

## 5<sup>th</sup> International Conference and Exhibition on **Pharmaceutical Regulatory Affairs**

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### **Pharmacogenomics: The future of clinical trials, new product development and the practice of medicine**

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**Description:** Pharmacogenomics, also known as personalized medicine, has received increased attention in recent years. But what is pharmacogenomics and is it really a new idea? Pharmacogenomic ideas and technologies have the potential to impact numerous areas of medicine including clinical trials, new product development & manufacturing and the practice of medicine. And with the recent deaths due to fungal meningitis from the New England Compounding Center, what will be the ramifications not just on traditional compounding, but more importantly on pharmaceutical and medical device manufactures now and in the future. Appreciating what the future may hold will better prepare us for what has yet to come. During this presentation, participants will be exposed to a broad mix of pharmacogenomic ideas and applications currently on the market, under development, on the drawing board and beyond. See 'Pharmacogenomics may change the way medicine is practiced' for more.

**Goal(s):** "Simply put... the goal of this presentation is to get people to think! To purposely provoke them, to look at the way we develop and manufacture medical products today and ask does it make sense? Regrettably, far too few seem to be willing to do this. Many seem to be content with the status quo; to continue to do what we have been doing in the past for no other reason than that's the way we have done it, OR that's the way others do it, or worse, that's what is required. Using many real case studies, I try to teach people how to think not what to think. This is all too uncommon in medical technology. My mantra is simple: if you always do what you always did, you'll always get what you always got. Alternatively, if you always think the way you always thought, you will also always get what you always got. It seems this happens all the time. The problem is if everyone thought this way, we would still be living in caves... in medical development, in medicine in general and in life, we must always question the status quo. We can and should do better! That's the takeaway from this workshop." – Dr. Michael Drues.

### **Biography**

Michael Drues, PhD, is the 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 programming, brain-storming sessions, prototype design, product development, bench top & animal testing, regulatory strategy & clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment. He received his BS, MS, and PhD 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 US 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. He 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 US 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, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, he teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination

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