

■ The Regulatory Process for Medical Device Approval

OVERVIEW

The Regulatory Process for Medical Device Approval explains how medical devices are regulated in the United States. Medical device classification and each classification's differing approval pathways are outlined in detail. FDA guidelines, quality system regulations, and risk management plans are also discussed in great detail. If you are new to the medical device industry, this class will provide an understanding of the breadth of the industry's regulatory requirements.

Five Takeaways:

1. Identify the medical device industry's major device sectors and worldwide regulatory organizations.
2. Classify medical devices based on potential risks.
3. Explain the major medical device approval pathways.
4. Discuss how the Code of Federal Regulations and Good Practices enforces regulatory compliance.
5. Develop a risk management plan for a medical device.

AGENDA

Medical Device Overview

Medical device defined
 Class I, II, III medical devices
 Companion diagnostics
 FDA medical device categories
 Top medical device companies

Medical Device Regulation

Medical device regulation history
 FDA organizational structure
 Medical device classification and risk
 Class I risk and controls
 Class II risk and controls
 Class III risk and controls
 FDA approval pathways
 510(k)
 De novo 510(k)
 Premarket notification (PMN)
 Premarket approval (PMA)

Predicate device
 Regulatory compliance requirements
 Good laboratory practices (GLP)
 Good clinical practices (GCP)
 Good manufacturing practices (cGMP)
 Quality system regulations (QSR) requirements
 Material controls
 Production and process controls
 Design controls
 Corrective and preventative actions
 Records and documents change controls
 Facility and equipment controls
 QSR examples: hiring and product development
 Risk management plan
 Managing human factor risks
 Risk analysis plan process
 Global regulatory agencies
 European Union approval process