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

T. 410.377.4429 or email info@biotechprimer.com
**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