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

END-TO-END REGULATORY & QMS CONSULTING

MEDICAL DEVICE QMS SERVICES

From ISO 13485 implementation to global regulatory audit readiness.



INDIA | UNITED STATES | EUROPE | GLOBAL

ISO 13485 | US FDA QMSR | EU MDR / IVDR | INDIA MDR

Gap assessment • Quality Manual & SOPs • Risk management • Validation • Technical documentation • Mock audits

MEDICAL DEVICES | IVD DIAGNOSTICS | STERILE / NON-STERILE

ISHA'S GMP CONSULTANCY PVT. LTD. | INDIA
+91-8667589984
info@ishasgmp.com
www.ishasgmp.com

ISHA'S GMP & TURNKEY CONSULTANCY EUROPE LTD
+353 89 989 1842
info@ishasgmpeu.ie
www.ishasgmpeu.ie

02 / ISO 13485: END-TO-END QMS

A practical framework for organizations designing, manufacturing, importing, distributing or servicing regulated medical devices.

ONE CONTROLLED SYSTEM. MULTIPLE MARKET REQUIREMENTS.

Build a documented, risk-based management system aligned to ISO 13485:2016 and customized for each product and target regulatory jurisdiction.

01 Quality governance & leadership

Quality policy and objectives, organization, management review, training and document governance.

02 Design & development controls

Design planning, inputs and outputs, design reviews, verification, validation and controlled transfers.

03 Supplier and outsourced processes

Supplier qualification, purchasing controls, contract manufacturing and critical subcontractor oversight.

04 Production & process controls

Work instructions, controlled environments, device files, traceability, calibration and validated processes.

05 Risk management & product safety

ISO 14971 risk files; benefit-risk support, design risk linkage and product safety evidence.

06 Feedback & post-market performance

Complaints, vigilance, nonconformities, CAPA, internal audits and continual QMS effectiveness.

DESIGNED FOR EFFECTIVE IMPLEMENTATION

Process mapping • Defined responsibilities • Controlled records • Practical training • Measurable KPIs

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03 / INTERNATIONAL REGULATORY PATHWAYS

Market-specific QMS alignment and supporting compliance documents for the device and IVD product lifecycle.

INDIA / CDSCO

Medical Devices Rules, 2017; Fifth Schedule QMS for medical devices and IVDs. Risk classification, licence and audit preparation.

UNITED STATES / FDA

21 CFR Part 820 QMSR incorporating ISO 13485:2016; relevant labelling, UDI, reporting, corrections and removals.

EUROPE / IRELAND / MDR & IVDR

Regulation (EU) 2017/745 and 2017/746. Article 10 QMS, Annex I safety/performance, technical documentation and PMS.

UNITED KINGDOM / MHRA

UK Medical Devices Regulations 2002 (as amended); appropriate QMS, product and post-market obligations.

CANADA / HEALTH CANADA + MDSAP

Medical Devices Regulations, ISO 13485-based QMS, with MDSAP audit preparation where applicable.

GLOBAL / APAC • LATAM • MIDDLE EAST

Applicable requirements of TGA (Australia), PMDA/MHLW (Japan), ANVISA (Brazil), SFDA (Saudi Arabia) and other regulators.

REGULATORY CROSSWALK DELIVERABLE

Country / authority → device classification → applicable QMS clauses → SOPs and technical evidence → gap closure and mock-audit readiness.

04 / OUR SPECIALIST QMS CONSULTANCY SERVICES

Structured support from first assessment through implementation, certification audits and routine regulatory inspections.

01 QMS Gap Assessment & Roadmap

ISO 13485, India MDR, US QMSR and EU MDR/IVDR clause-by-clause compliance matrix.

02 QMS Documentation & eQMS

Quality Manual, SOPs, formats, document control, training, controlled electronic records.

03 ISO 13485 Certification Readiness

Process design, implementation coaching, internal audit and certification-body preparation.

04 Design Control / Lifecycle QMS

Design planning, inputs, outputs, review, verification, validation, transfer and change.

05 Risk Management & CAPA

ISO 14971, FMEA, nonconformities, investigations, RCA, CAPA effectiveness.

06 Supplier & Contract Manufacturer Quality

Supplier assessment, quality agreements, critical-material oversight and change notification.

07 Qualification and Process Validation

IQ/OQ/PQ, equipment, cleanroom, packaging, sterilization and special-process validation.

