FDA's Regulation of Medical Devices: What The Beginner Needs to Know To Get A Medical Device to Market in the U.S.

Description: This webinar is intended to provide beginners with an introduction to the U.S. Food and Drug Administration's regulation of medical devices. The FDA regulates medical devices marketed and sold in the U.S. on the basis of potential risk according to a 3-level classification system. Class I medical devices are deemed to be low risk and possess the lowest regulatory threshold for entry into the market. Class II medical devices are deemed to present an intermediate risk to the user and requires the submission of a 510(k) Premarket Notification establishing substantial equivalence to a selected predicate device. Finally, Class III devices are considered novel and unique, and are deemed to pose a higher level of risk than the other device categories. Class III devices require FDA Premarket Approval prior to marketing and sale. This webinar provides an introduction to FDA and its regulatory authority as it relates to medical devices. The presenter will discuss FDA's medical device classification system and offer suggestions for determining how a particular device is classified and regulated. The process for going to market with a Class I, Class II and Class III device will be described with particular attention being paid to the preparation and submission of 510(k)s and PMAs. An overview of a medical device manufacturer's and/or distributor's regulatory responsibilities will be discussed, as will FDA's requirements governing medical device labeling.

Course Objective:

Upon completing this course participants should:

- Gain a basic understanding of FDA's structure and regulatory authority through an understanding of its laws and regulations applicable to medical devices.
- Develop a familiarity with FDA's Medical Device Classification System and learn the difference between Class I, Class II and Class III medical devices.
- Understand the difference between a 510(k) and a PMA, and when each is required.
- Learn what is included in a 510(k), how to prepare a 510(k) and the process for selecting a predicate device.
- Develop a basic understanding of FDA's Quality System Regulation (21 CFR Part 820).

Course Outline:

- An Introduction to FDA and the Medical Device Regulations
- The Medical Device Classification System
- Determining the Regulatory Status of a Proposed Medical Device
- Class I Medical Devices
- Class II Devices and the 510(k) Premarket Notification
- Class III Devices and Pursuing Premarket Approval
- Individual Device Exception ("IDE")
- User Fees and the Small Business Waiver Program
- An Introduction to the Quality System Regulation (21 CFR Part 820)
- Labeling and Promotion
- FDA's Rules Governing the Import and Export of Medical Devices
- Questions

Target Audience:

This course is designed for Beginners looking for an introductory class covering the fundamentals of FDA Medical Device Regulation. It is intended for those tasked with assisting with the development or actually developing a regulatory and business strategy for the marketing and sale of medical devices in the United States. This includes individuals responsible for ensuring medical device compliance, obtaining device clearance or approval, and the shipping and export of medical devices to the U.S.

The following personnel will benefit from the course:

- Medical Device Manufacturers
- Regulatory & Compliance Professionals
- Medical Device Designers / Design Engineers
- Corporate Legal Departments
- Medical Device Exporters and Importers
- Regulatory Consultants
- Research Analysts
- Production Supervisors
- Quality Control Personnel
- Medical Affairs Staff
- Regulatory Auditors
- Customs Brokers
- Medical Device Labelers
- Convenience Kit Manufacturers
- State Policy Officials
- Investment Analysts
- Venture Capitalists
- M&A Professionals

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