CONSULTANCY

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ISHA'S GMP CONSULTANCY

Company **PROFILE**

Welcome to Isha's GMP Consultancy

We support our customers, with the complete project management solutions which includes but not limited to GxP Auditing, Regulatory filings and solutions, Life cycle management, GMP compliance, IT Solutions for Pharmaceutical & Biotechnology industry, Green field projects, Turnkey projects, Business development, Product development and analytical solutions and services.

About us

Isha's GMP Consultancy team of senior consultants with over three decades of successful experience in varied fields in globally respected international pharmaceutical companies from US, Europe and India, deep understanding of market realities and regulatory challenges in India and overseas markets can provide strategic and/or operational guidance to Pharmaceutical/Biotechnology companies to achieve their aspirations for growth and profitability

Our Core Values

• Customer Focus

To provide end to end solutions to our customers by satisfying them with technical excellence, perfection and innovation. And to be a dynamic team, providing the highest quality and vibrant services to customers.

• Integrity

We are committed to being honest and ethical in everything we do and with everyone we deal with, always delivering on our promise., and make ourselves accountable for all our successes and failures and we provide Quality services at par expectations with Continuous learning.

CONSULTANCY

OUR SERVICES

- PLANT SET UP AND TURN KEY PROJECTS
- FDA SERVICES
- ANALYTICAL DEVELOPMENT
- CONTRACT MANUFACTURING/OUTSOURCING
- DOSSIER & DMF MANAGEMENT
- FORMULATION DEVELOPMENT
- API / INTERMEDIATE DEVELOPMENT
- QUALITY MANAGEMENT SYSTEM (QMS)
- TRAINING
- AUDIT SERVICES
- QP SERVICES
- QUALITY INVESTIGATION
- VALIDATION SERVICES
- MEDICAL DEVICES
- HR CONSULTING
- DUE-DILIGENCE AUDIT
- BUSINESS AND MARKETING DEVELOPMENT SERVICES
- DSIR CERTIFICATION

FDA-RELATED SERVICES

- COSMETIC
- AYURVEDA
- ALLOPATHIC
- HOMEOPATHIC
- BLOOD & BLOOD PRODUCTS
- VACCINES & SERA

FDA Services

- DATA INTEGRITY
- VIRTUAL FACILITY INSPECTIONS
- QUALITY ASSURANCE AND CONTROLS
- SCIENTIFIC AND TECHNICAL ASSISTANCE
- SYSTEMS EVALUATION
- FACILITIES DESIGN OR EVALUATION
- SYSTEM PROCESS VALIDATION OR QUALIFICATION
- REMOTE SERVICES
- TRAINING
- FDA FORM 483

Turnkey Projects

- PHARMACEUTICAL DOSAGE FORMS
- BIOPHARMACEUTICALS
- APIS & FINE CHEMICALS
- LABORATORIES AND R&D
- FOOD & BEVERAGES
- COSMETICS & PERSONAL CARE
- MARKET ACCESS

Turnkey Projects Services

- PROJECT FEASIBILITY STUDIES
- PROJECT REPORT PREPARATION
- SITE MASTER PLAN PREPARATION
- FACILITY DESIGNING
- DETAILED ENGINEERING DESIGNING
- STRUCTURAL & ARCHITECTURAL DESIGNING
- URS PREPARATION
- VENDOR OPTIMIZATION
- PROJECT EXECUTION & MANAGEMENT
- COMMISSIONING
- TECHNICAL DOCUMENTATION

Market Survey Reports

Market Survey Reports Elucidate the Present Market Potential as well as future scope of the product. Isha's GMP Team has prepared Market Survey Reports on various Pharmaceuticals API, Formulation and Biotechnology Products.

HR Consulting

At Isha's we offer outsourced HR services like

- Developing HR Policies & Manuals
- Compensation Benchmarking
- Employee Satisfaction Survey
- Executive Diligence & Reference Checks
- Statutory Compliance
- Recruitment
- Salary Offered
- KRA
- Mystery Shopping
- Payroll Management
- Training
- Master Vvendor Services (Onsite Recruitment Consultant)
- Customized Solutions to all Companies
- Statutory Compliance

Medical Devices

- Regulatory Consulting for Medical Devices
- Quality Management Consulting for Medical Devices
- Medical Devices Trunky Plant setup
- Global Product Registration for Medical Devices
- Market Entry and Market Research Analysis for Medical Devices
- Business Transformation and Growth Adviosry for Medical Device Companies
- Export Promotion
- Medical Devices Traning Courses
- ISO 13485 : 2016 Certification

Contract Manufacturing Outsourcing

- Sourcing – relying on our experience, a dynamic team, and a huge proprietary database, we help customers source from well-established factories, and trading houses, at competitive prices, and best quality. We help contract manufacturing or outsourcing of

A. Active Pharmaceutical Ingredients
B. Finished Dosage form (tablets, capsules, Softgel, syrups, suspensions, injections (SVP/LVP), ointments, Creams and Lotions and powders, etc..
C. Intermediates
D. Fine Chemicals
E. Bulk Chemicals
F. Nutraceuticals
G. Excepients
H. Food Additives

- 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.

