Medical Device Design Short-Courses

Vascular Sciences has been conducting short-courses specifically geared toward medical device design, development and testing since 1995. Companies ranging in size from start-up to fortune 100 companies, the European Patent Office and the FDA, have all requested these short-courses.

What sets these short-courses apart from all others is the approach: *Begin with the Body in Mind*™. This unique view of medical device design is not typically found in the medical device industry or in traditional academic settings.

Begin with the body in mind™

Begin with the body in mind™ is the common theme for all of Vascular Sciences' short-courses. In order to design safe and effective medical devices in a timely and efficient fashion, an understanding of how the body is designed to function and how it will likely respond to a medical device is key.

Who Should Attend?

These short-courses are designed for medical device professionals involved in the design, development, and manufacture of medical devices. Scientists, engineers and technicians working on device design and development, product and product development managers, business development managers, marketing managers, quality personnel, regulatory affairs professionals, investment and acquisition specialists and field service engineers will all benefit from these seminars.

Short-Course Format

Short-courses usually last two to three days and are presented using state-of-the-art multimedia including power-point with multiple embedded animations and videos (high-resolution color overheads can be used upon request). Case studies and product videos illustrating a variety of procedures and devices are presented in an interactive fashion. Ample time for question and answer, discussion and brainstorming is also included. Several group activities are included to maintain participant interest.

Short-courses typically include the following information:

- ✓ Overview of market including size, growth rates and numbers of procedures performed
- ✓ Review of relevant anatomy & physiology relative to medical device design & development
- ✓ Detailed discussion of pathology and pathophysiology due to disease or injury
- ✓ Numerous case studies and procedural videos demonstrating the use of current medical devices followed by a discussion of what they do well and how they could be improved
- ✓ Specific recommendations & guidelines on how to design safe and effective medical devices
- ✓ Suggestions on how to access the efficacy of medical devices both *in vitro* and *in vivo*
- ✓ Synopsis of regulatory requirements and issues of importance to the FDA
- ✓ View into the future including new products under development, market trends and opportunities and where we go from here

At the end of the seminar, each participant will leave with practical, hands-on information immediately applicable to medical device design, development and testing.

Public vs. In-House Short-Courses

Short-courses are conducted in both public and in-house formats. Public short-courses are open to anyone in the medical community regardless of affiliation. These seminars are typically held on predetermined dates in public venues such as hotel conference rooms. The agenda is fixed in advance although some adjustments may be made to accommodate the needs and interests of the individual

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participants. The number of participants attending public short-courses is limited to about 15 – 20 people in order to facilitate group discussions and encourage individual participation.

In-house or customized short-courses are limited to individuals from a single company or organization and their invited guests. These short-courses are typically held in a private venue such as on-site within a company or in a hotel conference room. Custom short-courses can be scheduled at the convenience of the sponsor. The agenda of each session can be tailored to best meet the needs of the sponsoring organization. The number of participants attending an in-house short-course is left to the discretion of the sponsor. However, limiting the number of participants tends to facilitate group discussions and encourage individual participation.

In-house short-courses have several advantages over public courses including:

✓ **No confidentiality issues** since everyone is from the same company. This allows for more question and answers, group discussions, brainstorming, etc. A confidentiality agreement allows more detailed discussion of company-related products and issues.
✓ **Tailored content** for your organization (i.e., more time on topics of relevance to you!).
✓ **Lower cost per attendee** since the course is held in your facility (or nearby hotel meeting room) rather than requiring your employees to travel to the course.
✓ **Convenient scheduling** allows you to choose the dates that best fit your schedule rather than having to conform to a predetermined schedule.
✓ **Limited group size** could be as small as you like (could limit just to R&D or could also include marketing, regulatory, etc.)

Course Manuals

Each participant receives a course manual consisting of over 400 pages of full-page pictures, recommendations and guidelines and a complete bibliography. Sample manuals are available on-line, by sending an e-mail to seminars@vascularsci.com or by calling our seminar hotline at (508) 801-9599. Full color manuals are also available.

