Medical Device Development Immersion Agenda

Live, Online | Level One

Medical Device Development Immersion is an interactive, two-day preparatory course designed for those who need to better understand all aspects of medical device development. Beginning with an overview of the medical device industry, the course quickly delves into the changing regulatory environment and the different regulatory pathways devices can undertake for FDA or EMA marketing approval. Attention is then focused on a detailed explanation of the five development phases—market opportunity, evaluation, design, verification, and manufacturing. The course ends with a brief look at commercialization, including reimbursement strategies. Learn from an industry expert with 30-years of experience in both large and start-up med device companies.

Five takeaways:

1. Fluency in the essential terminology and acronyms used in the medical device sector.
2. Improved communication with engineers, regulators, colleagues, and clients.
3. Ability to construct a medical device by following the traditional five phases of development.
4. Understanding of the medical device approval pathways in both the USA and European Union.
5. Conduct risk mitigation during medical device development.

Course Agenda

Day One

Medical Device Overview *9:00–10:00*
History of device regulation
FDA mission and organization
Medical device defined
Special categories: software, in vitro diagnostics, radiation emitting products, mobile medical devices, wellness products

Break *10:00-10:15*

Regulatory Approval Pathways *10:15-11:15*
FDA classification of regulatory controls
Class I, Class II, Class III devices
510(k), Predicates, de nova 510(k)
Exemptions to Class III devices
Device classification challenges
Combination products
EU device approval pathway

Break *11:15-11:30*

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MedDevice Regulations *11:30-12:30*
Quality systems regulations
Regulatory compliance: GMP, GLP, GCP
Risk management evaluation
Human factors and usability
Risk analysis plan
Postmarket surveillance; MedWatch
FDA postmarket actions and penalties

Lunch *12:30-1:15*

Phase I: Market Evaluation *1:15-2:15*
Development process overview
Product development Gantt chart
Regulation of medical device design
Market opportunity evaluation key requirements
Activity: Bionic Walker Customer Requirements

Break *2:15-2:30*

Phase II: Concept Evaluation *2:30-3:15*
Concept evaluation key requirements
Risk analysis plan process
Activity: Bionic Walker Concept Evaluation
Risk acceptability matrix
Quantifying risk
Activity: Bionic Walker Risk Assessment

Wrap-Up *3:15-3:30*

Day Two
Phase III: Engineering Design *9:00-9:45*
Engineering design key requirements
Specifications
Iterative design
Software design
Documentation

Break *9:45-10:00*

Verification & Validation *9:00-11:30*
Verification & validation key requirements
Product build strategies for testing
Labeling verification process
Human factor testing process
Standards testing process
Manufacturing tooling testing process
FDA Process validation guidance
Biocompatibility & ISO 10993
Activity: Bionic Walker Create A Specification & Test Plan

Break *11:30-11:45*

Phase V: Manufacturing Transfer *11:45-12:30*
Manufacturing key considerations
Manufacturing transfer
Manufacturing scale-up

Lunch *12:30-1:15*

MedDevice Approval *1:15-2:15*
Pre-submission discussions with FDA
Clinical trials
Investigational device exemption (IDE)
Expanded pre-approval access
Approval timelines
FDA submission types
MDUFAIII
Submission approval timelines

Break *2:15-2:30*

Commercialization *2:30-3:15*
Reimbursement strategy
CMS vs FDA
Issues affecting private payers

Wrap-Up *3:15-3:30*