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COURSE BROCHURE

Medical Device Regulatory Affairs Across the Product Lifecycle Training Course

3 – 7 January 2027
Kuala Lumpur

Medical Device Regulatory Affairs Across the Product Lifecycle Training Course

Ref: 3225_122693 **Date:** 3 – 7 January 2027 **Location:** Kuala Lumpur **Fees:** 4600 GBP

Medical Device Regulatory Affairs Across the Product Lifecycle is a 1-week training course for regulatory affairs, quality and product specialists at device makers, built around a lifecycle regulatory roadmap for one device family. Regulators expect evidence that stays current from classification to withdrawal, so one gap can stall a launch. Jupiter Prime Training delivers this course on medical device regulatory affairs.

Why Medical Device Regulatory Affairs Matters Now

Three forces shape medical device regulatory affairs today. Software and connected functions keep changing devices after launch, so change control has become a constant duty rather than an occasional one. Notified reviewers and health authorities ask for clinical evidence that is refreshed throughout the market life, not frozen at approval. Hospital buyers also read safety notices before choosing a supplier. A maker that keeps its technical documentation, clinical evaluation and vigilance records aligned launches sooner; one that lets them drift faces delays, field actions and lost tenders. The course rests on international quality, risk and clinical investigation practice.

Who Gains Most from Medical Device Regulatory Affairs

- Specialists who classify devices and choose the conformity route for each market
- Staff who compile and maintain technical documentation and design history files
- Quality specialists who run complaint handling, corrective action and supplier controls
- Product and engineering leads who plan design changes and software updates
- Clinical and medical affairs staff who gather and appraise clinical evidence

A device maker gains most when regulatory, quality and product colleagues attend together and leave with one shared view of each submission and post-market duty.

Medical Device Regulatory Affairs Capabilities

Participants practise the judgements that carry a device from concept through clearance, surveillance and retirement.

- Assess a device's risk class and intended purpose — the conformity route chosen for each market
- Specify design inputs, verification and validation evidence — the reviewer reading the technical file
- Weigh clinical data from literature, equivalence and investigations — the clinical evaluation conclusion
- Design a post-market surveillance plan with trend thresholds — quality and safety committees
- Apply vigilance reporting rules to incidents and field actions — the health authority and hospital users

- Communicate the regulatory impact of a design change — product owners deciding release timing

Key Medical Device Regulatory Affairs Terms

- Intended purpose — the use, users, patient group and setting the maker states for a device, which drives its classification.
- Technical documentation — the organised evidence file showing a device meets requirements.
- Clinical evaluation — a structured appraisal of clinical data that confirms a device's safety, performance and benefit for its intended purpose.
- Post-market surveillance — the planned collection and review of real-world data on a marketed device.
- Vigilance — the reporting and investigation of serious incidents and field safety corrective actions to the health authority.
- Unique device identification — a coded label and database entry that traces each device model and batch through the supply chain.

Medical Device Regulatory Affairs Day by Day

Day 1: Device Classification and Market Routes

- Intended Purpose Statement — Scope of Claims and Classification Basis
- Risk Class Rules — Choice of Conformity Assessment Route
- Combination Products and Accessories — Borderline Status Decisions
- Regulatory Strategy Map — Sequence of Target Market Submissions
- Economic Operator Roles — Duties of Importers, Distributors and Representatives

Day 2: Design Controls and Technical Documentation

- Design Input and Output Matrix — Traceability for Reviewer Questions
- Verification and Validation Protocols — Evidence of Performance Claims
- Risk Management File — Acceptability of Residual Hazards
- Software Lifecycle Records — Release Readiness of Embedded Code
- Technical File Index — Completeness Before Submission Lock

Day 3: Clinical Evidence and Market Submissions

- Clinical Evaluation Plan — Sufficiency of Literature and Equivalence Data
- Clinical Investigation Design — Endpoints, Sites and Ethics Approval
- Submission Dossier Structure — Reviewer Navigation and Deficiency Risk
- Labelling and Instructions for Use — Claims Aligned With Evidence
- Deficiency Letter Responses — Timelines and Negotiating Further Data

Day 4: Surveillance, Vigilance and Change

- Post-Market Surveillance Plan — Data Sources and Trend Thresholds
- Complaint and Incident Triage — Reportability and Investigation Depth
- Field Safety Corrective Action — Recall Scope and Customer Notices
- Significant Change Assessment — Need for New Review or Notification
- End-of-Life Withdrawal Plan — Spare Parts, Support and Archive Duties

Day 5: Practising the Lifecycle Regulatory Roadmap

- Classification Case Rehearsal — Defending the Chosen Route to Reviewers
- Technical File Gap Audit — Prioritising Missing Evidence
- Mock Incident Exercise — Reporting Clock and Root-Cause Narrative
- Periodic Safety Update Draft — Benefit-Risk Conclusion for Leadership
- Lifecycle Regulatory Roadmap — Milestones From Launch to Retirement

Applying Medical Device Regulatory Affairs After the Course

- Lead a gap audit of one technical file and assign owners to each missing item.
- Run a significant change review on the next planned design or software update.

Medical Device Regulatory Affairs Questions FAQ

What is medical device regulatory affairs and why does it matter now?

Medical device regulatory affairs is the work of proving and keeping a device's safety and performance across its life. It matters now because authorities expect evidence to stay current after launch, and connected devices change often, so every update carries a regulatory decision.

Which roles gain most from medical device regulatory affairs training?

Regulatory, quality, clinical and product specialists at device makers gain most. The course links classification, technical files, incident handling and design changes to the decisions they feed.

How does medical device regulatory affairs differ from a general quality management course?

Medical device regulatory affairs focuses on market access and authority duties rather than factory processes. This one follows a single device from classification through clinical evidence, submissions, vigilance, change and withdrawal, at a core practitioner depth.

What do you bring back from medical device regulatory affairs training?

You bring back a lifecycle roadmap for one device family. It sets out the classification rationale, evidence gaps, submission order, surveillance thresholds and change triggers in one agreed reference.

Medical Device Regulatory Affairs: The Way Forward

The lifecycle regulatory roadmap first informs which market submission to file next and what evidence it still needs. Regulatory, quality and product leads use it to plan releases and surveillance reviews together. After its first use, revisit the change triggers and trend thresholds once real complaint data shows where assumptions were too loose.