



REGULATORY TRAINING

MEDICAL DEVICE REGULATORY TRAINING ON VARIOUS TOPICS.

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INTRODUCTION

Operon Strategist is a medical device regulatory consulting company which provides regulatory advisory & guidance to various manufacturers in the healthcare industry to ensure the strategic development of these manufacturers. We serve our clients by providing turnkey services, system implementation, training, licensing, regulatory approvals and certifications. We provide a complete turnkey solution to manufacturers looking to set up a world-class manufacturing unit. We also provide customized packages as per the requirements of the client.

Our global presence caters to clients from around the globe & includes small start-ups to world's renowned medical device manufacturers. As a trusted partner to our clients, we strive to provide services within budget, agreed on timeline & to the highest quality standards in order to exceed expectations.

Day -1

Introduction of Medical Device, Definition, Classification and ISO 13485

- I. **Introduction to Medical Devices: Definition**
- II. **Classification of Medical Devices.Europe & USA**
- III. **Quality Management System (ISO 13485)**
 - a. Scope
 - b. Normative references
 - c. Terms and definitions
 - d. Quality management system
 - i. General requirements
 - ii. Documentation requirements
 - iii. Management responsibility
 - iv. Management commitment
 - v. Customer focus
 - e. Quality policy
 - f. Planning
 - g. Responsibility, authority and communication
 - h. Management review Resource management
 - i. Provision of resources
 - j. Human resources
 - k. Infrastructure
 - l. Work environment and contamination control

- m. Product realization
- n. Planning of product realization
- o. Customer-related processes
- p. Design and development
- q. Purchasing
- r. Production and service provision
- s. Control of monitoring and measuring equipment
- t. Measurement, analysis and improvement
- u. General
 - i. Monitoring and measurement
 - ii. Control of nonconforming product
 - iii. Analysis of data
 - iv. Improvement

Day -2

Design & Development Documentation

- I. Design Planning
- II. Design Input
- III. Design Output
- IV. Design Review
- V. Design Verification
- VI. Design Validation
- VII. Design Changes
- VIII. Design Transfer
- IX. Design History File
- X. Design Transfer

Day -3

Technical File Documentation

- I. General Administrative Information
 - a. Applicable Legislation
 - b. Device identification
 - c. Device Classification & Classification Rationale
 - d. Accessories All variations /configurations
- II. Device description
 - a. General description of the device. Trade name and general description including intended purpose
 - b. Mode of action (MOA).
 - c. Justification as to why the product is a medical device.
 - d. Basic UDI-DI.
 - e. Any novel features.
 - f. Description of raw materials incorporated into critical functional elements and those making direct/indirect contact with the human body.
 - g. Technical specifications such as features, dimensions, and performance attribute that are made available to the user. Reference to previous generations of the device.
 - h. Intended Use
 - i. "Intended patient population and conditions to be treated."
- III. Declaration of Conformity (DOC)
 - a. List Applied Standards Applied in Full or in Part
 - b. Table of applicable standards.
- IV. General Safety & Performance Requirements (GSPRs)
 - a. Manufacturing Process & Subcontractors
 - b. ISO certificates/audit reports
 - c. Detailed manufacturing process maps/flows.
 - d. Design Verification & Validation
 - e. Specifications. Protocols
 - f. Test reports.
 - g. Verification and validation traceability (with appropriate linkage to GSPRs).
 - h. Stability studies on products that are representative of what is being supplied to the market.
- V. Risk Management File (RMF) (typically - ISO 14971)
 - a. Risk Management Plan (RMP).
 - b. Risk Analysis (Hazard Analysis/FMEA or another method).
 - c. Risk Management Report (RMR)
 - d. Clinical Evaluation (typically MEDDEV 2.7.1)

WHY OPERON STRATEGIST ?

We being experienced in Layout Designing, Validations, Machines procurements, Product designs and technology, Medical devices QA and regulatory works for more than 80 Medical Devices Manufacturers. With setting up manufacturing for more than 30 clients in India and rest of world. Operon possesses the special niche to guide for Medical Devices Manufacturing in India and any part of the world.

We have a dedicated Project Management Team that actively plans and reports every fortnight to the management of the project via adequate data of work done. We always work to complete project before/in timelines.

Our expertise with regulatory affairs are to assist for below:

- Turnkey Project for Medical Devices Manufacturing Units
- CE Marking (Certification required for Selling in European Countries)
- USFDA 510 k (For Selling the product in USA)
- MDSAP, ISO 13485 & 21 CFR 820 documentation training and Implementation.
- Indian FDA / CDSCO Licensing and approvals.
- Multiple countries export registration.

Some of the clients that we have worked for:

- Dr. Reddy's Laboratory, India.
- Australian Orthopaedics, Australia / India.
- PSS Urology, USA.
- Ace Medical, India.
- PCC, Saudi Arabia.
- Multicare Surgical Pvt Ltd, Nepal
- Nanda Dental, India.
- Dr. Sabarwal Wound Care, India
- Harsoria Healthcare, India



THANK YOU FOR YOUR ATTENTION

Operon Strategist, Pune(India)

Telephone: +91-93702 83428

Email: enquiry@operonstrategist.com

Address: MSR Capital, Office no. 10, 3rd floor, Pimpri Colony, Pimpri, PUNE

Adwwaa AlWatania for Pharmaceutical Consultancy (AAPC), Muscat (Oman)

Telephone: +96896663030

Email: Info@aapcco.com

Website : www.aapcco.com

Address: P.O.Box : 406, Postal Code: 124 Rusail, Sultanate of Oman