

SUMMARY

Dan is an acknowledged quality systems expert that has provided consulting services for over 200 medical device and pharmaceutical companies in design controls, software validation, and safety risk management practices. He has been contracted by FDA to train investigators and to provide inputs to software validation guidelines. Speaker at over 50 American Society for Quality (ASQ) and other professional conferences. Author and presenter of over 50 seminars on Computer System Validation, Safety Risk Management, and Part 11 requirements to meet FDA and ISO Guidelines. RAB certified ISO 13485:2003 lead auditor with experience from over 100 audits of medical device and pharmaceutical companies. Reviewer for International Organization for Standardization (ISO) WG10 defining software process assessment standards. Ten years experience as a software engineering instructor at undergraduate and graduate levels.

CONSULTING

Consultant to leading companies in the medical device and pharmaceutical industry to support definition of regulatory strategies, implementation of quality systems, 510(k) and PMA submissions, and optimization of design control and computer system validation processes. Consulting role includes assuring regulatory compliance as well as providing recommendations for continual improvement in accordance with the best practices of industry leaders. Consulting style integrates expertise in FDA and ISO regulations, lessons learned from experiences in working with over 200 customers in engineering design and validation methods, keen understanding of quality system principles and knowledge of business management practices.

DESIGN AND VALIDATION EXPERIENCE

Provides software consultation and independent testing services for medical and pharmaceutical manufacturers and the FDA. Clients include manufacturers of: imaging systems, pharmaceuticals, infusion pumps, catheters, linear accelerators, diagnostic equipment, lasers, and others. Services include: system validation, application of design controls, training, documentation support, software and system safety risk management, assay design, and definition of standard operating procedures to meet the requirements of the FDA GMP/cGMP Regulations and ISO 13485:2003. Performs engineering audits/assessments and provides support to staff on development methods, design approaches, programming standards, metrics, and test techniques to meet FDA validation guidelines for regulatory compliance and submissions. Services focus on implementation of cost effective process improvement capabilities as well as satisfaction of regulatory requirements.

SEMINARS AND PRESENTATIONS

Dan is the leading industry author of seminars on design control and validation approaches to meet FDA and ISO guidelines for general audiences, FDA inspectors, and on-site developer facilities. Author of seminars on safety risk management, design controls, and electronic record and electronic signature compliance. Seminars have focused on practical application of cost effective techniques and lessons learned emphasizing regulatory requirements as well as good business practices. Also presented seminar on the Software Engineering Institute software Capability Maturity Model and software maturity levels.

FDA SUBMISSIONS

Dan provides 510(k) and PMA submissions to the FDA for a wide range of medical devices from cardiac lasers to diagnostic devices. His insights to device classification categories and study requirements have resulted in significantly reduced review times and substantially greater scope of device clearances. FDA experience and history as a consultant to the FDA has greatly facilitated coordination with FDA reviewers.

AUDITOR

Twelve years of quality system audit experience and seven years as a certified ISO 13485:2003 lead auditor (over 100 quality system and process improvement audits). Audits have targeted compliance with FDA regulations and ISO standards as well as process improvement. Practical audit recommendations are based on best practices from industry leaders. Audit recommendations have resulted in significant cost saving and reduced time to market as well as increased regulatory compliance.

ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES

Performed gap analysis for numerous companies regarding compliance with 21 CFR Part 11 requirements for electronic records and electronic signatures. Support efforts included training programs, development of procedures, system prioritization, and definition of an implementation plan. Implementation strategies are designed to reduce compliance risk and maximize business benefit.

SOFTWARE DEVELOPMENT EXPERIENCE

Extensive experience in the development and management of software development applications. Software development efforts have been fully documented consistent with established regulatory requirements. Development experiences range from real-time applications for medical devices and airspace management to applications in quality system measures, diagnostic devices, and manufacturing processes.

INSTRUCTOR

Over ten years experience as a faculty member at National University School of Computer and Applied Sciences and instructor for University of California at San Diego (UCSD) Extension program. Classes include software engineering, programming languages, design methods, process improvement, and software verification and validation.

CERTIFICATION

- Certified Quality Systems Lead Auditor by Registrar Accreditation Board (RAB), Nov. 1994.
- Certificate in Data Processing (CDP) from the Institute for Certification of Computer Professionals, 1983.

EDUCATION

- MS/Computer Systems Management, Naval Postgraduate School, 1983
- BS/Systems Engineering, U.S. Naval Academy, 1977

PUBLICATIONS

1. Olivier, Daniel P., March 2006, A Comparison of Software Development Methods in a Regulated and Commercial Environment, Software Quality Professional.
2. Olivier, Daniel P., Chase, Marta, June 2004. Design Control Practices for IVDs, IVD Technology.
3. Olivier, Daniel P., 2003. The Biomedical Quality Auditor Handbook, Chapter 11 *Risk Management* and Chapter 17 *Software*. ASQ Quality Press.
4. Olivier, Daniel P. and Christine Engelke, July 2002. Putting Human Factors Engineering into Practice. Medical Device and Diagnostics Industry Magazine.
5. Olivier, Daniel P. and Dwane Paschal, October 2001. Using Measurement to Improve Quality. Medical Device and Diagnostics Industry Magazine.
6. Olivier, Daniel P., September 2000. Developing Design Control Strategies to Meet Technology Advances. Medical Device and Diagnostics Industry Magazine.
7. Olivier, Daniel P., April 2000. Audits that Go Beyond Compliance and Assure Process Improvement. Regulatory Affairs FOCUS.
8. Olivier, Daniel P., May 1999. Management Review: Establishing Quantitative Measures. Regulatory Affairs FOCUS.
9. Olivier, Daniel P., March 1999. Process Improvement through Error Analysis. Medical Device and Diagnostics Industry Magazine.
10. Olivier, Daniel P., Orkin, Frederick, March 1999. *Computers and Quality*. Juran's Quality Control Handbook, Fifth Edition. McGraw-Hill, Inc.
11. Olivier, Daniel P., September 1998. Design Controls: Achieving Compliance and Staying Competitive. Regulatory Affairs Focus.
12. Olivier, Daniel P., August 1997. Ten Techniques for Trimming Time to Market. Medical Device and Diagnostics Industry Magazine.
13. Olivier, Daniel P., July 1996. Implementation of Design Controls Offers Practical Benefits. Medical Device and Diagnostics Industry Magazine.
14. Olivier, Daniel P., July 1995. Software Safety: Historical Problems and Proposed Solutions. Medical Device and Diagnostics Industry Magazine.
15. Olivier, Daniel P., 1994. IEEE Software Engineering Standards: Medical Device Applications, Designer's Handbook: Medical Electronics. Canon Communications, Inc.
16. Olivier, Daniel P., Konrad, Michael D., and Weber, Markus. June 1994. Using Software Assessment Standards. Medical Device and Diagnostics Industry Magazine.
17. Olivier, Daniel P., July 1993. Required Documentation for Software Validation. Medical Device and Diagnostics Industry Magazine.
18. Olivier, Daniel P., October 1992. ISO 9000-3: Valuable New Guidance for Software QA. Medical Device and Diagnostics Industry Magazine.
19. Olivier, Daniel P., January 1992. Inspections: A Successful Approach to Achieving High Quality Software. Medical Device and Diagnostics Industry Magazine.
20. Olivier, Daniel P., June 1991. Lessons Learned in the Application of Software Safety. Medical Device and Diagnostics Industry Magazine.