ISHA'S GMP CONSULTANCY

WELCOME TO isha's GMP CONSULTANCY

Our Services

- Turnkey & Greenfield Projects
- Quality Management System Services
- Contact Manufacturing & Outsourcing
- Audit and Compliance
- Risk & CAPA Management System
- Analytical Development
- Business & Marketing

www.ishasgmp.com

Welcome to Isha's GMP Consultancy

We "Isha's GMP Consultancy," is an independent research Quality Assurance consultancy working in the Life Sciences, Pharmaceutical, Cosmetics, Environmental, Agro chemical and Analytical sectors.. The range of services offered by us includes facility design, quality management system, dossiers & eCTD, formulation development, pharmaceutical & Biotechnology and outsourcing for Pharmaceutical & Biotechnology, immunobiologicals and anti gas gangrene serum, anti snake venom serum (ASVS), Nutraceutical, Agro Sciences and Cosmetics Products.

Our mission & , motto is to bridge the requisite gap between industries and various international regulatory agencies.We are having the expertise in the field pertaining to GxP Audits, GxP Training, Regulatory assistance, Turnkey projects and Quality Assurance services.

Excellent exposure in setting up of QMS and sound experience of all regulatory requirements like USFDA, MHRA, MCC, MCAZ, EU GMP, TGA, ANVISA, INVIMA, WHO GMP, PIC's, EPA (European Environmental Protection Agency (EPA) and other International regulatory bodies with various dosage forms like, tablets, capsules, syrups, suspensions, injections, ointments, Creams and Lotions and powders, Ampoules, vials, Eye /Ear / Nasal drops and Lyophilisation and other sterile manufacturing activities of Active Pharmaceutical and formulation finished dosage, immunobiologicals and anti gas gangrene serum, anti snake venom serum (ASVS), Metered Dose Inhalers (MDIs) and Dry Powder Inhalers (DPI), etc..

About Us

Isha's GMP Consultant based at Chennai and has been promoted by Mr.R.Senthil Kumar a dynamic result oriented professional of rich experience in the areas of Quality Assurance & Control, Regulatory Affairs, Projects, Process Development and design, Liaison & Coordination in Pharmaceutical industry (Both API and Finished dosage form).
We pride ourselves on having the ability to provide clients with worldwide full service support across all the GxPs. Our professionals are subject matter experts in their fields. We can help you achieve your goals on time, within budget and meeting the quality standards you deserve.

It targets serving prospective small, medium and large Pharma, Biotech & immunobiologicals /Cosmetics/Agro companies who aspire to upgrade their quality and documentation system conforming to both local and international regulatory standards and to get accreditation from USFDA, MHRA, MCC, MCAZ, PIC's, EU GMP, TGA, ANVISA, INVIMA, WHO GMP, EPA (European Environmental Protection Agency (EPA) /ISO 9000 at an unbelievable and much economical budget.

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ISHA'S GMP CONSULTANCY

Our Services

- Plant Set Up And Turn Key Projects
- Analytical Development
- Contract Manufacturing/Outsourcing
- Dossier & DMF Management
- Formulation Development
- Quality Management System (QMS)
- Training
- Audit Services
- QP Services
- Quality Investigation
- Validation services
- FDA related services
- Due-Diligence audit
- Data Integrity
- Business and Marketing Development Services
- DSIR certification
- Placement Services Corporate Training
- Certification of Management System
- Technology transfer
- HVAC & Clean Room Solutions
- Accounting & Financial Services

Pharma Plant Setup and Turnkey Projects

Designing of Pharma Plant is a skilled job. Wrong design leads everything wrong in future. All kind of international Audits success is depend on design of the Plant. Isha's GMP Consultancy with it & experts team handles all kind of Turnkey Pharma/Biotech Project.

We have with us extensive experience in meeting the designing demands of manufacturing facilities for pharmaceutical medicines. Our knowledge on local construction resources, building constraints as well as regulatory requirements also helps us to successfully establish for our clients GMP-compliant manufacturing facilities.

Service Highlights

- Facility designs that find application in the manufacturing of sterile & non- sterile pharmaceutical products.
- For making facility both versatile and cost-effective, we take into consideration at facility design stage concept of energy conservation & multi-product manufacturing
- We also ensure of the facility meeting international cGMP requirement keeping into consideration that product manufactured may be exported to overseas markets.

"Isha's" can help you in conceptualizing your dream project

- Alternative plant layouts meeting GMP requirements
- Men/material flow drawings on the approved layout
- Conceptual design paper on Pressure Differential system, Air Conditioning ,Heating and Ventilation with proposed Air Flow Diagram.
- Conceptual design paper on treatment, purification, filtration and distribution of various utility systems like Water, Steam, Compressed Air, Gases, Solvents, etc.
- Estimate requirements of various utilities
- Develop P&IDs for Process and Utilities
- Electric Power requirements for the plant, suggest High Tension and Low Tension Distribution schemes
- Conceptual design for ETP and Fire fighting Systems.
- Prepare civil finishes schedule.