Life Science Services

- Site audits and qualification of API/Formulations manufacturers in compliance to ICH Q7, excipient manufacturers, contract manufacturers and suppliers, packaging and labelling 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

Our third-party audits meet the highest standards in quality and independence.

Validation

- 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.

Drug Master File

Isha's GMP consultancy are developing as a prime destination for all the dossier & CTD management challenges of a modern competitive pharmaceutical industry.

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

Formulation Development

Product Development Services

- Literature Search
- I P Review
- Pre-Formulation Development
- Compatibility Studies
- Formulation Development and Optimization
- Packaging Development
- Process Development and Optimization
- Scale-Up and Technology Transfer
- Process Validation Studies

Analytical Development Services

- Analytical methods development and validation
- Cleaning methods development and validation
- Stability studies as per ICH Guidelines
- Method Transfer

Intellectual Property Right

- Landscape Preparation
- Support for formulation development IP related activities
- Infringement and Non-infringement Analysis
- ANDA Certifications

Pharmacokinetic Department

- Bio-Study protocols preparation and planning of Bio studies
- Bio equivalence study monitoring.
- Review of Bio study report and supporting for Regulatory submission

Isha's GMP services provides excellence in quality and compliance. We support the services throughout the entire process of planning, selecting, designing and developing to meet the growing demands of the global market standards.

Quality Management System (QMS)

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.,.

- 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

Our professionals ensure QMS achieves three objectives:

- Continuous improvement
- Regulatory requirements
- Establish “right-sized” processes for the phase and scope of the organization

Compliance Experts:

Whether you are proactively or reactively looking to develop and implement a QMS, our team can help.

Embracing the principles of the International Conference on Harmonization Q10 (ICH Q10) model, our experts certify your QMS can verify that required product quality is routinely met. Our team makes sure that suitable process performance is achieved, the set of controls are appropriate, improvement opportunities are identified and evaluated, and the body of knowledge is continually expanded.

DSIR Certification

- **Certifications Consulting:**

  Recognition/Approval application filling in DSIR: We help organizations of different areas like chemical, pharmaceutical, agrochemical, dyes, textile, electronic, mechanical etc. to comply with the standards and attain Department of Science & Industrial Research (DSIR) certifications and Approvals for In-House R&D center.

Technology Transfer (TT)

Technology transfer is a process that spans the key phases of pharmaceutical development right through to commercial manufacturing including:

- Product transfers including API and drug product manufacture.
- Processing, packaging and cleaning operations.
- Pre-inspection approval assessments.
- Quality control – analytical method transfer.

Corporate training

Training Development

We have developed Training Curriculums for almost any kind of industry and are continuously improving our training content and method. This experience has made us a trusted partner in Curriculum development for organisations or companies.

API - Intermediate - Synthesis – Services

Isha’s GMP Consultancy has been at the forefront in offering fine and specialty chemicals and intermediates for API as well as a preferred provider of Contract Research and Manufacturing Services (CRAMS) and are intending to have a leading presence in domestic and global markets, by providing strong advantage in quality, speed and cost across the markets. As a reliable and competent supplier, our growth is directly linked with client satisfaction through our manufacturing capabilities:

Process capability

- Nitration
- Sulfonation
- Esterification
- Aromatic Rearrangement Reaction
- Acylation
- Diazotization Reaction
- Sandmeyer Reaction
- Halogenation
- Acetal Formation
- Condensation Reaction
- Reduction Reaction
- Suzuki Coupling Reaction
- Fusion Reaction
- Mannich Reaction

Technology

- Batch Reaction
- Low Temperature
- High Pressure Reaction
- High Vacuum Distillation (up to 0.1 mm Hg of vacuum)
- Filtration & Drying

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 Panelling, 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.

Field of Experts in IN HVAC

Design, Supply, Erection, Commissioning & Maintenance of HVAC SYSTEMS

- BIOTECH Industries
- PHARMA Turnkey Projects
- Industrial Ventilation Projects
- Clean Room Applications
- Chillers
- AHU's (Air Handling Unit)
- CSU's (Ceiling Suspended Units)
- VRF (Variable Refrigeration Frequency)
- Package Units
- Ductable Splits
- Cassette Units
- Hi-Wall Splits

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:

- SERVICES
- ADVANCE SERVICES
- MONTHLY FINANCIAL REPORT AND PACKAGE
- CONTROLLER SERVICES

Financial Services

- Financial Auditing
- Taxation PLANNING GST service
- Internal audit service
- Profit and Loss a/c and Balance sheet.
- Payroll services

We offer our clients the following key solutions

- End-to- end financial outsourcing
- Financial Statement preparation
- Audit Readiness
- Fixed Asset Management Services

Operational Excellence

- Value stream mapping which exposes waste and bottlenecks in the processes The TPM Approach to Manufacturing Excellence
- To increase Overall Equipment Effectiveness (OEE),
- Reducing the Costs of Poor Quality because Poor quality costs a typical company 15-20% of sales annually
- Building an Effective employee Suggestion System
- Improving Quality with Six Sigma Process