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)
- Data Integrity Management
- 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)

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.

- **Good Manufacturing Practice (GMP) for Management**
- **Root Cause Analysis Tools**
- **Good Laboratory Practice (GLP)**
- **Auditing and Compliance & CAPA Management**
- **Cleaning Validation**
- **Quality Systems Design & Implementation**
- **Data Integrity Management**
- **Quality Risk Management**
- **Clean Room Practice**
- **Sterile Area Practice & Behaviour**
- **Pharmaceutical Product Lifecycle Management**
- **Pharmaceutical Quality System**
- **Pharmaceutical development of Drugs substance**
- **Sterile Medical Product Manufacturing**
- **Supply Chain Management**
- **Good distribution practice (GDP)**

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:

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
- End-to- end financial outsourcing
- Financial Statement preparation
- Audit Readiness
- Fixed Asset Management
- Services
- Account reconciliation and reconstruction
- Payroll processing

CONTACT US

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Branch office
Under registration at
Ireland, United Kingdom

ISHA'S GMP CONSULTANCY

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.

We are providing the services to various renowned industries and companies who venture to upgrade their incumbent quality & documentation system, and facility to conform the both local and international regulatory standards and to get accreditation from USFDA / EDQM / MHRA / TGA / ANVISA / INVIM / MCC, etc at most competitive and viable budget.

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.

- Active Pharmaceutical Ingredients
- Immuno biologicals and anti gas gangrene serum, anti snake venom serum (ASVS).
- Cosmetics/Food and Nutraceutical
- Intermediates
- Excipients
- Finished Dosage Forms (Solid oral, Liquid Oral, Dry Injectables, Paranterals (SVP/LVP), Ointments, Creams and , Metered Dose Inhalers (MDIs) and Dry Powder inhalers (DPI)

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 SystemTechnology transfer
- HVAC & Clean Room Solutions
- Accounting & Finanical
- Corporate Training
- Technology Transfer

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

During BASIC ENGINEERING the following definitions of the project will be developed

- 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.

Isha's can assist you in a number of ways to answer all these and many more questions. The typical approach will be to first gather functional requirements of the proposed facility which includes production process together with the required level of automation, dosage forms, batch sizes, containment needs, type of equipment and machinery, inventory norms, expansion philosophy, etc.