Engage in the largest Medical Design & Manufacturing Conference in the MidWest

Wednesday, October 29, 2014
2:45 pm - 3:05 pm

Recent advances in bioresorbable polymers: Degradation properties, test methods and biodegradable metals

- Overcoming the factors that influence polymer breakdown and degradation
- Reviewing recent advances in biomaterials and test methods
- Uncovering the potential of bioresorbable metals

Michael Drues, Ph.D., *President*, **Vascular Sciences**

Thursday, October 30, 2014
1:00 pm - 1:45 pm

The Premarket Notification a.k.a. 510k: Using substantial equivalence to your advantage!

The 510K is the most common regulatory pathway used to bring new medical devices to market. But because of a few highly publicized problems, 510k submissions are experiencing greater regulatory scrutiny by prior to clearance. Although most submissions are eventually cleared, nearly 75% of first-time 510k applications are initially rejected leading to average review times of 114 days in 2014. This creates costly delays for manufactures – many of which could be minimized if not avoided completely! One area receiving the greatest regulatory scrutiny is the substantial equivalence argument. Using the case study approach, participants will:

- Understand the regulatory requirements of substantial equivalence and how to use them to your advantage
- Learn to design a substantial equivalence regulatory strategy using regulatory logic and how to defend it
- Appreciate the various methods available to make a convincing substantial equivalence argument
- Be aware of several new FDA guidance documents and how to use them to your advantage
- Discuss the proposed changes currently under debate and what the future may hold for the 510K program

Michael Drues, Ph.D., *President*, **Vascular Sciences**

1:45 pm - 2:30 pm

Best practices in responding to complaints, recalls and warning letters

This practical workshop will guide you through the dangers of inadequate complaint handling, crisis management and how to avoid future recalls and warning letters.

- Responding effectively to FDA's form 483 observations
- Preparing for a follow up inspection and enforcement action
- Discussing FDA expectations and negotiation techniques

Michael Drues, Ph.D., *President*, **Vascular Sciences**

About Michael Drues, Ph.D.

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 & 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.