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

GLOBAL REGULATORY COMPLIANCE • END-TO-END QMS

QUALITY MANAGEMENT SYSTEMS

One integrated approach to pharmaceutical, medical device, laboratory, cosmetic, AYUSH, biotechnology and food quality systems.

INDIA | USA / EU / UK | APAC | MIDDLE EAST | GLOBAL

QMS • GMP • ISO • ICH • GxP

Gap assessment / Documentation / Implementation / Audit readiness

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02 / CORE INTERNATIONAL QMS FRAMEWORKS

Selected standards, guidelines and legally applicable manufacturing quality regulations.

ISO 9001:2026
Enterprise quality management; current ISO edition

ICH Q10
Pharmaceutical Quality System (PQS)

ICH Q9(R1)
Quality Risk Management (QRM)

ICH Q7
API Good Manufacturing Practice

ICH Q8(R2) / Q12
Quality by Design and lifecycle management

WHO GMP
Pharmaceutical manufacturing quality guidance

PIC/S PE 009
Harmonized pharmaceutical GMP guide

EU GMP / EudraLex Vol. 4
EU medicinal product GMP and annexes

US FDA 21 CFR 210 / 211
US drug current GMP requirements

ISO 13485:2016
Medical device Quality Management System

US FDA 21 CFR 820 QMSR
US medical device QMS regulation

ISO 14971:2019
Medical device risk management

ISO/IEC 17025:2017
Testing / calibration laboratory competence

ISO 15189:2022
Medical laboratory quality and competence

ISO 22716:2007
Cosmetic Good Manufacturing Practices

ISO 22000:2018
Food Safety Management System

FSSC 22000 / BRCGS
Food safety certification schemes

HACCP / Codex
Food hazard analysis and critical controls

ICH E6(R3)
Good Clinical Practice for trials

GDP / GVP / GLP
Distribution / pharmacovigilance / lab GxP

REGULATORY NOTE

Standards and guidance do not replace a country-specific manufacturing licence.

03 / INDIA: REGULATORY QMS REQUIREMENTS

Major Indian authorities and frameworks for regulated manufacturing and laboratories.

CDSCO / State Drug Authorities

Pharmaceuticals & formulations

Revised Schedule M: Pharmaceutical Quality System and GMP

Ministry of Ayush / State Authorities

Homoeopathic medicines

Schedule M-I GMP

CDSCO / State Drug Authorities

APIs / bulk drugs

Schedule M and relevant API GMP / ICH Q7 controls

FSSAI / State Food Safety Authorities

Food / nutraceuticals / supplements

FSMS; Schedule 4 GMP / GHP and HACCP-based controls

CDSCO / State Licensing Authorities

Medical devices and IVDs

Medical Devices Rules, 2017 - Fifth Schedule QMS

NABL

Analytical / calibration laboratories

ISO/IEC 17025:2017 accreditation

CDSCO / State Licensing Authorities

Cosmetics & personal care

Cosmetics Rules, 2020 - Seventh Schedule GMP

NABL

Medical / diagnostic laboratories

ISO 15189:2022 accreditation

Ministry of Ayush / State Authorities

Ayurveda, Siddha, Unani, Sowa-Rigpa

Applicable drug rules, including Schedule T GMP

BIS / Other competent authorities

Sector-specific products

Applicable Indian Standards and statutory product requirements

INDIA COMPLIANCE PRIORITY

Map each site, product category and licence to its exact statutory QMS clauses.

04 / GLOBAL AUTHORITIES: AMERICAS & EUROPE

Market-entry compliance is governed by applicable national laws and product classification.

NORTH & SOUTH AMERICA

- **USA | US FDA**
  21 CFR 210 / 211 (drugs); Part 820 QMSR (devices)
- **Canada | Health Canada**
  Food and Drug Regulations, GMP; device QMS / MDSAP
- **Brazil | ANVISA**
  National medicines GMP and device GMP resolutions
- **Mexico | COFEPRIS**
  NOM-059 (medicines); NOM-241 (medical devices)
- **Argentina | ANMAT**
  Applicable Argentine GMP / device rules

EUROPE & UNITED KINGDOM

- **European Union | EMA / EC / NCAs**
  EU GMP Vol. 4; MDR 2017/745; IVDR 2017/746
- **United Kingdom | MHRA**
  UK medicinal GMP and applicable device QMS
- **Ireland | HPRA**
  EU medicines GMP; MDR and IVDR
- **Germany | BfArM / PEI / Länder**
  EU GMP and applicable EU device regulations
- **France | ANSM**
  EU GMP; EU MDR and IVDR
- **Italy | AIFA**
  EU GMP and relevant national requirements
- **Spain | AEMPS**
  EU GMP; EU MDR and IVDR
- **Switzerland | Swissmedic**
  Swiss therapeutic products law and GMP

EU GMP and FDA drug cGMP are not interchangeable with device regulations. Compliance must be mapped by product and licensed activity.

