Medical Device Development Immersion Course Agenda

Medical Device Development Immersion is a two-day course examining all aspects of medical device development in detail. Starting with the changing regulatory environment, different regulatory pathways are reviewed, and a comparison of FDA vs. EU approval process is made. The five phases of medical device development, market opportunity, evaluation, design, verification, and manufacturing, are described in detail. Take this course to develop an understanding of the entire process required to bring a new medical device to market.

Five takeaways:

1. An improved ability to communicate with engineers, colleagues and manufacturers
2. Medical device terminology and processes
3. A toolbox to help design a medical device prototype
4. Knowledge of the various approval pathways for each medical device class
5. Risk mitigation in medical device development and approval

Course Agenda

Day One

Medical Device Overview *9:00-10:30*
Medical device defined
Medical device diversity
Industry sectors and top companies
History of device regulation
FDA approval pathways: 501(K), PMA

Break *10:30-10:45*

Medical Device Regulations *10:45-12:00*
Quality system regulations (QSRs)
Current good manufacturing practices
Good laboratory practices
Good clinical practices
Risk management plan
Exemptions
Rest of world approval pathways
Special categories: home brew and combinations

Lunch *12:00-1:00*

Medical Device Regulations continued *1:00-2:00*
Regulatory challenges
Diagnostics
Predicates and new technologies
Clinical trials
Medical device reporting

Medical Device Development *2:00-4:15*
Phase I: market opportunity
Market analysis
Risk management plan
Phase II: concept evaluation
-Formulation steps
-Feasibility

Medical Device Development continued *2:00-4:15*
Phase III: engineering design process
-Design
-Development
-Prototyping

Q&A|Review *4:15-4:30*

Day Two
Review *9:00-9:30*

Medical Device Development *9:30-11:00*
Phase IV: Verification
Phase V: Manufacturing Transfer
-Documentation
-Equipment IQ/OQ/PQ
-Biocompatibility
-Sterilization
-Shipping and storage

Break *11:00-11:15*

Medical Device Approval *11:15-1:00*
Clinical trials
Need for a gold standard
Regulatory submissions
Business preparations
Product launch preparations
Coding and reimbursement

Lunch *1:00-2:00*

Commercialization *2:00-3:15*
Manufacturing scale-up
Product launch
Post-launch assessment

Break *3:00-3:15*

Current Issues *3:15-4:15*
The increasing role of the FDA
Why are the newest devices in Europe?

Q&A/Review *4:15-4:30*