ISHA'S GMP CONSULTANCY PVT. LTD.

— Ensuring Global GMP Compliance

A Global Consulting Partner for GMP, Regulatory Compliance & Turnkey Project Solutions



TURNKEY PROJECT CONSULTANCY

Concept to Commissioning of GMP Compliant Manufacturing Facilities

Pharmaceuticals | Biotechnology | Medical Devices
Nutraceuticals | Food & Beverages | Cosmetics



Our Offerings

- **Facility Design & Turnkey Projects** (Concept to Commissioning)
- **GMP & QMS Implementation** (WHO-GMP / Schedule M / ISO)
- **Regulatory & Licensing Support** (Drugs, Medical Devices, Cosmetics, Food)
- **Validation & Qualification** (DQ / IQ / OQ / PQ)
- **GMP Audits & Gap Assessment** (CAPA, Readiness & Mock Audit)
- **Training & Capability Building** (GMP, GDP, GDocP, QMS, Validation)

Turnkey Project Scope – End to End Solutions

Feasibility Study » Site Master Planning » GMP Facility Design & Engineering » Cleanroom & HVAC » MEP & Utilities (BMS, EMS) » Equipment Selection & Procurement » Commissioning & Validation (DQ/IQ/OQ/PQ) » QMS & Regulatory Readiness

Our Business Services

- ✔ Concept, Basic & Detailed Design
- ✔ URS, Vendor Evaluation & Procurement Support
- ✔ Installation, Commissioning & Handover
- ✔ Quality Management Systems (QMS)
- ✔ Regulatory Filing & Market Access
- ✔ GMP Audits, Compliance & Remediation (CAPA)
- ✔ GxP Training & Workforce Competency

Industry Sectors We Support

- Pharmaceuticals (API & Formulations)
- Biotechnology & Biologics
- Medical Devices & IVD
- Cosmetics & Personal Care
- Nutraceuticals & Dietary Supplements
- Food & Food Ingredients
- Ayush & Herbal Products
- Testing & R&D Laboratories

Global Regulatory Alignment – Project Design, Compliance & Market Access Support

- **USFDA** (United States)
- **MHRA** (Medicines & Healthcare Products Regulatory Agency, United Kingdom)
- **TGA** (Therapeutic Goods Administration, Australia)
- **WHO-GMP** (World Health Organization Good Manufacturing Practice)
- **PIC/S** (Pharmaceutical Inspection Co-operation Scheme)

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ISHA'S GMP & TURNKEY CONSULTANCY — EUROPE LTD
From concept to compliance

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