Using GEP (Good Engineering Practice) to achieve GMP Detailed Engineering is the essential bridge between the basic engineering and construction phase of a project. It is "converting dreams into reality".

Analytical Development

Isha's GMP Consultancy has the professional exposure in analytical method development (HPLC, GC) for raw materials, intermediates, drug substances (APIs), and drug products (Formulation) qualification/validation of such methods, and analyses of APIs/Formulation and related materials (raw materials, intermediates).

We have an expertise in troubleshooting and problem solving of synthetic processes, comprised of method development/validation of HPLC and GC methods.

We have the leading experience in analytical method development in both proprietary and non-proprietary drug products.

Method development aptly supported by the validation guiding principles according to ICH guidelines.

Contract Manufacturers

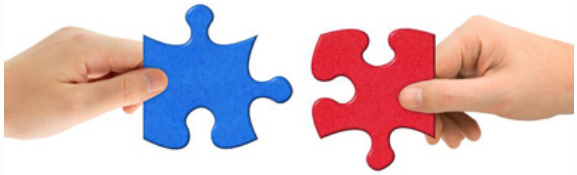
Tie-ups with Contract Manufacturers – the emergence of India as a world-player in pharmaceuticals has brought foreign companies the opportunity to outsource part of their production to Indian manufacturers, thus cutting costs, and production hassles. We consult companies, both Indian, and foreign on their contracting requirements.

- Marketing services – for companies, both Indian, and Foreign, wishing to find customers for their product range.
- We have tie-ups with certain manufacturers and are their agents, for pre-specified geographies. For certain customers, we are their purchase/sourcing partners, thus simplifying procedural issues such as Audits, vendor approval etc.

Dossier & DMF Management

Drug Master File

- CTD DMF
- ACTD DMF
- Korean DMF
- US DMF
- eCTD DMF
- EU DMF

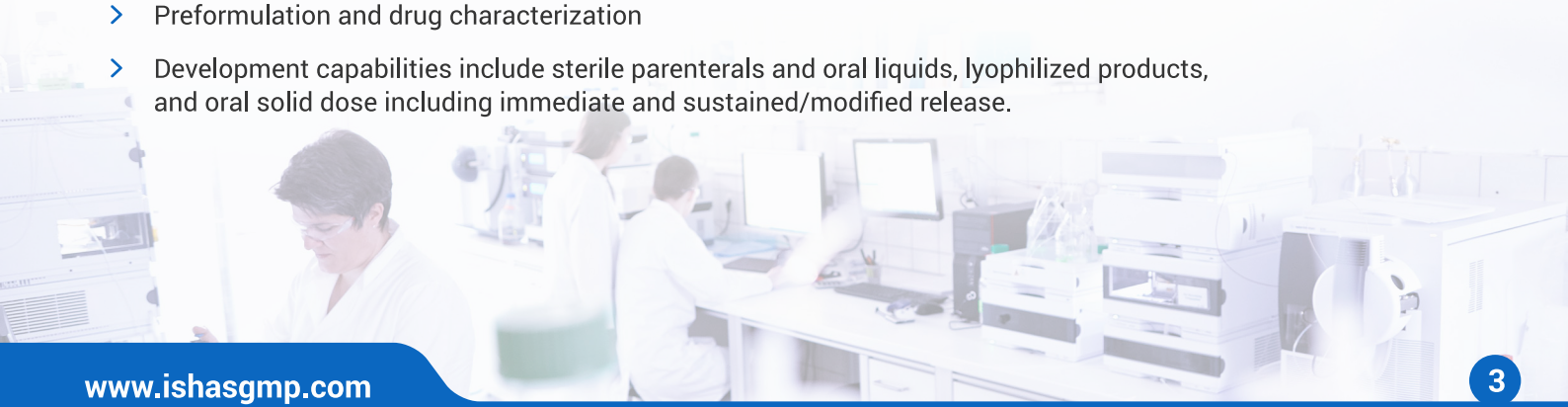


Formulation development

Formulation development is at the very foundation of what we offer to you, our client. Our staff of dedicated scientists can develop solutions; API's synthesis, solid dosage forms; solids or liquid formulations of oral capsules; immediate or modified-release tablets; topicals to meet your needs and that of the targeted marketplace. Our scientists have extensive experience with challenging drug candidates with poor solubility, are inherently unstable, or not readily bioavailable. We provide creative solutions to these and other pharmaceutical development challenges utilizing both proprietary and non-proprietary technologies.