05 / GLOBAL AUTHORITIES: ASIA-PACIFIC, MEA

Illustrative principal authorities; confirm country-specific licensing and registration requirements.

ASIA-PACIFIC

- **Australia | TGA**
  PIC/S-aligned medicinal GMP; device QMS
- **New Zealand | Medsafe**
  National medicines GMP and device controls
- **Japan | MHLW / PMDA**
  GMP / GQP; medical device QMS ordinance
- **China | NMPA**
  Drug GMP; Medical Device GMP
- **South Korea | MFDS**
  Korean GMP / KGMP
- **Singapore | HSA**
  PIC/S GMP; ISO 13485 / GDPMDS
- **Malaysia | NPRA / MDA**
  Medicines GMP; device QMS
- **Thailand | Thai FDA**
  PIC/S-oriented pharmaceutical GMP
- **Indonesia | BPOM**
  CPOB medicines GMP
- **Vietnam | Ministry of Health**
  Applicable GMP rules
- **Taiwan | TFDA**
  PIC/S GMP; medical device QMS

MIDDLE EAST & AFRICA

- **Saudi Arabia | SFDA**
  Medicines GMP; medical device QMS
- **United Arab Emirates | EDE**
  National pharmaceuticals / devices rules
- **Oman | Ministry of Health**
  National GMP, licensing and quality controls
- **South Africa | SAHPRA**
  National medicines GMP and device rules
- **Nigeria | NAFDAC**
  Applicable medicine and device regulations
- **Kenya | PPB**
  Pharmaceutical GMP and device requirements
- **Tanzania | TMDA**
  Medicines GMP and device requirements

GLOBAL READINESS

Country-specific gap assessment • Local documentation • Inspection support

06 / QMS BY INDUSTRY & PRODUCT SEGMENT

Select a foundation based on the product, route of administration, manufacturing activity and target market.

01 API & BULK DRUGS

ICH Q7 • Schedule M • ICH Q9 / Q10

02 NON-STERILE PHARMA

Schedule M • WHO GMP • EU GMP • 21 CFR 211

03 STERILE INJECTABLES / IV FLUIDS

GMP plus sterility assurance and contamination control

04 BIOTECH / BIOLOGICS / VACCINES

GMP • ICH Q5 series • biologics-specific controls

05 MEDICAL DEVICES

ISO 13485 • ISO 14971 • MDR / QMSR / Fifth Schedule

06 IN-VITRO DIAGNOSTICS

ISO 13485 • IVDR / local IVD regulations

07 COSMETICS & PERSONAL CARE

ISO 22716 • national cosmetics GMP

08 AYUSH / HERBAL PRODUCTS

Schedule T / M-I • relevant WHO herbal GMP guidance

09 NUTRACEUTICALS & SUPPLEMENTS

FSSAI FSMS • ISO 22000 • HACCP

10 FOOD & BEVERAGES

ISO 22000 • HACCP • FSSC 22000 • BRCGS

11 TESTING / CALIBRATION LABS

ISO/IEC 17025 • applicable GLP / lab controls

12 CLINICAL / DIAGNOSTIC LABS

ISO 15189 • GCP / national requirements where relevant

07 / QMS DOCUMENTATION ARCHITECTURE

One scalable system of procedures, controlled records, technical evidence and management oversight.

01 | GOVERNANCE & SYSTEM CONTROL

- Quality policy, objectives and Quality Manual
- Document control, record retention and GDocP
- Management review and internal auditing
- Personnel competency and training
- Quality risk management and data integrity

02 | QUALITY EVENTS & LIFECYCLE

- Deviations, investigations and nonconformities
- CAPA, effectiveness checks and change control
- Complaints, recalls and vigilance
- Annual product quality review and trending
- Continual improvement and management KPIs

03 | OPERATIONS & VALIDATION

- Supplier qualification and incoming materials
- Production / batch records and in-process controls
- DQ, IQ, OQ, PQ, commissioning and validation
- Cleaning, maintenance and calibration controls
- Storage, traceability and distribution

04 | LABORATORY & TECHNICAL QUALITY

- Sampling, specifications and test methods
- OOS / OOT, reference standards and lab events
- Method validation and stability programmes
- Electronic data, audit trails and access controls
- Sterile, device or food controls as applicable

2026 QMS HIGHLIGHTS

ISO 9001:2026 published 16 Sep 2026 • FDA medical device QMSR effective 2 Feb 2026

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