Testimonials

To read what previous seminar attendees have said about these seminars, visit our web site.

Course Topics

Vascular Sciences offers a series of short-courses to help companies design safe and effective medical devices in a wide range of clinical specialties. A listing of currently offered seminars follows. If you're interested in a topic that is not listed, call or e-mail us. We are always developing new offerings.

About the Instructor

Michael Drues, Ph.D., is President of Vascular Sciences in North Grafton, Massachusetts. Vascular Sciences (www.vascularsci.com) offers a full range of services including: prototype design, product development, testing and evaluation, animal and clinical trials, regulatory affairs, technology assessment and business development and intellectual property valuation.

Dr. Drues received B.S., M.S., and Ph.D. degrees in Biomedical Engineering at Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device companies ranging in size from start-ups to Fortune 100 companies. His areas of expertise include medical device design, biocompatibility, physiology and experimental surgery, business development and regulatory affairs.

Dr. Drues is also an Adjunct Professor of Medicine at Northeastern University in Boston, Massachusetts, where he teaches courses in pathophysiology, biotechnology and regulatory affairs.

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Medical Device Design Short-Course Offerings

Designing Cardiovascular Devices: *Begin with the Body in Mind*™

Description: Provides an overview of cardiovascular anatomy, physiology and pathophysiology from a medical device perspective. Unique Begin with the Body in Mind™ approach first tries to understand how the body is "designed" to work – then how to design a medical device to work with the body – not against it! Multiple examples of cardiovascular devices and procedural videos are presented with a discussion of what they do well and where improvements can be made. Suggested Length: 3 Days.

Designing Peripheral Vascular Devices: *Begin with the Body in Mind*™

Description: Provides an overview of peripheral vascular anatomy, physiology and pathophysiology from a medical device perspective. Unique *Begin with the Body in Mind*™ approach first tries to understand how the body is "designed" to work – then how to design a medical device to work with the body – not against it! Multiple examples of peripheral vascular devices and procedural videos are presented with a discussion of what they do well and where improvements can be made. Suggested Length: 2 Days.

Designing Neurovascular Devices: *Begin with the Body in Mind*™

Description: Provides an overview of neurovascular vascular anatomy, physiology and pathophysiology from a medical device perspective. Unique *Begin with the Body in Mind*™ approach first tries to understand how the body is "designed" to work– then how to design a medical device to work with the body – not against it! Multiple examples of neurovascular devices and procedural videos are presented with a discussion of what they do well and where improvements can be made. Suggested Length: 2 Days.

Minimally Invasive Technologies: *Begin with the Body in Mind*™

Description: Overview of minimally invasive technologies including minimally invasive surgery and catheter-based procedures. Multiple examples from cardiology, gastroenterology, urology and other specialties are presented with a discussion of what they do well and where improvements can be made. Suggested Length: 2 Days.

Combination Products: Devices, Drugs and Genes *(New)*

Description: Provides an overview of combination products and the benefits and challenges in combining drugs and genes with medical devices. Basic molecular biology and biochemistry is discussed from the perspective of medical device design. Additional testing and regulatory requirements are discussed. Suggested Length: 2 Days.

Regulatory Affairs for Non-Regulatory Professionals *(New)*

Description: Overview of the regulatory requirements to bring new medical devices to the market and effective strategies in dealing with the FDA. Major differences between medical devices, drugs and biologics will be discussed with emphasis on the emerging area of combination products. Details of domestic vs. international approvals will all be presented. Suggested Length: 2 Days.

Biotechnology for Medical Device Professionals *(New)*

Description: Provides an introduction to the biotechnology industry including important concepts in molecular biology, biochemistry and immunology from the perspective of medical device design. Additional testing and regulatory requirements are discussed. Major differences between medical devices, drugs and biologics will be discussed with examples from the emerging area of combination products. Suggested Length: 2 Days.

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