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Who does design control best? (Successful medical device manufacturers do)

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Abstract

Design Control can be seen either as a hindrance to engineers or as a very efficient tool for organizing and integrating research and development efforts with those of manufacturing, quality and regulatory. I have had the good fortune to be a contributor to nine mergers or acquisitions of successful medical device companies with which I've had affiliations in the past 25 years. A unique hallmark of each of these success stories has been the embracing of a robust design control system by all involved, from Senior Management through every functional area in the company. From initial concept to review and approval of specifications, design inputs can be documented in a relatively painless but methodical way. Likewise, clear, concise design outputs have been a common denominator for successful medical device companies. With the advent of the new ISO 14971:2012 principles for risk management, and the need to integrate post-commercialization device experience into the product life cycle, design controls have quickly evolved into a scalable technique for managing regulatory obligations, investor expectations and lean manufacturing. This presentation will highlight a brief background of the history of design controls, include the context for design control versus the present environment that the medical device industry finds itself in now, and will compare the best design control practices of the acquired companies with which I've worked. Last, I will also discuss what to do when good medical devices go bad, with respect to design controls and the medical device regulations (specifically, the Quality System Requirements).

Biography

Steve Jwanouskos has over 25 years of medical device industry experience, all involving novel medical technologies that have transformed medicine. Special areas of focus have been new devices for cardiovascular, ophthalmology, radiation oncology, immunology, and orthopedics. Devises have included intravascular ultrasound, laser and radio-frequency ablation, software-controlled electronic systems, permanent implants, combination products, and wireless diagnostic telemetry. Network includes professional contacts in Japan, Taiwan, Canada, U.K., Germany, Hungary, Poland, Benelux, and Australia. Educated at the University of Minnesota (Bachelor of Science, Rhetoric: Scientific and Technical Writing and Editing).