

15 **Galaxy Pharma Pvt. Ltd. Karachi, Pakistan**

SECTOR: Nutraceuticals

SERVICES: Preparation of plant layout & plant engineering design for Civil, Electrical, HVAC, Utilities, machine URS etc.

16 **Kendrick Pharmacy Ltd. Ghana**

SECTOR: Tablet, capsule, liquid Oral

SERVICES: Preparation of plant layout & plant engineering design for Civil, Electrical, HVAC, Utilities, machine URS etc.

International assignments • 6/6

17 **Pearl Health Science Ltd. Uganda**

SECTOR: Tablet, Capsule, Liquid oral

SERVICES: Preparation of concept engineering design

18 **Chief Donatus Pharmaceutical Nigeria**

SECTOR: Tablet, capsule, Liquid Oral

SERVICES: Preparation of plant layout & plant engineering design for Civil, Electrical, HVAC, Utilities, machine URS etc.

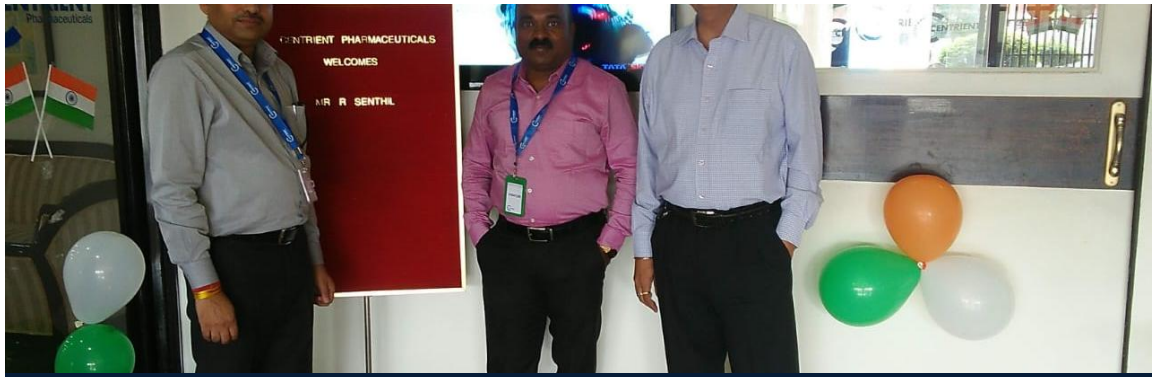
Knowledge-sharing & field engagements



Site visit / team engagement



Professional programme



Project-team activity



On-site activity

GxP learning, meetings & collaborations



Training and technical discussions



Site / institutional engagement



Team collaboration



External engagement

Field visits, operations & site engagement



Project site visit



On-site technical discussion



Engineering engagement



Cross-functional team activity

Company leadership and governance



Mr. Pramod H. Pimplikar

Chairman

M.Pharm; PGDPM



Mr. D. P. Venkatesan

Managing Director

B.Pharm; MBA



Mr. P. P. Bhalero

Projects & Engineering Guidance

Mechanical Engineer; PG Project Management

Core leadership & management



Mr. Sanjay Kumar Mandal

Chief Executive Officer



Mr. N. Kamalakar Rao

Principal Consultant – Formulation Development & Technology Transfer

M.Pharm



Mr. R. Vidhayanathan

Finance & Accounts Consultant

B.Com; PGDFM; ACS



Mr. R. Senthil Kumar

Director – GxP Operations

M.Sc; D.I.S.M.; MBA

Advisory & specialist network • 1/10



Dr. Mergu Raju

Principal Consultant – Formulation Development & Technology Transfer

M.Pharm; Ph.D.



Dr. Rajendra Prabhu

Sr. Consultant – Biotechnology Projects

Ph.D.; Biomedical Science



Dr. Sunil Avdhut Kanvinde

Sr. Consultant – Life Science Management

M.Pharm; Ph.D.; DIM; LL.B.

