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Communication With FDA: What Do We Say And How Do We Say It?

Date: July 23, 2014
Time: 1pm - 2:30pm EDT
Duration: 90 Minutes - Online
Price: $299 - Introductory Rate

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Course Description:

Effective communication with FDA is critical in successfully bringing any therapeutic product to market. However, communication includes much more than the written regulatory submission. Effective communication in all its forms must be concise, carefully considered, and reviewed to achieve the desired outcome.

One must ask several questions before engaging in correspondence with FDA. When are we required to communicate with FDA? More importantly, when should we communicate with FDA? What should we say and how should we say it? What should we *not* say and how should we *not* say it? It's not what you say that matters – it's what people hear!

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

- When are we required to communicate with FDA? When should we? Is it ever too early?
- What should we say and how should we say it? What should we *not* say and how should we *not* say it?
- Who should communicate with FDA and who should not? When should it be verbal, and when in writing?
- When should we communicate formally vs. informally?
- How do we avoid timely and costly mistakes and how can we use creative ways to use communication with FDA to our advantage!

Who Should Attend

Geared for both experienced life science professionals as well as those new to the industry, this webinar is designed for those who need a better understanding of how to communicate effectively with FDA to bring pharmaceutical, biotech, and medical device products to market. This unique seminar demonstrates important regulatory requirements and concepts using case study discussions of real products from a variety of clinical specialities. Strategies for using regulation as a competitive advantage will also be discussed. Scientists, 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.

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.

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