

23D – Design Controls

Presenter

Joseph Azary, Manager Quality & Regulatory Division, Orchid Design - jazary@rcn.com

Session Summary

Joe Azary provides an overview of design control process, which includes design planning, design organizational interface, design input/output, verification and validation. During the session, he also discusses clinical evaluation, efficacy, safety, and design risk management.

About the Presenter – Joseph Azary

Joseph Azary, Manager Quality & Regulatory Consulting Division, Orchid Designs, Joe has over 19 years in the medical device/healthcare products industry. He has a bachelor's degree in Biological Sciences from the University of Connecticut and a Masters Degree in Business Administration (MBA), with a concentration in Public Health, from Sacred Heart University. Joseph is an ASQ Certified Quality Auditor (CQA), Regulatory Affairs Certified (RAC), and he completed and passed the Lead Assessor Training Course. While in college, Joseph worked as a Laboratory Technician at a hospital performing blood and urine analysis and prepping patients for EKG's. Additionally, Joseph worked as an Analytical QC Chemist at Procter & Gamble /Vicks division.

He was employed in various regulatory and quality positions by the U.S. Surgical Corporation, Johnson & Johnson, and Fuji Photo Film's medical division. Responsibilities in these jobs ranged from quality system development, internal and supplier auditing, ISO certification, recall coordination, customer complaint handling, adverse event reporting, environmental, health & safety compliance, FDA compliance and submissions, and international regulatory compliance.

Joseph ran his own consulting firm, Azary Technologies between 1999 & 2008. In 2008 Orchid Design acquired Azary Technologies. Joseph currently runs the Quality & Regulatory consulting division at Orchid Design. He has worked with over 160 companies ranging from Fortune 500 companies to small startup companies. Joseph has experience with all types of medical devices ranging from cardiovascular, neurological, sterile disposables, surgical instruments, radiology and x-ray, software, electrosurgical equipment, endoscopes, wound dressings, gynecological devices, physical therapy devices and wheelchairs, orthopedic implants, in-vitro diagnostic, combination devices, pediatric, ultrasound, and a variety of medical devices. He worked with companies that manufacture electronics, plastic molding, metal machine, assembly, chemical mixing, and clean room assembly.

Orchid Design provides services ranging from Quality System Development (ISO 13485, FDA QSR), Regulatory Compliance, Internal and Supplier Auditing, Training, FDA submissions including 510k, FDA Compliance including labeling, registration, listing, recalls, and MDR reporting, U.S. Agent services, and international regulatory compliance including CE marking (European MDD) and Canadian Medical Device Regulations.