SYLLABUS

MEDICAL DEVICE REGULATORY PROJECT MANAGEMENT

Medical Device Regulatory Project Management

The Early Considerations in a Development Project

- Early development stages
  - Capturing the value proposition
  - Qualification and Classification of the product or software
  - Lessons learned – Critical regulatory considerations at the early stage
  - Regulatory strategy
- Planning and initiating the project
  - Timelines, responsibilities and team communication
  - Document and records management

Applying Regulatory Requirements to Project Management

- The role of global regulations and standards in medical device project management
- Key regulatory considerations throughout the medical device lifecycle:
  - General Safety and Performance Requirements
  - Clinical Evaluation
  - Risk Management
- Other regulatory considerations for project management:
  - Quality system requirements (ISO 13485, FDA QSR)
  - Design Control
  - Vendor control

Applying Clinical Evaluation in a Project

- The importance of conducting a literature review
- Clinical investigations and post-market activities

Applying Risk Management in a Project

- Risk management practicalities
  - Risk management according to ISO 14971 and the MDR
  - Relation to Biocompatibility, Electrical safety, Software life cycle and Usability
- Benefit-risk analysis as the final outcome

Managing Medical Device Project Cycles

- Product life cycle thinking: Does the project have an end?
- Design Control as the middle cycle: The typical project cycle
  - Design Inputs, Outputs, Verification, Validation, Process Validation, Transfer, Changes and Reviews
- The micro cycles of project management: The daily work
  - Plan-Do-Check-Act / Build-Validate-Learn / Agile methodologies
- Maintaining alignment and adapting to change
  - Corrective and preventive actions and methods
  - Project metrics

End of Course Feedback Session
Delegates will get the opportunity to finish the course by asking any remaining questions and queries regarding the course content.

Participants

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