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Communication with FDA: What do we say and how do we say it? TM

All medical companies are required to communicate with FDA but most do not do it well. Don't think so? Consider this: 70-75% of FDA submissions are rejected by FDA first time out of the box. So if we are communicating effectively how do explain this?

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!

Using case studies from a variety of clinical specialties, all of these and more will be discussed in this interactive webinar. Strategies for using regulation as a competitive advantage will also be discussed.

Biography

Michael Drues is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including stimulating & innovative educational programing, creative regulatory strategy & complete regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, clinical trial design, reimbursement, clinical acceptance, business development & technology assessment. Dr. Drues received his B.S., M.S., and PhD 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 Medicaid Services (CMS) and other regulatory and governmental agencies around the world. Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Medical Technology & Biotechnology at several universities & medical schools on-ground & on-line.

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