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The Premarket Notification/510k Submission: Using Substantial Equivalence to your Advantage!

Date: October 16, 2014
Time: 1pm - 2:30pm EDT
Duration: 90 Minutes - Online
Price: $299 - Introductory Rate

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Course Description:

The premarket notification (PMN), better known as the 510K, is the most common regulatory pathway medical device manufacturers use to bring new medical devices to market in the US. But because of a few highly publicized problems associated with some commonly used medical devices, 510k submissions are experiencing greater regulatory scrutiny by FDA prior to clearance. Although most submissions are eventually cleared, nearly 75% of first-time 510k applications are initially rejected leading to average 510k review times in 2014 of 114 days. This creates costly delays for medical device manufactures – many of which could be minimized if not avoided completely!

One of the areas receiving the greatest regulatory scrutiny in the 510k submission is the substantial equivalence argument. Simply put, without a strong substantial equivalence argument, your 510k submission may not be successful. But what does substantial equivalence really mean and how do you show it? How do you use not just what the regulation says, but also what it *does not say* to your advantage? Using the case study approach, these questions and others will be discussed and answered in an interactive fashion and participants will:

- understand the regulatory requirements of substantial equivalence and how to use them to your advantage
- learn to design a substantial equivalence regulatory strategy using regulatory logic and how to defend it successfully
- appreciate the various methods available to make a convincing substantial equivalence argument
- be aware of several new FDA guidance documents that have issued recently and how to use them to your advantage
- discuss some of the proposed changes currently under debate and what the future may hold for the 510K program
- learn tips to gain approvals quickly and avoid common pitfalls

In this webinar you will learn how to design the substantial equivalence component of a successful 510k submission to get a medical device to market as quickly and efficiently as possible and to avoid problems before they occur.

Who Should Attend

Geared for both experienced medical device professionals as well as those new to the industry, this webinar is designed for those who need a better understanding of the premarket notification (PMN), better known as the 510K, submission process. Scientists, engineers and technicians working on device design and development, product and product development managers, business development managers, marketing managers, QA/QC personnel, regulatory affairs professionals, investment and acquisition specialists, and field service engineers will all benefit from this webinar.

Instructor Bio

Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including (but not limited to): stimulating & innovative educational programing, brain-storming sessions, prototype design, product development, benchtop & animal testing, regulatory strategy, intelligence & clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment.