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Conducting effective FDA pre-sub meetings: Tell don't ask… lead don't follow!

For medical device companies, ineffective communication with FDA often leads to time-consuming and costly delays. Manufacturers may assume a classification or regulatory pathway for a new device – only to learn later that FDA disagrees. Unfortunately, most of these delays are completely avoidable! The 'pre-sub' program – an expansion of the pre-IDE program– allows manufacturers to request meetings regarding devices currently under development and/or regulatory review. Although CDRH issued guidance on the pre-sub program in 2014, many companies do not use this program effectively, and some don't use it at all for fear their regulatory burden will be increased rather than reduced. When used effectively, pre-subs can offer significant advantages to the manufacturer by getting their device to market sooner. But if not used properly, pre-subs can add tremendous burden by increasing time to market. This presentation will use the case study approach to present the pre-sub process in an interactive fashion including:

When should the pre-sub program be used and when should it not be?
How does the process work and what can the manufacturer expect?
When is it better to meet formally or informally? Should you meet in person or via teleconference?
What info should be provided in advance and what should be provided at the meeting?
What happens after the meeting? How should the manufacturer follow-up? Are the results binding?
Are there other ways to communicate with FDA beyond pre-subs and when should they be used?

In this presentation, participants will learn best practices to avoid timely and costly mistakes and creative ways to use the pre-sub program to their advantage! For additional information, check out: How to Make the Most of Your Pre-Sub Interactions with FDA; Communicating With FDA: How (And When) To Get It Right; 3 Tips to Vastly Improve Your FDA Communication Strategy; How to Make the Most of Your Pre-Submission Interactions with FDA How to Properly Use the FDA Pre-Submission Process and Why It's So Important; When and How To Interact With the FDA; FDA Pre-Submission Meetings: Strategies for Medtech Entrepreneurs; Communication With FDA: What Do We Say and How Do We Say It? ; Guerilla Regulatory Strategy

Biography

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 stimulating & innovative educational programing, creative regulatory strategy & completive 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 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, 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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