PEOPLE | PROCESS | COMPLIANCE
FOR A HEALTHIER TOMORROW

ISHA'S GMP CONSULTANCY PVT. LTD.

Ensuring Global GMP Compliance®

Global GMP & Regulatory Excellence

GLOBAL
KNOWLEDGE
LOCAL IMPACT

Integrated consultancy solutions for pharmaceuticals, biotech, medical devices, food, cosmetics and life sciences.

ISHA'S GMP CONSULTANCY PVT. LTD. is a trusted global consultancy delivering end-to-end solutions for GMP compliance, regulatory support, turnkey projects, validation, audits, training and market access across regulated industries.



- Turnkey Projects
- GMP & FDA Services
- Life Science Services
- Medical Devices
- Specialized Services
- Market Research & HR Consulting

www.ishasgmp.com | info@ishasgmp.com | +91 86675 89984 | +91 99764 91578

PEOPLE | PROCESS | COMPLIANCE
FOR A HEALTHIER TOMORROW

ISHA'S GMP CONSULTANCY PVT. LTD.

Ensuring Global GMP Compliance®

GLOBAL
KNOWLEDGE
LOCAL IMPACT

About Us

Integrated Compliance & Project Consulting Partner

ISHA'S GMP CONSULTANCY PVT. LTD. is a trusted global consultancy providing end-to-end consulting solutions for GMP compliance, regulatory support, facility projects, validation, audits, training and market access across pharmaceuticals, biotech, medical devices, food, cosmetics and life sciences. We partner with organizations to build compliant, efficient and future-ready operations.



What We Deliver

GMP Compliance
Build and maintain compliant operations

Regulatory Support
Guidance for global regulatory requirements

Facility Projects
End-to-end support from concept to commissioning

Validation & Qualification
Systems, equipment and process validation

Training & Audit Readiness
Build capability for regulatory success

Market Access Support
Strategic guidance for global markets

Industries We Serve



Pharmaceuticals
Innovative and generic medicines



Biotechnology
Biologics, vaccines and advanced therapies



Medical Devices
Quality and regulatory support for safer products



Food & Nutraceuticals
Safe, high-quality and compliant products



Cosmetics & Personal Care
Compliance for beauty and wellness products



Laboratories & R&D
Support for research, development and analytical laboratories

Practical Solutions
Real-world, implementable and cost-effective approaches

Global Perspective
International experience with local understanding

Industry Expertise
Deep domain knowledge across regulated industries

Client Focus
Long-term partnerships built on trust and results

ISHA'S GMP CONSULTANCY PVT. LTD.

Ensuring Global GMP Compliance®



Turnkey Projects

From Concept to Commissioning

End-to-end project consultancy for pharmaceutical, biotech, API, food, cosmetic and life science facilities – delivering world-class, compliant and future-ready manufacturing and research environments.



Pharmaceutical Dosage Forms

Tablets, Capsules, Injectables, Liquids, Ointments & More



Biopharmaceuticals

Vaccines, Monoclonal Antibodies, Recombinant Products, Cell & Gene Therapies



APIs & Fine Chemicals

API Manufacturing, HPAPIs, Intermediates and Specialty Chemicals



Laboratories & R&D

Analytical Labs, Microbiology, Stability, R&D and Pilot Facilities



Food & Beverages

Processed Foods, Nutraceuticals, Functional Foods and Beverages



Cosmetics & Personal Care

Skincare, Haircare, Personal Care and Specialty Cosmetic Products

Project Execution Process

A STRUCTURED APPROACH FOR SUCCESS

01 Feasibility

Concept study, site evaluation & regulatory assessment

02 Planning

Project strategy, budgeting, timelines & risk assessment

03 Design

URS, process design, facility layout, engineering & detailed design

04 Procurement

Vendor selection, equipment sourcing & FAT coordination

05 Execution Support

Site supervision, installation support, construction management

06 Qualification & Handover

IQ, OQ, PQ, validation support & final handover

Key Capabilities

INTEGRATED EXPERTISE FOR END-TO-END DELIVERY

Facility & Layout Planning

Efficient, GMP-compliant and scalable designs

Cleanroom & HVAC Concepts

Contamination control and utility optimization

Equipment Selection

Right technology for process and compliance needs

Utilities & Support Systems

Process, clean utilities and facility systems design

Project Management Support

Timely execution with cost and quality control

Compliance Readiness

cGMP, regulatory alignment and audit preparedness

ISHA'S GMP CONSULTANCY PVT. LTD.

