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Understanding the Medical Device Classification System: Best Practices for Selecting the Best Fit

Date: July 15, 2014
Time: 1pm - 2:30pm EDT
Duration: 90 Minutes - Online
Price: $299 - Introductory Rate

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Course Description:

Many assume that the medical device classification system is a "no-brainer," and that classification determinations are based simply on risk, but there are numerous exceptions. How does one determine the class of a medical device? FDA's classification database may tell the classification of an existing device but it won't tell you why. What if you want to change classifications? The regulatory logic you use is critical in selecting a classification which will ensure desired outcomes and actually work to your competitive advantage. What if you are working on a device that has not been classified? When should you approach FDA and – more importantly – how? Many companies have experienced long and costly delays in bringing devices to market because of classification mistakes, many of which could have been easily avoided.

This course will give you the necessary tools to understand the device classification system and make educated, risk-based choices for selecting the regulatory pathway that best fits your product. Participants will gain a clear understanding of device re-classification and learn best practices for approaching – and communicating with – the FDA.

Using a case study approach, all of these questions (and others) will be answered in an interactive fashion, including:

- What is the classification system and why do we have one?
- How do I determine classification?
- Can I change classification?
- How can I use classification to my advantage?
- What's new in classification?
- How does classification vary in other parts of the world?

In this webinar you will learn how to avoid costly mistakes and, more importantly, discover creative ways to use the medical device classification system to your competitive advantage. Simply put, the more effective your classification strategy, the quicker and easier you will get your products to market while making it more difficult for your competitors at the same time –the true art of regulatory strategy.

Who Should Attend

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.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world.

Finally, Dr. Drues is an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology at several universities and medical schools. He regularly teaches graduate courses in Regulatory Affairs and Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs and Product Development, Combination Products, Pathophysiology, Medical Technology, Translational Medicine and Biotechnology.

For additional information, call (508) 887-9486 or e-mail mdrues@vascularsci.com

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