Medical Device Regulatory Lifecycle Management Training Course

4 – 8 January 2027
Seoul

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Ref: 1266_193587 **Date:** 4 – 8 January 2027 **Location:** Seoul **Fees:** 10000 Euro

Overview

Medical Device Regulatory Lifecycle Management Training Course is a one-week course for regulatory, quality, clinical, engineering, manufacturing, surveillance, and lifecycle professionals who need a Device Regulatory Lifecycle File. The course connects medical device regulatory lifecycle strategy, classification, design controls, clinical evidence, market authorization, manufacturing change, traceability, vigilance, and post-market surveillance. Participants coordinate evidence and decisions from intended use through controlled retirement. Agile Leaders Training Center treats device lifecycle governance as one traceable operating system.

Who Should Attend

- Functions responsible for device regulatory strategy and submissions
- Teams responsible for quality systems and design controls
- Functions responsible for clinical evidence and benefit-risk evaluation
- Teams responsible for engineering, manufacturing, and supplier changes
- Functions responsible for vigilance and post-market surveillance
- Professionals responsible for product lifecycle and market continuity

The course assumes participants already support regulated devices, quality records, clinical evidence, engineering changes, or post-market processes and leaves out introductory product development.

Departments and Industries

The course supports departments and industries that maintain medical device regulatory lifecycle evidence and decisions.

- Regulatory affairs, quality assurance, and compliance functions
- Clinical affairs, safety, and post-market surveillance teams
- Research, design engineering, manufacturing, and supplier quality functions
- Medical device, diagnostic, digital health, and healthcare technology companies
- Importers, distributors, service organizations, and contract manufacturers

Learning Objectives

By the end of this course, participants will be able to:

- Analyze intended use, classification, and regulatory pathways
- Build lifecycle requirement and evidence traceability
- Apply design, risk, clinical, and quality interfaces
- Evaluate submission and market-readiness evidence
- Diagnose change, vigilance, and surveillance gaps
- Prioritize corrective action and retirement decisions

Course Agenda

Day 1: Classification and Regulatory Strategy

- Device Intended-Use and Claims Definition Canvas
- Risk-Based Device Classification Decision Tree
- Regulatory Pathway and Market Sequence Map
- Lifecycle Regulatory Requirement Register
- Regulatory Strategy Decision Record

Day 2: Design, Risk and Clinical Evidence

- ISO 13485:2016 Quality System Interface Map
- Design-Control and Regulatory Traceability Matrix
- Device Risk and Benefit-Risk Evidence Linkage
- Clinical Evidence Planning Framework
- Verification and Validation Evidence Index

Day 3: Authorization and Production Readiness

- Premarket Submission Readiness Checklist
- Labeling and Claims Consistency Review
- Unique Device Identification and Traceability Map
- Supplier and Manufacturing Control Evidence Pack
- Market Authorization Commitment Register

Day 4: Change and Post-Market Control

- Device Change Regulatory Impact Assessment
- Vigilance and Incident Escalation Workflow
- Post-Market Surveillance Plan and Signal Log
- Corrective and Preventive Action Decision Method
- Lifecycle Continuity and Controlled Retirement Plan

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Day 5: Regulatory Lifecycle Practice

- Exercise: Classification and Pathway Decision Review
- Exercise: Design and Clinical Evidence Traceability Test
- Exercise: Manufacturing Change Impact Assessment
- Exercise: Post-Market Signal and Corrective Action Decision
- Capstone Exercise: Device Regulatory Lifecycle File

Practical Exercises

The course uses suggested activities that connect lifecycle decisions to evidence, ownership, and regulatory action.

- Suggested activity: classify a diagnostic device and document the pathway rationale.
- Suggested activity: test design and clinical evidence traceability for a connected device.
- Suggested activity: assess a supplier change for a reusable device.
- Suggested activity: evaluate a post-market signal and controlled retirement decision.

FAQs

Who should attend the Medical Device Regulatory Lifecycle Management Training Course?

The course suits professionals responsible for regulatory affairs, quality, clinical evidence, engineering changes, manufacturing controls, vigilance, surveillance, or lifecycle decisions. It assumes experience with regulated device records or processes.

How does medical device regulatory lifecycle training differ from general quality management training?

Medical device regulatory lifecycle training connects classification, pathways, clinical evidence, authorization, change control, vigilance, surveillance, and retirement, while general quality management training concentrates on the management system and process controls.

What belongs in a medical device regulatory lifecycle file?

A device regulatory lifecycle file should connect intended use, classification, pathway decisions, requirements, design and clinical evidence, submissions, production controls, changes, surveillance, corrective actions, and retirement records.

How should a medical device change be assessed?

A medical device change should be assessed against intended use, classification, approved claims, design and risk records, clinical evidence, manufacturing controls, labeling, traceability, market commitments, reporting duties, and required regulatory action.

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How does post-market surveillance affect lifecycle decisions?

Post-market surveillance affects lifecycle decisions by converting complaints, incidents, trends, field information, and performance evidence into signal evaluation, benefit-risk review, corrective action, design change, communication, or retirement decisions.

Conclusion

The course integrates classification, regulatory strategy, design and clinical evidence, authorization, manufacturing control, change assessment, surveillance, and retirement. Participants take back a Device Regulatory Lifecycle File containing linked decisions, evidence, controls, and actions. The file gives cross-functional teams one traceable basis for lifecycle governance.