

MEDICAL DEVICE REGULATORY AFFAIRS FOR NON-REGULATORY PROFESSIONALS:

What do non-regulatory professionals need to know? Presented by: *Michael Drues, Ph.D.*

Seminar Overview and Objectives

Geared for both experienced medical device 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 new medical devices to the market. This unique seminar demonstrates important regulatory requirements and concepts through actual product case studies discussions emphasizing not simply following regulations but asking do the regulations make sense and what to do when they don't!

Major medical device approval pathways are presented with a discussion of the advantages and challenges of each. Pre-clinical and clinical trial phases will be discussed highlighting how issues relate back to product design and development. Important topics such as pediatric devices, off-label use and medical device direct-to-patient advertising will also be discussed. Differences between medical devices, drugs and biologics will be discussed with emphasis on the emerging area of combination products. Some differences between domestic vs. international approvals will be touched upon. Multiple examples of medical devices and procedural videos are presented in an interactive format with a discussion of what they do well and where improvements can be made. Suggested length: 2 three-hour sessions.

Upon completing the seminar, each attendee will be able to:

- ✓ Understand the major regulatory requirements that apply to medical devices
- ✓ Learn to work more effectively with regulatory personnel and the FDA
- ✓ Be able to anticipate questions from FDA reviewers
- ✓ Learn to design a regulatory strategy to minimize product approval delays
- ✓ Appreciate the goals and challenges of medical device clinical trials
- ✓ Understand the similarities and differences between medical devices, drugs and biologics
- ✓ Recognize the advantages and challenges of combination products
- ✓ Identify opportunities for future growth

Who Should Attend?

This seminar is designed especially for non-regulatory professionals involved in the design, development, and manufacture of medical devices. Those working in research and development, manufacturing, quality, business development, sales and marketing, legal, business and accounting, field service and related areas will all benefit from this seminar.

About the Instructor



Michael Drues, Ph.D., is President of Vascular Sciences in Grafton, Massachusetts. Vascular Sciences offers a full range of consulting services to medical device, pharmaceutical and biotechnology companies including: prototype design, product development, testing and evaluation, animal and clinical trials, business development, strategic planning, technology assessment and regulatory affairs. 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).

Dr. Drues is an Adjunct Professor of Medicine & Biotechnology at Northeastern University (Boston), Steven's Institute of Technology (Hoboken), Boston College (Boston), University of Wisconsin (Madison), Drexel Medical School (Philadelphia), Regis College (Boston) and University of California (Irvine). He regularly teaches both undergraduate and graduate courses in pathophysiology, biotechnology, regulatory affairs and clinical trials. Dr. Drues conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the European Patent Office and the FDA. Current offerings include: Designing Cardiovascular Devices, Designing Gastrointestinal & Urinary Devices, Designing Better Medical Devices: Begin with the body in Mind™, Minimally Invasive Technologies, Combination Products and Convergence, Overview of Biotechnology, Emerging Trends in the Medical Device Industry™, Big Picture Issues in Clinical Trials™ and Regulatory Affairs for Non-Regulatory Professionals.

Visit www.meddevgroup.org/courses.htm for more details and to register!

For additional information, *please contact Dr. Michael Drues at mdrues@vascularsci.com or call (508) 887-9486.*

Seminar Agenda

<p>Session I (6 – 9PM)</p>	<p>Overview and Introduction</p> <ul style="list-style-type: none">• Medical Devices vs. Drugs vs. Biologics• Understanding the FDA: CDRH vs. CDER vs. CBER – Differences in regulation and philosophy• Recommendations for dealing effectively with the FDA• Where to go to find out more – DSMICA, Guidance and more <p>Medical Device Regulation (Part I):</p> <ul style="list-style-type: none">• Medical device approval options – Advantages and disadvantages of each & who decides?• Medical Device Classification System – Why does it exist and does it make sense?• Pre-Market Notification (510K) and “substantial equivalence”• The Least Burdensome Philosophy – how to use it to your advantage• Future of the 510K – Major changes are in the air!• Third Party Review – Who can use it and who can't? <p>Medical Device Regulation (Part II):</p> <ul style="list-style-type: none">• Investigational Device Exemption (IDE) and the Pre-Market Approval (PMA)• Industry User Fees – A blessing or a curse?
<p>Session II (6 – 9PM)</p>	<p>Medical Device Regulation (Part III):</p> <ul style="list-style-type: none">• Medical Device Clinical Trials – Establishing label claims and off-label use• Clinical trials design strategies – pilot vs. pivotal studies• Dealing with adverse events• Role of Placebos/Sham Surgeries in Medical Device Clinical Trials• Post-Approval Studies – CDRH Bioresearch Monitoring Program & Postmarket Requirements <p>Case Study: Regulation of Biomaterials – What does the future hold?</p> <p>Medical Device Regulation (Part IV):</p> <ul style="list-style-type: none">• Humanitarian Device Exemption (HDE) and Custom Device Exemption (CDE) <p>Case Study: Challenges of Pediatric Medical Devices</p> <p>Overview of Simulation Testing Requirements</p> <ul style="list-style-type: none">• How do you test your device on the bench top? Meeting the GMP (QSR) requirements• Generating data for marketing claims, failure mode prediction and recreation• Trade-show demonstrations and physician training <p>Combination Products and Convergence</p> <ul style="list-style-type: none">• What is a combination product? Why are they important? How are they regulated?• Is “primary mode of action” an out-dated concept?• Role of the Office of Combination Products (OCP)• Examples of combination products – Advantages over the device alone approach <p>What does the future hold?</p>

Note: Times are approximate and may be adjusted depending on audience feedback.

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