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Future medical applications in 3-D printing: Clinical benefits, regulatory issues & manufacturing challenges™

Is printing a knee really any different than printing a drug? The regulatory strategies are exactly the same! Interested in 3-D printing applications in medicine, not just what we are doing today but what we could be doing in the future and how do we get there? For example, can we 'print' medical devices? can we 'print' permanent implants? can we 'print' combination products? can we 'print' drugs (i.e., new molecular entities)? can we 'print' living tissue? What are the technical and regulatory challenges these new technologies pose? Using case studies from a variety of clinical specialties, all of these and more will be discussed in this interactive webinar. Strategies for using regulation as a competitive advantage will also be discussed.

- understand what is currently being done in biomedical 3-D printing
- appreciate the technical and regulatory challenges and how to address them
- be aware of applications and technologies underdevelopment

Biography

Michael Drues is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including stimulating & innovative educational programing, creative regulatory strategy & complete regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, clinical trial design, reimbursement, clinical acceptance, business development & technology assessment. Dr. Drues received his B.S., M.S., 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. Dr. Drues 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 Medicaid 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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