08 Technical Documentation Support

Device description, evidence matrix, GSPR checklist, technical file and medical device file.

09 Post-Market & Vigilance QMS

Complaints, traceability, FSCA/recall, PMS/PMCF or PMPF as applicable.

10 Audit & Inspection Readiness

Internal audits, mock FDA/CDSCO/notified-body audits, observations and CAPA response.

CONSULTANCY SUPPORT IS TAILORED TO PRODUCT CLASS, MANUFACTURING ACTIVITY & MARKETS.

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05 / TECHNICAL QUALITY & VALIDATION EXPERTISE

Additional medical device engineering standards and validation activities selected according to device design and intended use.



RISK + DESIGN ENGINEERING

- ISO 14971 and ISO/TR 24971 risk management
- IEC 62304 software lifecycle; IEC 62366-1 usability
- IEC 60601 family where electrical safety applies
- ISO 10993 biological evaluation as applicable

VALIDATION + STERILITY ASSURANCE

- Process and packaging validation, IQ/OQ/PQ
- ISO 11607 sterile barrier / packaging
- ISO 11135, ISO 11137, ISO 17665, as relevant
- ISO 14644 cleanroom and contamination controls

PRODUCT INFORMATION + EVIDENCE

- ISO 20417 information supplied by manufacturer
- ISO 15223-1 medical device symbols
- Clinical evaluation, investigation or performance data
- Technical file structure, verification and traceability

LIFECYCLE + SOFTWARE OVERSIGHT

- Change control, cybersecurity and software releases
- Critical supplier qualification and traceability
- Complaint trending and post-market controls
- Risk-file updates and CAPA effectiveness checks

Standards are applied only when relevant to the product, intended use and market rules.

06 / QMS DOCUMENTATION & DELIVERABLES

A sample project deliverable register, adapted to the manufacturer's existing processes, product complexity and regulatory scope.

01 GOVERNANCE & DOCUMENT CONTROL

- Quality Manual, policy, objectives and process map
- Master SOP index and controlled templates
- Organization chart, responsibilities, training matrix
- Management review, internal audits and QMS KPIs

02 DESIGN, RISK & PRODUCT FILES

- Medical Device File / product specifications
- Design plan, inputs, outputs and traceability matrix
- Verification and validation evidence index
- Risk management plan, report and risk register

03 MANUFACTURING & SUPPLY CHAIN

- Supplier assessment and approved vendor controls
- Work instructions, production and release records
- Equipment qualification, calibration and maintenance
- Process/packaging/sterilization validations as applicable

04 POST-MARKET & AUDIT READINESS

- Complaint handling, vigilance and recall workflows
- PMS / PMCF / PMPF documentation as applicable
- Change control, deviations, RCA and CAPA register
- Mock audit, gap closure and evidence submission tracker

DELIVERABLE FORMAT

Controlled MS Word / PDF procedures • Excel registers • Forms • Training • Audit evidence

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07 / FROM GAPS TO GLOBAL AUDIT CONFIDENCE

Our engagement approach helps convert regulatory requirements into implemented processes and verifiable records.

01

SCOPE

Product, target markets, risk class and site activities.

02

ASSESS

Clause-mapped QMS and technical documentation gap audit.

03

IMPLEMENT

SOPs, risk files, validation, CAPA, training and records.

04

VERIFY

Mock audits, objective evidence review and closure support.

PRODUCTS & TECHNOLOGIES WE SUPPORT

- Sterile & single-use devices
- IVD diagnostics and reagents
- Software as a medical device
- Orthopaedic & implantable devices
- Surgical instruments & equipment
- OEM / contract manufacturing

WHY WORK WITH ISHA'S GMP?

Integrated services

QMS, regulatory, audit, risk and validation workstreams.

Practical implementation

Documented processes embedded into routine operations.

India + Europe presence

Coordinated support across domestic and export markets.

READY TO STRENGTHEN YOUR MEDICAL DEVICE QMS?

Request a regulatory QMS gap assessment and tailored consultancy proposal.

References: ISO 13485; FDA 21 CFR 820 QMSR; EU MDR / IVDR; India MDR 2017 Fifth Schedule.

Applicability and approvals depend on product, market, classification and regulator. Updated Nov 2026.

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& TURNKEY CONSULTANCY
EUROPE LTD

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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

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