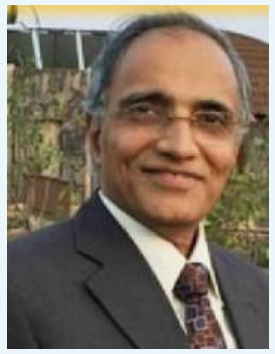


Dr. Mithlesh Narendera Trivedi

Sr. Consultant – GMP

Ph.D.; Organic Chemistry

Advisory & specialist network • 2/10



Mr. Samir A. Vasavada

Sr. Consultant – Pharma Operations

M.Pharm



Mr. Vijay Bhosre

GMP Senior Consultant



Mr. Sanjay Shukre

Sr. Consultant – Projects Management

B.E. (ECE); FIETE; MIE; C.Eng.



Dr. Yuvaraj

Principal Consultant – Clinical Research

Ph.D.; D.Sc.

Advisory & specialist network • 3/10



Dr. Sudesh Kumar H. N.

Sr. Consultant – HVAC & Clean Room Solutions



Dr. Prema P.

GMP Consultant

M.Pharm (Gold Medalist); Ph.D.



Mr. N. Murgungesan

Sr. Consultant – Projects & Engineering



V. Bharanidharan

Consultant – HRMS

B.CS.; MBA (HR)

Advisory & specialist network • 4/10



P. Sudhakar

Sr. Consultant

M.Sc (Gold Medalist)



Rabinson Thiviyanathan

Sr. Consultant

M.Sc; M.Phil; MBA



M. Viswanatha Sharma

Licensing Consultant

B.Pharm



A. Manivannan

Clean Room & Project Consultant

B.Eng.

Advisory & specialist network • 5/10



D. Srinivasa Rao

Sr. Consultant

M.Pharm; PGDBA



Mr. Lalit Kumar

GMP Consultant – Medical Devices

MBA; Six Sigma; B.Tech (ME)



Dr. Vandana A. Upadhyaya

Sr. Consultant

B.Pharm; N.D.



Velappan

Sr. Consultant

B.Sc Chemistry

Advisory & specialist network • 6/10



Iyyappan

Sr. Consultant

M.Sc Chemistry; Diploma in Instrumentation



Joseph Sahaya Raj R.

GLP & Analytical Consultant

B.Pharm



Kannan

Sr. Consultant

M.Pharm; MBA



Bala Ji K.

Sr. Consultant

M.Sc Microbiology

Advisory & specialist network • 7/10



Manish Joshi

Sr. Consultant

M.Sc



Venkatarengan S.

Sr. Consultant

MBA; M.Sc; B.Sc



Vijay Kumar K.

Sr. Consultant

B.Pharm; MBA



Vaibhav Meshram

Senior Project Manager

Advisory & specialist network • 8/10



Kundan Chougule

GMP Consultant

B.Eng.



Chirag Panchal

GMP Consultant

B.Eng.



Malla Sravan Kumar

GMP Consultant

M.Pharm



B. Balakrishnan

Sr. Consultant – Project

B.Sc Chemistry

Advisory & specialist network • 9/10



P. Gopalsamy

Principal Consultant – Analytical & GLP

M.Sc Chemistry



Kundan Chougule

GMP Consultant

B.Eng.



Akshay P. Repale

GMP Consultant

M.Sc Biotech



Mounesh Chirra

GMP Consultant

M.Pharm

Advisory & specialist network • 10/10



Kalyanasundaram

Sr. Consultant – Project

M.Sc Chemistry



A. Guruprasad

GMP Consultant

M.Sc Chemistry; Diploma Industrial Safety



Anitha Annamalai

GMP Consultant

M.Pharm; PG Diploma in Patent Law



Dr. Mayilvaganan Dorai

Technical Director - Life Sciences Innovation Strategist

Ph.D., - Applied Microbiology

PARTNER PROPOSITION

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Execute with coordination

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THANK YOU

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European GMP, regulatory compliance
and turnkey project consultancy