



Corporate Profile & Consultancy Services

Medical Devices • IVDs • Regulatory Affairs • Quality Management

Presented by Dr. Lalit Raj Singh

Founder & Principal Consultant

fiducielife.com | consult@fiducielife.com

Fiducie Life at a glance

A consultancy partner for quality, regulatory compliance and market access.



Enabling Global Quality Compliance and Regulatory Excellence

Fiducie Life OPC Pvt. Ltd. supports healthcare and life-science organizations in translating regulatory requirements into practical quality systems, compliant documentation and market-entry plans.

Regulatory

Strategy, pathways, submissions and lifecycle support.

Quality

QMS design, implementation, audits and remediation.

Market access

Product commercialisation and market-entry planning.

People

Training, capability building and team development.

Core expertise

Integrated support across product, process, people and compliance.

Regulatory affairs

Regulatory strategy and pathway assessment
Submission planning and dossier review
Change control and lifecycle obligations

Quality management

QMS establishment and implementation
ISO / GMP / GDP readiness
Internal audits, CAPA and remediation

Technical documentation

Technical file and design documentation review
Risk management and GSPR support
Evidence and traceability alignment

Advisory & growth

Market access and product commercialisation
Partner and team capability development
Training and strategic advisory

Industries and product categories

Support tailored to the product's regulatory pathway and lifecycle.

Medical devices

General medical devices, equipment and accessories

IVDs

Rapid / POCT, self-testing, ELISA, CLIA and clinical reagents

Pharmaceuticals

Pharmaceutical and selected life-science products

Herbal healthcare

Traditional herbal medicinal products and related categories

Biotechnology

Biotech and health-related product development

Cosmeceuticals

Cosmetic and personal-care products with compliance needs

Medical devices & IVD regulatory affairs

Pathway planning and submission readiness across selected markets.



How we can support

Product classification and regulatory pathway assessment

Medical devices & IVD regulatory affairs

Pathway planning and submission readiness across selected markets.

How we can support

- Product classification and regulatory pathway assessment
- Registration / submission planning and documentation review
- EU MDR / IVDR technical documentation and GSPR alignment
- CDSCO India regulatory support and application readiness
- US FDA pathway and quality-system readiness advisory
- Post-market obligations, change control and lifecycle support

Selected regulatory frameworks

India — CDSCO / Medical Devices Rules

European Union — MDR 2017/745 & IVDR 2017/746

United States — FDA requirements

Canada — Health Canada

Brazil — ANVISA

Japan — MHLW / PMDA

Quality systems & compliance

Build and strengthen systems that support consistent execution and audit readiness.

01 Establish

QMS framework, process mapping, roles and documentation



02 Implement

Procedures, records, training and operational deployment



03 Verify

Internal audits, supplier controls and compliance checks



04 Improve

CAPA, root-cause analysis, remediation and effectiveness

Applicable systems may include ISO 13485, ISO 9001, ISO 14971, GMP and GDP—based on product scope and client needs.

Pharma, herbal & life-science support

Practical regulatory and quality support adapted to product type and market.

Traditional herbal products

Regulatory pathway assessment
Dossier and evidence review
Manufacturing / quality readiness

Pharma & life sciences

GMP / GDP readiness support
Quality documentation review
Compliance gap assessment

Animal healthcare

India regulatory approval planning
Audit preparation and readiness
Documentation and compliance support

Scope is confirmed case by case against product classification, intended market and applicable requirements.

Global regulatory & market access

Coordinate regulatory requirements with product and commercialisation objectives.

A structured market-entry lens

- Clarify target markets and product claims
- Map classification, registration and evidence needs
- Identify local representation / partner considerations
- Align quality and technical documentation for submissions
- Plan launch dependencies and post-market responsibilities

Selected markets / frameworks

India	CDSCO
European Union	MDR / IVDR
United States	FDA
Canada	Health Canada
Brazil	ANVISA
Japan	MHLW / PMDA

Strategic advisory & product commercialisation

Bring regulatory, quality and business considerations into one decision process.

Strategic advisory

Product and portfolio planning
Regulatory risk / readiness reviews
Decision support for leadership

Market access

Market-entry sequencing
Partner / channel considerations
Commercialisation readiness

Team development

Training and capability building
Role / process clarity
Mentoring and knowledge transfer

Engagements can be scoped as focused projects, advisory retainers, training assignments or collaborative consulting work.

Our consulting engagement approach

A clear, collaborative sequence—from understanding the need to sustaining improvements.



Scope, timelines and deliverables are agreed with each client before work begins.

Ways to collaborate

Flexible engagement models for organizations and consulting partners.

Project-based

Defined scope, milestones and deliverables

Part-time / retainer

Ongoing expert support aligned to business priorities

Joint consultancy

Complementary expertise and shared delivery responsibility

Training & workshops

Focused capability development for teams

Audit readiness

Gap assessment, preparation and follow-up actions

Expert advisory

Focused subject-matter input for key decisions

Engagements are tailored to the client's requirements, product scope, timelines and working model.



**Let's build compliant, market-ready
healthcare products.**

Dr. Lalit Raj Singh

Founder & Principal Consultant

[Lalit Raj Singh | LinkedIn](#)

Fiducie Life OPC Pvt. Ltd.

Website: fiducielife.com

Email: consult@fiducielife.com

India: +91 8077994787 | +91 7460999111