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MEDICAL DEVICE REGULATORY AFFAIRS 101:

Are You Sure You Know The Best Regulatory Strategy For Your Device?™

Are you looking to break into the medical device industry? Are you already working in the medical device industry but feel overwhelmed with the regulatory jargon? Are you an experienced medical device professional and want to understand how to use regulation to your competitive advantage? If you answered yes to any of these questions, then this seminar is for you!

Geared for both experienced medical professionals as well as those new to the industry, this seminar is designed specifically for non-regulatory professionals who need a better understanding of the regulatory requirements necessary to bring medical devices 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.

All medical device pathways to market are presented with a discussion of the advantages and challenges of each. Multiple examples of products on the market, under development and on the drawing board (including videos!) are presented in an interactive format. The seminar concludes with a look at the regulatory challenges for the future of the medical device industry including combination products, tissue engineering, nanotechnology and beyond!

Read 'Are You Sure You Know The Best Regulatory Strategy For Your New Medical Device?' available [here](#).

Interested in what past attendees have said? Visit my LinkedIn [page](#) to read recommendations and testimonials!

Dates / Times:	Two 3.5-hour evening sessions: November 12 and 19, 2015 from 5:30-9pm
Location:	Wellesley Community Center, 219 Washington Street, Wellesley, MA
Cost:	\$299 including course manual (register in advance and save!)

Group discounts and referral bonuses available – discounts for unemployed – call for details!

Instructor Biography



Michael Drues, Ph.D., author of [Guerrilla Regulatory Strategy](#), is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including 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, contact Dr. Drues directly at (508) 887-9486, e-mail mdrues@vascularsci.com or via LinkedIn at www.linkedin.com/in/michaeldrues. © Copyright 2015 by Vascular Sciences. All rights reserved.