Ensuring Global GMP Compliance®

PEOPLE | PROCESS | COMPLIANCE
FOR A HEALTHIER TOMORROW

GLOBAL
KNOWLEDGE
LOCAL IMPACT

GMP & FDA Services

Strengthening Quality, Systems and Inspection Readiness



We provide end-to-end GMP and FDA consultancy services to help pharmaceutical, biotech, medical device, food, cosmetic and life science companies build robust quality systems, ensure data integrity, and achieve inspection readiness.

FDA Data Integrity



Assess and strengthen data integrity systems, controls and ALCOA+ compliance.

FDA-Related Services



Regulatory support, gap assessments and alignment with FDA expectations.

Virtual Facility Inspections



End-to-end support for remote FDA and global regulatory inspections.

Scientific & Technical Assistance



Expert scientific guidance for compliance, product development and lifecycle support.

Facilities Design or Evaluation



Design review, facility evaluation and GMP-compliant infrastructure solutions.

Systems Evaluation



Comprehensive assessment of quality and technical systems for regulatory compliance.

System Process Validation or Qualification



Process validation, cleaning validation, equipment qualification and computerized system validation.

Quality Assurance & Controls



Strengthen QA and QC systems, documentation, review processes and batch release activities.

Remote Services



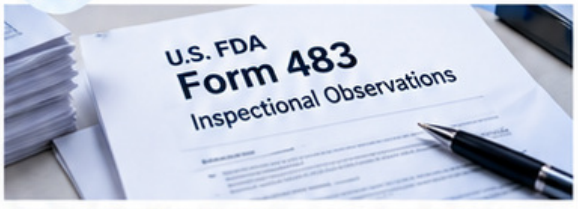
Flexible remote consulting, audits and training support globally.

Training



Customized training programs on GMP, FDA regulations, data integrity and quality systems.

FDA 483 Response Support



Expert support for assessment, root cause analysis, CAPA development and effective response to FDA 483 observations.

Typical Outcomes

- **Improved Compliance**
- **Stronger Data Integrity**
- **Inspection Preparedness**
- **Sustainable Quality Systems**

www.ishasgmp.com | info@ishasgmp.com | +91 86675 89984 | +91 99764 91578

ISHA'S GMP CONSULTANCY PVT. LTD.

Ensuring Global GMP Compliance®

SCIENCE
COMPLIANCE
BETTER HEALTH
FOR TOMORROW

Life Science Services

Regulatory, Quality and Technical Support Across the Product Lifecycle

ISHA'S GMP CONSULTANCY PVT. LTD. provides end-to-end life science consultancy services to help pharmaceutical, biotech, medical device, food, cosmetic and allied industries achieve compliance, operational excellence and faster market access.



Third-Party Selection Services

Identify and qualify reliable CMOs, CDMOs and suppliers with risk-based evaluation.



Regulatory Affairs

Strategic support for global regulatory submissions, registrations and lifecycle management.



Quality Management System

Develop, implement and strengthen QMS aligned with cGMP and global standards.



Audit Services

Supplier, CMO, facility and system audits with actionable insights.



Due Diligence Audits

In-depth technical and compliance assessment for informed decision making.



QP Services

Qualified Person support for batch certification and regulatory compliance in EU and global markets.



Quality Investigation

Support for deviation, OOS/OOT, OOE and root cause investigation with CAPA.



Validation Services

Process, cleaning, analytical, computerized system and equipment validation.



Business & Marketing

Market research, opportunity assessment and strategic support for global expansion.



DSIR Certification

End-to-end support for DSIR recognition and R&D related compliance.



Formulation Development

Development of innovative and generic formulations with robust and scalable processes.



