LIFE SCIENCE
TRAINING INSTITUTE

Training by Type | Training by Industry | Resources | FAQ | Testimonials

How To Take Advantage Of The Companion Diagnostics Opportunity

Date: November 13, 2014
Time: 1pm - 2:30pm EST
Duration: 90 Minutes - Online
Price: $299 - Introductory Rate

REGISTER NOW!

Course Description:

It's not enough for pharmaceutical companies to simply bring a new drug to market. Regulators and insurers are asking companies to develop tests to identify which patients will benefit from a drug *before* they take it, thereby sparing other patients needless side effects and expense. Further, clinical trials can be made smaller and less costly by restricting them to patients most likely to benefit from the drug.

The promise of companion diagnostics (CDx's), a subset of in vitro diagnostics, has a market valued at $26B and is expected to grow 23% per year in the coming decade. With the price of individual genome sequencing now $1K and dropping, more than 90 collaborations between pharmaceutical and medical device companies have already begun. Current applications include lung cancer, colorectal cancer, breast cancer and melanoma. CDx's also represent a platform technology that can be applied to many conditions including CNS, infectious disease, cardiovascular disease and more. As a result, more than 10M tests using CDx's are expected to be ordered between 2014 and 2024.

Using the case study approach, participants will gain a working understanding of the following:

- What are CDx's and how are they used?
- How are CDx's currently regulated?
- How can CDx's make clinical trials smaller, cheaper, and perhaps eliminate placebos?
- How to effectively partner a pharma and device company to commercialize CDx's?
- What does the future hold?

This unique webinar demonstrates important regulatory requirements and concepts using case study discussions of real products from a variety of clinical specialities. Multiple examples of products on the market, under development and on the drawing board (including videos!) are presented in an interactive format. The webinar concludes with a look at the challenges for the future of the companion diagnostics and how we can meet them.

Who Should Attend

Geared for both experienced medical device and pharmaceutical professionals as well as those new to the industry, this webinar is designed specifically for those who need a better understanding of the regulatory requirements necessary to bring companion diagnostics to market. It is also designed for those coming from the pharmaceutical or medical device worlds and now are working on companion diagnostics.

Scientists, engineers and technicians working on device design and development, product and product development managers, business development managers, marketing managers, QA/QC personnel, regulatory affairs professionals, investment and acquisition specialists and field service engineers will all benefit from this webinar.

Instructor Bio

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, 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.