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De Novo Path to Device Approvals: Tips for Speedy, Successful Outcomes

Date: February 24, 2014
Time: 1pm - 2:30pm EST
Duration: 90 Minutes - Online
Price: $299 - Introductory Rate

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Course Description:

For years, the De Novo pathway for device approvals has been seldom used as it was a traditionally cumbersome and lengthy process. Although the De Novo option has been less utilized than the 510K and Pre-Market Application (PMA), recent regulatory changes have made the De Novo pathway more attractive to device manufacturers. Furthermore, the De Novo pathway can provide a competitive advantage as a barrier to entry for your competition. Join our interactive online training course where you will learn:

- Regulatory changes that will speed your products toward approval – and how to implement them
- How to use the De Novo pathway as a competitive regulatory strategy to create a barrier to entry for your competition
- When and why: Is De Novo the answer for you?

Who Should Attend

Geared for both experienced medical device professionals as well as those new to the industry, this course is designed for those who need a better understanding of the current regulatory requirements for utilizing the De Novo pathway, and if it is the right choice for your product. This unique seminar demonstrates important regulatory requirements and concepts using case study discussions of real products from a variety of clinical specialities. 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, andand consulting company offering a broad range of services to medical device, pharmaceutical and biotechnology companies.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University. 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 and 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.

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