API Intermediate / Synthesis Services

Process development, scale-up and technology transfer for APIs and key intermediates.

Why Clients Choose Us

Cross-Functional Expertise
Multi-disciplinary team with industry experience

Practical Documentation
User-friendly, regulatory-ready documents

Implementation Support
From strategy to on-ground execution

Global Compliance Mindset
Aligned with US, EU and other international regulations

PEOPLE | PROCESS | COMPLIANCE
FOR A HEALTHIER TOMORROW

ISHA'S GMP CONSULTANCY PVT. LTD.

Ensuring Global GMP Compliance®

Medical Devices

Quality, Regulatory and Market Access Support

GLOBAL KNOWLEDGE LOCAL IMPACT

End-to-end consulting for medical device development, manufacturing, registration and commercialization. We help you navigate global regulations, build quality systems, set up compliant manufacturing facilities and gain faster market access for safe, effective and innovative medical devices.



Regulatory Consulting for Medical Devices



Quality Management Consulting



Medical Device Turnkey Plant Setup



Global Product Registration



Market Entry & Market Research Analysis



Business Transformation & Growth Advisory



Export Promotion



Medical Device Training Courses



ISO 13485:2016 Certification



Medical Device Registration



Indian Authorized Agent for Medical Devices



Standards & Market Readiness

ISO 13485:2016
Quality Management for Medical Devices

EU MDR
Market Access Support

US FDA
Regulatory Guidance

Global Markets
Registration & Compliance

Faster
Time-to-Market

Safer
Devices

www.ishasgmp.com | info@ishasgmp.com | +91 86675 89984 | +91 99764 91578

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



Specialized Services

Focused Support for Capability Building and Operational Excellence



Corporate Training

Customized GMP, regulatory and technical training programs to build strong, compliant teams.



Technology Transfer

End-to-end support for technology transfer, process validation and commercialization.



HVAC & Clean Room Solutions

Design, qualification and monitoring support for HVAC systems and clean room compliance as per global standards.



Accounting & Financial Services

Professional accounting, financial advisory and regulatory finance support for life sciences businesses.



Operational Excellence

Process optimization, quality systems and continuous improvement initiatives for higher efficiency and compliance.

Market Research & HR Consulting

Insights, People and Strategies for Sustainable Growth







- Market Access
- HEOR
- Pharmaceutical Market Survey Report
- B2B Market Research
- Training
- Recruitment
- Salary Offered
- KRA
- Organizational Restructuring
- Master Vendor Services
- Payroll Services
- Statutory Compliance

Let's Build Compliance Together

Your Trusted Partner for Expert Solutions, Stronger People and a Healthier, Compliant Tomorrow.



ISHA'S GMP
& TURNKEY CONSULTANCY
EUROPE LTD

From concept to compliance

Global Presence & Contact Information

GLOBAL
KNOWLEDGE
LOCAL IMPACT

From concept to compliance — your trusted GMP, regulatory and project consulting partner.



EUROPE OFFICE

ISHA'S GMP & TURNKEY CONSULTANCY EUROPE LTD

3 Graydon Green,
Newcastle, Dublin,
D22Y9V9, Ireland

Eircode: D22Y9V9

+353 89 989 1842

info@ishasgmpeu.ie

www.ishasgmpeu.ie



CORPORATE OFFICE – CHENNAI, INDIA

ISHA'S GMP CONSULTANCY PRIVATE LIMITED

Regency flat, Sri Hi-Tech construction, 55/66, 1st Cross Street, CRR Puram, LNT Colony, Manapakkam, Chennai - 600125

+91 86675 89984

info@ishasgmp.com

www.ishasgmp.com



REGIONAL / BRANCH OFFICE – VAPI, GUJARAT, INDIA

ISHA'S GMP CONSULTANCY PRIVATE LIMITED

338, Third Floor, Shoppers Gate,
Vapi-Chala Road, At & P.O. Vapi,
Dist. Valsad - 396191, Gujarat

+91 99764 91578

info@ishasgmp.com

www.ishasgmp.com

Pharma | Biotech | Medical Devices | Food | Cosmetics | Life Sciences