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The many connotations of risk and the consequences of getting them wrong

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Risk is a topic of importance from both regulatory and quality perspectives. However, despite have systems and standards in place, not dealing with risk appropriately continues to be a frequent cause of problems to the industry. Risk mitigation typically starts with a brainstorming session: the product development team randomly rattles off risks and writes them down. This "cherry-picking" approach is a haphazard process because whether you spend an hour or a year, you can never be certain you have captured all the important risks. This workshop is not the typical ISO14971, QMS or Design Control approaches which although commonly followed, all take a very limited view of risk and is simply not adequate! During this workshop, a systematic, engineering-minded approach to risk is presented. Multiple examples of devices are used to demonstrate:

What are the three buckets of risk and how to apply them?
What's the difference between a risk mitigation strategy and a risk management plan?
How to deemphasize or not draw attention to certain risks?
What's the relationship between risk mitigation and product liability?
How to handle risks in off-label uses without creating product liability nightmares?
How to factor regulatory risk into the equation?

Ultimately risk is not a simple matter. Manufacturers need to understand the impact of risk mitigation strategy on a regulatory submission as it can make or break a submission, especially a 510(k) or de novo. Your risk management plan is also very important, not just to meet the design control requirements, but in terms of product liability, as well. A successful medical device manufacturer must carefully consider not only what you say regarding risk and how you say it, but also what you don't say and how you don't say it! What to know more? See: How to Think Outside the Checkboxes of Risk Management. Using the Bucket Method for Medical Device Risk Management. Significant Risk vs. Nonsignificant Risk Devices - What's the Difference? Risk Management from a Regulatory & Product Development Perspective. Intersection of Usability and Risk Management (April, 2017). The Many Connotations of Risk and Consequences of Getting Them Wrong. Risk Management for Medical Device Manufacturers

Biography

Michael Drues, Ph.D., 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 & completive 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 Ph.D. 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 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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