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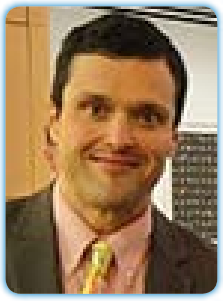

Michael Drues

Vascular Sciences, USA

Commercializing disruptive medical technologies in an evolutionary world

Most product development in medical technology is evolutionary, i.e. make a drug or medical device then modify it slightly to create a new drug or device. There are many advantages to this approach but there are disadvantages as well. For example, the light bulb did not evolve from the candle nor did the car evolve from the horse. You can tweak a horse as many times as you want but you will never end up with a car! The light bulb and the car are examples of revolutionary a.k.a. destructive technologies. Our current regulatory environment was designed for and indeed encourages evolutionary advancements. However, when it comes to bringing revolutionary or disruptive technologies to market, the regulatory challenges are immense. Using case studies from 3-D printing, pharmacogenomics, tissue engineering and nanotechnology, this presentation will discuss the regulatory challenges of commercializing revolutionary technologies in an evolutionary world and how manufacturers can successfully meet them.

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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