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Combination products and convergence: An overview of clinical benefits, regulatory issues & manufacturing challenges

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An estimated 30% of all new healthcare products under development today are combination products. Why? Because drugs, biologics and medical devices, when used alone, can only slow or stop the progression of disease or injury. In order to tackle the clinical problems of the future, these products will be combined (called combination products) to treat a wide range of diseases from heart attack and stroke to Alzheimer's, cancer, diabetes and beyond! In fact, every area of medicine will benefit because we can potentially erase the damage of disease or injury not just stop it - that's not the next evolutionary advance in medicine, that's a revolutionary advance, a change in the ethos of how why approach medical problems! Today, the best known example of a combination product is the drug-eluting stent. Other examples include companion diagnostics and antibody-drug conjugates but that's just the beginning. What about delivering multiple drugs and biologics on a single device? And what if we apply these drugs and biologics to the device at the patient's bedside based on that particular patient, i.e., personalized medicine? Or we use one combination product to deliver another combination product? In fact, the true scope of combination products is even broader and includes the emerging areas of therapeutic foods and consumer products as well. The possibilities are endless and the best is yet to come! The quintessential example of a combination product is what we are now doing in tissue engineering (a.k.a. regenerative medicine) and biomedical nanotechnology. During this interactive workshop, participants will be exposed to a wide range of examples of combination products on the market, under development and on the drawing board.

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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