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FDA Registration: Medical Devices, IVD and Combination Products

Instructor: Charles H Paul

Date: Thursday, 1 June 2017 | Time: 11:30 AM PDT, 2:30 PM EDT | Duration: 90 Minutes

The medical device submissions process in the US is a complex process. The regulations at times can be confusing and appear to be vague or contradictory. It is imperative to understand the similarities and differences in submissions approaches when formulating a marketing strategy for your medical device. Incorrect classification decisions for medical devices for example, can be costly and extend the submissions process far beyond what it should. Formulating a proper submissions strategy begins with understanding the regulatory requirements, the avenues or approaches to submissions, the power of proper device classification, and how those submissions should be best undertaken. This webinar will explain and explore these topics.

Objectives of the Presentation

- List and describe the regulations that govern both medical device classification and medical device submissions
- Explain the medical device classification process
- Discuss the importance of making proper medical device classification decisions
- Explain the 510(k) submissions process
- List and describe the 510(k) submissions pathways
- List and describe the PMA submissions process
- Explain the De Novo medical device submissions process
- Explain the Human Device Exemption process

Why Should you Attend

The medical device market is the largest market of all of the life sciences and it is generally valued at upwards of $90 billion with the expectation of continuous growth. This growth demands that the market be continually fed with new and innovative products. Regulation, here in the US as well as in the EU have made the approval of products for market a complex process requiring manufacturers, to ensure their own survival, to be fully knowledgeable of the regulatory submissions process.

FDA classifies medical devices in the United States as Class I, II or III. However, it is far more complicated than that. Most Class I devices are 510(k)-exempt, but not all. Most Class II devices require a 510(k), but some are 510(k)-exempt. Some Class III devices require a PMA and some only require a 510(k). In this webinar the speaker will explain the optimal approach to obtaining market approval or clearance for a specific medical device, IVD and combination product with the U.S. Food and Drug Administration. This translates directly into cost savings and faster time to market for a company's products.

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Areas Covered

This webinar course will introduce you to the FDA Registration for Medical Device, IVD and Combinations products:

- Device Classification
- Class I Medical Device
- Class I device exemptions
- Class II Medical Device
- Investigational Device Exemption (IDE)
- Class III Medical Device
- PMA Application Contents
- PMA filing
- Reclassification
- In vitro Diagnostics (IVD) - Basics
- Combination Product

Who will Benefit

- Regulatory Affairs specialist
- R&D Engineers
- Medical Affairs specialist
- Clinical Affair specialist
- Quality Engineers
- Marketing
- Quality Professionals
- Product Development Professionals
- CROs
- Consultants
- Senior Management
- Contractors and Subcontractors

Webinar Cost :-

$250.00 Live Session | **$375.00 Recorded Session** | **$500.00 Training CD** | **$1250.00 Corporate Live Session**

$500.00 Live Session + Recorded Session | **$625.00 Live Session + Training CD**

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Instructor Profile:

Charles H. Paul is the President of C. H. Paul Consulting, Inc. - a regulatory, Lean Manufacturing, training, and

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technical documentation consulting firm. Charles is a management consultant, instructional designer and regulatory consultant and has led C. H. Paul Consulting, Inc. since its inception over 25 years ago. He regularly consults with Fortune 500 pharmaceutical, medical device, and biotechnology firms assisting them in achieving human resource, regulatory, and operational excellence. He is a regular presenter of webinars and on-site seminars in a variety of related subjects from documentation development to establishing compliant preventive maintenance systems. The firm works globally completing projects throughout the EU, UK, South America, and Asia.