We provide services for

- Years of development experience across a wide range of difficult to formulate drugs
- Flexible facilities and conditions capable of handling very small batch sizes as well as highly toxic compounds and controlled substances
- Preformulation and drug characterization
- Development capabilities include sterile parenterals and oral liquids, lyophilized products, and oral solid dose including immediate and sustained/modified release.



Quality Management System

Isha's GMP Consultancy can cater a vast assortment of policies, processes and procedures for planning and execution (Production/ development/ service) in the core business area of a pharmaceutical & biotechnology /Cosmetic organization, either in the field of Active pharmaceutical manufacturing or in the formulation plants, immunobiologicals plants and Metered dose inhalers plants.

Isha's adds value to through quality systems. Moreover, riveting the market specific quality guidance enforced by the various regulatory authorities including USFDA , MHRA UK, TGA Australia, MCC South Africa, ANVISA Brazil, WHO Geneva , HPFBI Canada and etc.,.

We are aiming at an integrated solution, with a fixed time scale and related standards. Quality Management System services tailored to your needs at low costs in a time-efficient manner.

- Adding value through management systems
- Performing the Gap Analysis
- Planning Activity
- Training Activities for Executives
- Documentation & Guidance in Implementation
- Conducting Internal Audits
- Conducting Management Review Meeting Implementation of pharmaceutical Quality Management System(QMS)
- Redesign of QMS to incorporate major changes and changing business needs
- Quality Risk Management (QRM)., Facility, Products, QMS, Quality control, Production, warehouse, Computer system and supply chain, etc..
- Writing of: SOPs, Batch records, Protocols (Validation, Qualification, Stability, etc)
- Conducting investigations (OOS, deviations, equipment or utility issues, etc.)
- Overseeing the CAPA program
- Audits: execution of internal and external audits
- Master Batch Record control
- Production Batch Records review
- Assist before, during, and after audits by Regulatory Agencies (FDA, MHRA, EMEA, etc)
- Product release
- Handle customer complaints
- Label control
- Generation and improvement of Quality Management System(QMS)

Audit Services

- Site audits and qualification of API/Formulations manufacturers in compliance to ICH Q7, excipient manufacturers, contract manufacturers and suppliers, packaging and labeling contractors, warehouse contractors and contract laboratories.
- Site audits of finished products
- Pre-inspection approval assessments
- API/Formulation QP audits and certifications
- Auditing facilities to ensure an appropriate level of due diligence
- Pre-regulatory assessment audits and gap analysis
- Mock regulatory audits
- CMO fact finding inspections and investigative inspections

Data integrity

FDA and MHRA data integrity requirements are considered a fundamental aspect of the quality system. The quality system includes all GMP operations such as change control, CAPA, deviations, and validation. In the last 25-30 years that industry have migrated from paper-based QMS processes to electronic systems. Unfortunately, validation continues to be a paper-based process that is plagued with data integrity challenges.Paper-based validation creates a significant amount of business and compliance risk related to data integrity. This risk is related to the number of manual activities like data entry, manual protocol execution, risk assessment, lack of audit trails and trace ability.

- ***Data manipulation***
- ***Data falsification***
- ***Omission of data***
- ***Permanent deletion of failed results***
- ***Non attributable data***

Quality Investigation

Many organisations face ongoing challenges in conducting Root Cause Investigation related to the handling of deviations, out of specification results, product complaints, Microbiological contamination, product recall and other major manufacturing incidents. What we offer is an independent, open-minded experienced, resource to support your team to facilitate detailed root cause assessment and CAPA implementation plans.

We recognise the importance of a structured approach to conducting Root Cause Investigations, and can provide guidance and support in this critical area.

Validation Service

We can manage all your validation requirements from project management to report writing that is from URS, FRS, DQ, FAT, SAT, Commissioning documents, VMP, IQ, OQ, PQ, PV to Validation report writing. Our experienced validation engineers can be based in your facility to execute validation testing and work with you to streamline the testing to increase efficiency and optimise testing value.

We can provide solutions for conducting risk assessments using tools like fish bone, 5 why, FMEA.

- ***Protocol Generation***
- ***Protocol Execution***
- ***Final Report Preparation***
- ***Quality Review***

Facilities Design or Validation

Isha's is skilled in assisting organizations as they encounter facilities design, construction, or adaptation—or as they encounter facilities-related compliance problems. Through a powerful blend of compliance, regulatory, scientific, and technical expertise, is highly effective in:

- Analyzing, developing, and/or enhancing engineering requirements, specifications, and drawings, including HVAC, water, sterilization, and dust-control systems o Developing environmental and processing-room requirements
- Recommending effective flow of materials, equipment, and personnel
- Assessing and enhancing facilities requirements vis-à- vis manufacturing, assembly, packaging/labeling, and distribution operations
- Addressing the facilities requirements of laboratory operations
- Performing factory acceptance testing of equipment (FAT)
- Conducting audits during construction and installation phases
- Qualifying facilities for sterile, low-bioburden, and non- sterile products
- Qualifying facilities for intermediates, APIs, and finished drug products
- Qualifying facilities for medical device components and finished products

Technology Transfer (TT)

We offer a complete solution for Technology Transfer (TT). Our dynamic and experienced technical, QC and QA teams have the ability to manage all your TT requirements without an increase in headcount. We can provide TT services in an optimum time scale with rigorous efficiency.

