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

STRATEGY | SUBMISSIONS | MARKET ACCESS

GLOBAL REGULATORY AFFAIRS SERVICES

From regulatory strategy to product approvals, market readiness and lifecycle compliance.



PHARMA | MEDICAL DEVICES | BIOLOGICS | GLOBAL

REGULATORY STRATEGY • DOSSIERS • LICENSING

Global registration pathways • CTD/eCTD & technical files • Regulatory liaison • GMP and QMS readiness • Variations • Post-market compliance

INDIA | EUROPE / UK | USA / CANADA | ASIA / GLOBAL

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 / GLOBAL REGISTRATION AND MARKET ACCESS

Clear, product-specific regulatory pathways built around target countries, product risk, evidence requirements and commercial timelines.

ONE GLOBAL PLAN. COUNTRY-SPECIFIC EXECUTION.

We develop regulatory roadmaps, identify applicable authorities and submission routes, coordinate required local representation, and prepare traceable evidence packages.

INDIA / CDSCO • STATE AUTHORITIES

Drug and medical device licences; imports, clinical trial and new drug pathways; cosmetics and other product-specific approvals.

UNITED STATES / US FDA

Drug and biologic pathways and medical device 510(k), De Novo or PMA, as applicable; registration, listing and lifecycle reporting.

EUROPE / EU • IRELAND

Marketing authorisation support for medicinal products; EU MDR/IVDR conformity assessment, technical files and EUDAMED.

UNITED KINGDOM / MHRA

Medicines and devices pathways; product registration and authorisation support, safety reporting and local requirements.

ASIA-PACIFIC / JAPAN • AUSTRALIA • ASEAN

PMDA/MHLW, TGA, HSA, NPRA and other applicable country-specific product registration and quality documentation.

MIDDLE EAST • AFRICA • LATAM

SFDA, ANVISA, SAHPRA, NAFDAC and other regulators; market-specific dossier, labelling and partner coordination.

OUTPUT: REGULATORY MARKET-ENTRY MATRIX

Authority • pathway • evidence • local agent • milestones • cost drivers • change triggers

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03 / PHARMACEUTICALS AND BIOLOGICS

Regulatory affairs support for APIs, finished dosage forms, sterile products, biologics, vaccines and advanced therapies.

GLOBAL DOSSIER & APPROVAL SUPPORT

From drug development and product registration to marketing-authorisation maintenance, our specialists help translate quality, safety and efficacy evidence into a structured regulatory strategy.



CTD / eCTD / ACTD Dossiers

Module preparation, content gap assessment, publishing coordination and region-specific dossier adaptations.

API & Drug Substance Submissions

Drug Master File (DMF) and Active Substance Master File (ASMF) support, technical data and change management.

Product Registration & Variation

New drug / generic pathways, regulatory queries, renewals, variations and post-approval change assessments.

Clinical & Development RA

IND / CTA pathway support, BA/BE and clinical documentation, scientific advice meeting preparation.

CMC & Quality Regulatory Review

Process descriptions, controls, specifications, validation, stability, comparability and quality sections.

Labelling, Safety & Lifecycle

SmPC / PIL / labelling coordination, packaging reviews, pharmacovigilance interface and regulatory intelligence.

Relevant frameworks: CDSCO / NDCT Rules • US FDA • EMA / EU • ICH • WHO

04 / MEDICAL DEVICES AND IVDS

Complete support for classification, conformity assessment, technical documentation, submissions and post-market obligations.

FROM DEVICE CLASSIFICATION TO MARKET AUTHORISATION

Product-specific support across India MDR 2017, ISO 13485, US FDA QMSR, EU MDR/IVDR, UK requirements and selected global device markets.

01 Device Classification & Pathway

Intended use, classification rationale, regulatory strategy, GMDN/EMDN and market-specific requirements.

02 India CDSCO Licensing

Manufacturing / import applications, MD forms, site and device master-file support and query-response coordination.

03 EU MDR / IVDR & CE Marking

Annex II/III technical files, GSPR checklists, notified-body documentation and EUDAMED assistance.

04 US FDA Market Entry

510(k), De Novo or PMA strategy as applicable; pre-submission support, device listing and UDI requirements.

