Medical Device Development Primer Course Agenda

Medical Device Development Primer is a one-day preparatory course designed for those seeking introductory industry understanding. This course examines all aspects of medical device development, including a detailed description of the five development phases—market opportunity, evaluation, design, verification, and manufacturing. The course delves into the changing regulatory environment and focuses on the different regulatory pathways that devices can undertake for FDA or EMA marketing approval.

Five takeaways:

1. Fluency in essential terminology and acronyms of the medical device industry
2. Knowledge of the various approval pathways for a medical device to be marketed to patients
3. An understanding of how to mitigate risk in a medical device
4. An improved ability to communicate with engineers, colleagues and clients
5. The ability to construct a medical device by following the traditional 5 phases of development

Course Agenda

Medical Device Overview *9:00–9:30*
Medical device defined
Medical device diversity

Medical Device Regulations *9:30–10:30*
Quality system regulations (QSRs)
Current good manufacturing practices
Good laboratory practices
Good clinical practices
Risk management plan
Exemptions

Break *10:30-10:45*

Medical Device Regulations *continued*
10:30–12:00
Rest of world approval pathways
Home brew and combination devices
Regulatory challenges
Diagnostics
Predicates
New technologies
Clinical studies

Lunch *12:00–1:00*

Medical Device Development *1:00–3:00*
Phase I: market opportunity evaluation
-Market analysis
-Risk management plan
Phase II: concept evaluation
-Formulation steps
-Feasibility
Phase III: engineering design process
-Design and development

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-Software development
-Prototyping
-Medical device reporting

Phase IV: verification

Phase V: manufacturing transfer

-Documentation
-Equipment IQ/OQ/PQ

Break *3:00–3:15*

Medical Device Approval *3:15–4:15*

Clinical trials
Need for a gold standard
Regulatory submissions
Coding and reimbursement

Q&A|Review *4:15–4:30*