- We check deficiencies in the facilities and requirement for manufacture of product and we will demonstrate 3 Nos consecutive commercial batches for each product.
- We will provide required documentation for manufacturing
- Continue technology support for up-gradation & troubleshooting for at least 1 year post-start of manufacturing at commercial level of the product.

We shall provide following in the respect of know-how / technology of the product for each product

- Raw material specification, quantitative requirements, their sources and their safety data sheets.
- Product specification and Pharmacopial reference
- Process details including critical steps, time cycle and process flow chart.
- Specification of utilities, quantitative requirements and environmental conditions including classification for each stage of processing.
- SOP, Master Formula / protocol for manufacturing the above products
- In-process control techniques & in-process control parameters.
- Analytical testing procedure for raw material as well as finished product.
- Details of the facilities required for manufacturing of above products giving brief specification.
- Protocol for Stability study data for the products.
- Protocol for process validation and analytical validation
- Demonstrate at least 3 consecutive successful batches.
- Trouble shooting strategy for deviations in raw material or any process parameter.
- Any specific storage condition for raw material, in-process material and finished product.
- Conduct training of operating personnel for technology of product.

Time frame

Time frame for technology transfer product wise will be 6 months for each product (excluding stability study) provided the material and facility is made available at site.

FDA Consultant Services

We offers a full range of services for State, Central licensing (CDSCO), that need to comply with the Indian Food & Drug Administration

Document preparation
Document review
Application
Compliance problem Solving
Preparation/Review of Regulatory fillings
System evaluation
Special services (As per actual) & many more

Training Development

we have a GMP Training Course to suit. All our courses are delivered in-company and are tailored to your particular requirements and can include company specific information & examples. All the topics listed under each course are suggested only and can be customized for you as the client. The number of people per session and the number of sessions per day are all agreed with you, the client, to ensure minimal disruption to operations.

HVAC & CLEAN ROOM SOLUTIONS

HVAC & Clean room solutions. Is a one stop solution for all Clean room requirements like Design and execution related to HVAC, Clean Room, Wall Paneling, Electrical, Architect & Civil, Utilities systems. We also support by providing annual maintenance for entire facility and quality system consultation along with documentation to meet regulatory requirements. Our services includes, supply of relevant equipment's for these industries also.

Field of Experts in Clean Room

- Design and execution of PHARMA Air Conditioning ,Ventilation & Clean rooms systems for Electronic Industry Mechanical Industries, Pharmaceuticals, Research Laboratory and Biotechnology and Bio-safety Level-3 laboratories.
- Design and execution of Clean rooms and Utilities Electronics, Semi conductor Industries , Supply of clean room wall panels, equipment's and special products.
- Plant Engineering Services & Quality Air management system.
- Complete modification of old Pharma, Biotech & Health careplant & Electrical (Building & Equipment) & Renewable Energy systems.
- Architectural & Civil and General Engineering

ACCOUNTING & FINANCIAL SERVICES

Accounting & Financial consultants help you understand what the various reports mean, and how the data you're seeing affects your company. Accounting consultants help with a number of tasks related to accounting & financial services:

1. SERVICES 2. ADVANCE SERVICES 3. MONTHLY FINANCIAL REPORT AND PACKAGE 4. CONTROLLER SERVICES

We offer our clients the following key solutions

- End-to- end financial outsourcing
- Financial Statement preparation
- Audit Readiness
- Fixed Asset Management Services
- Account reconciliation and reconstruction
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- Financial Statement preparation
- Audit Readiness
- Fixed Asset Management Services
- Account reconciliation and reconstruction
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We provide end to end solutions

- We provide the perfect, practical, effective and competitive business solutions to the organizations to optimize their operational efficiency.
- We are backed by proficient managers and team leaders who put in every effort to provide the best services to our clients.
- We offer logical and effective planning and implementation strategies.
- Our main focus is to enhance the features of our client'sorganization to meet the requirements of certification norms.

1. SERVICES 2. ADVANCE SERVICES 3. MONTHLY FINANCIAL REPORT AND PACKAGE 4. CONTROLLER SERVICES

ISHA'S GMP CONSULTANCY

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