05 Clinical / Performance Evidence

Clinical evaluation, CER, PMCF; IVD performance evaluation, scientific validity and PMPF where applicable.

06 QMS, Risk and Post-Market

ISO 13485, ISO 14971, design control, PMS, vigilance, FSCA, CAPA and US QMSR audit readiness.

Device pathways depend on intended use, risk class, evidence and destination market.

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05 / COSMETICS, AYUSH, FOOD AND NUTRACEUTICALS

Targeted regulatory support across health and consumer product categories with distinct national legal frameworks.



COSMETICS & PERSONAL CARE

- India Cosmetics Rules, 2020 registration / licensing
- Ingredient, claims, safety and labelling checks
- EU cosmetics PIF / CPNP and Responsible Person coordination
- Country-specific import / product notification support

AYUSH & HERBAL MEDICINES

- Product categorisation and applicable AYUSH frameworks
- State licensing and GMP documentation assistance
- Herbal specifications, evidence and label reviews
- Export market route and document mapping

FOOD & NUTRACEUTICALS

- FSSAI licensing / food category assessments
- Health supplements / nutraceutical labelling compliance
- Ingredient, additives and claim-gap review
- Import / export and market-specific registration support

CROSS-SECTOR MARKET SUPPORT

- Product classification and claims analysis
- Compliance matrix and document gap closure
- Notarisation, legalization and certificate support
- Partner / importer and local representative coordination

Classification, licensing and claim requirements vary by product and jurisdiction.

06 / REGULATORY DOSSIERS AND DELIVERABLES

A controlled submission package and evidence trail, adapted to the product, authority and route-to-market.

01 STRATEGY & FEASIBILITY

- Product categorisation and regulatory pathway report
- Market-entry and submission requirement matrix
- Regulatory gap assessment and action tracker
- Submission programme, dependencies and milestones

02 CORE REGULATORY DOCUMENTATION

- CTD / eCTD / ACTD and CMC content support
- DMF / ASMF / product or device master files
- Device technical documentation and GSPR matrix
- Labelling, IFU, declarations and certificates

03 AUTHORITIES & SUBMISSIONS

- Application forms, annexures and evidence index
- Country-specific portal submission coordination
- Authority questions and deficiency-response matrix
- Local representative / agent / NB liaison support

04 POST-APPROVAL MAINTENANCE

- Variations, renewals and regulatory change assessments
- Product registrations and licence tracking register
- Vigilance / PMS and safety reporting coordination
- Lifecycle updates, recalls and inspection support

WORKING FORMAT

Submission-ready dossiers • Evidence registers • Portal annexures • Query responses

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07 / A PRACTICAL ROUTE TO REGULATORY SUCCESS

Coordinated consultancy engagements that turn regulatory requirements into clear actions, controlled submissions and ongoing compliance.

01

DISCOVER

Product, claims, countries, classification and development stage.

02

PLAN

Pathway, dossier gap, responsibility matrix and milestones.

03

PREPARE

Compile evidence, review content and submit through proper route.

04

MAINTAIN

Address queries, manage changes, renewals and safety obligations.

PRODUCT CATEGORIES WE SUPPORT

- APIs and finished pharmaceuticals
- Biologics, vaccines and biosimilars
- IVD reagents and medical devices
- Sterile and implantable medical devices
- Cosmetics, personal care and herbals
- Food supplements and nutraceuticals

WHY ISHA'S GMP?

Integrated expertise

Regulatory, QMS, GMP, audit and validation services.

Global perspective

Support for India, EU/Ireland, US and export markets.

Lifecycle partnership

Planning through post-approval compliance.

READY TO ENTER YOUR NEXT REGULATED MARKET?

Request a market-entry assessment and customised regulatory affairs proposal.

References: CDSCO MDR 2017 and NDCT 2019; FDA QMSR & device pathways; EU MDR/IVDR / EUDAMED; ICH CTD. Updated Nov 2026.

Regulatory approval, timelines and eligibility remain subject to the competent authority and product evidence.

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& TURNKEY CONSULTANCY
EUROPE LTD

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LOCAL IMPACT

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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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