

Medical Device Overview and Regulation

57-MINUTE ONLINE COURSE | LEVEL 2

SUGGESTED PREREQUISITES: DIAGNOSTICS' ROLE IN MEDICINE TODAY

OVERVIEW

Medical Device Overview and Regulation explores the diversity of the medical device industry by highlighting its various sectors, top companies and major regulatory bodies worldwide. Device classification and each classification's differing approval pathways are outlined in detail. The course concludes with a look at the quality system regulations and risk management plans you must follow. If you are new to medical device, Medical Device Overview and Regulation will provide an understanding of the industry's regulatory breadth.

Five Takeaways:

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

AGENDA

- **Overview of Medical Device Types** identifies the major medical device sectors and describes the history of medical device regulation.
- **FDA Medical Device Classification** explains how to classify medical devices into Class I, Class II, or Class III based on risk assessment.
- **FDA Approval Pathways for Medical Device** maps the medical device approval pathways, including how approval of a product can be obtained if a new device is being compared to a predicated device.
- **FDA Regulatory Compliance for Medical Device** surveys various compliance laws including the Code of Federal Regulations, Good Lab Practices, Good Clinical Practices, and current Good Manufacturing Practices as they relate to medical devices.
- **Medical Device Risk Management Plans** demonstrates how to develop a risk management plan for a medical device.
- **Medical Device Regulatory Bodies Worldwide** lists the worldwide regulatory bodies for medical devices.