

## 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

## Quality Management System

- 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.



## 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

## Contact Us



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Company PROFILE



# CONSULTANCY

# 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 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

## 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



## Formulation Development

### Product Development Services

- Literature Search
- IP 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.