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Biomedical nanotechnology: The smaller the thing, the bigger the challenge !

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Regulation and innovation are often diametrically opposed. In other words, the more regulation we have, the less innovation that takes place and vice versa. While certainly not always the case, it is often true and there are many examples. Perhaps even more interesting however, is that the reverse is also often true; in other words, when there is little regulation, when the regulation that does exist is vague or nebulous, or indeed, when there is no regulation at all, this can also inhibit innovation. Biomedical nanotechnology is the perfect example. How do you successfully bring a product to market when there is no precedent and little or no regulation or guidance to follow? To many, this represents an insurmountable obstacle. To others however, although the challenges are indeed great, this presents the opportunity to create a path where few have gone before. In addition, it offers the opportunity to design a regulatory strategy that will not only get your product on to the market but act as a barrier to entry for your competition as well. Using regulatory strategy as a competitive weapon demonstrates the true art of regulatory science. Using the case study approach, the author will explore some of the myriad of applications being considered in the broad area of biomedical nanotechnology. He will also discuss some of the challenges that regulatory professionals face when working on new frontiers such as these. The presentation will conclude with a unique group-based case study designed to involve the audience and allow them to begin to develop the skills necessary to work in this interesting and exciting area.

Biography

Michael Drues, PhD, 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. 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 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. 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 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. Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Medical Technology & Biotechnology at several universities & medical schools on-ground & on-line.

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