SOFTWARE QUALITY CONSULTING

consulting • training • auditing

Steven R. Rakitin

Summary:

Medical Device Software and FDA compliance, Safety-critical software, Software Quality Assurance, Verification & Validation, Software Development, Auditing, Process Improvement, Training, Testing, Expert Witness.

Education:

- BS Electrical Engineering/Power Systems, Northeastern University
- MS Computer Science, Rensselaer Polytechnic Institute
- IEEE Software Reliability Seminar
- ISO-9000 Lead Auditor Training
- ASQ Certified Quality Auditor (CQA)
- ASQ Certified Software Quality Engineer (CSQE)
- Introduction to the SEI Capability Maturity Model

Experience:

Software Quality Consulting Inc. 1998 - present

President

My consulting practice is focused on helping clients design and develop medical device software in a manner that is safe and compliant with applicable FDA regulations, guidance documents, and international standards. I have worked with over 100 medical device manufacturers providing consulting, auditing and training services as needed. I have also participated in several industry conferences as an invited speaker, have published papers on medical device software topics, and participated in industry-FDA committees that have published guidance on software-related topics.

Ciba Corning Diagnostics Corp. 7 years

Manager of Regulatory Compliance

In this role, I was responsible for assessing compliance with FDA GMP regulations and ISO-9000 standards by performing periodic audits at five development and manufacturing facilities. I prepared 510k submissions for several products and worked with FDA reviewers to get the submissions cleared.

Manager of Software Quality Assurance

Established SQA function for the R&D organization. In this role, I was responsible for Software Verification and Validation for several in-vitro diagnostic medical instruments and data management products. I actively participated in R&D software and hardware development activities. I provided technical and administrative management for SQA Group of 8 people.

I developed a Software Engineering Handbook tailored to the needs of business. I developed a similar handbook for software developed used to create test equipment. I led a cross-functional team in developing a New Product Development Process encompassing Engineering, Manufacturing, and Service.

Viewlogic Systems, Inc. 2 years

Director of Corporate Quality

Reporting to the President, I established a corporate Quality function with overall responsibility for improving Viewlogic's Quality System. My primary focus was on product and process improvements, Customer Satisfaction, and ISO-9001/TickIT compliance. I coordinated software process improvement initiatives with software development groups working in both Unix and NT environments. I helped create and manage a new program for measuring Customer Satisfaction. I initiated a Supplier Quality program for third party software. I developed improved software-licensing processes. I provided training to improve effectiveness of internal testing. I helped establish a Viewlogic User Group and had frequent customer contact.

GenRad, Inc. 2 years

Manager of Operating Systems Group

I was responsible for developing GenRad-specific modifications for Ultrix and SunOS to support GenRad's 275x Board Test product line based on a MicroVAX Fileserver and Sun Workstations. I developed requirements and high-level design for a Unix disk partition utility using the Quality Function Deployment (QFD) methodology. Developed test plans for evaluating alpha and beta releases of GenRad's Ultrix and SunOS.

Wang Laboratories, Inc. 4 years

Principal Engineer

Advanced Workstation (42x) Project. User Interface Team. Developed a common set of user interface widgets for Wang application developers. Wrote a functional description of widget features and application program interfaces. Designed and implemented support functions for several widgets including icons, paragraph fields, and text integration across applications.

Distributed Management Facility Project. Project leader for Network Management product. Reverse-engineered the product and wrote a Functional Spec and a System Design Spec. The System Design Spec provided the basis for a cooperative test plan developed with the QA group for testing prior to first customer ship.

Telco Systems Fiber Optics Corp. 2 years

Principal Engineer

TELTRAC Project. TELTRAC was a menu-driven, real-time, network monitoring and control application developed for Telco's telecommunication equipment. Reverse engineered the TELTRAC product and wrote a complete Functional Spec, which served as the basis for adding new features, developing marketing brochures, and improving customer-training courses. Based on this document, developed a comprehensive System Integration Test Procedure. Developed a Software Life Cycle Model as part of Telco's New Product Development Process.

Telos Consulting Services, Inc. 3 years

Member of Technical Staff

Assigned to M/A-Com Linkabit, Inc. The Dual Modem was a military airborne system that provided network control protocol and user interface to establish air-to-ground communications. Designed the user interface and wrote a Detailed Software Design Specification, including a functional overview, module descriptions, pseudo-code, and data structure declarations.

Assigned to Millipore Corp. - Waters Chromatography Division. Designed and implemented screen editors and menus, which allow users to perform Gel Permeation Chromatography for a Workstation-based product. Designed and implemented a menu-driven user interface for a Gradient-controller product.

SofTech, Inc. 5 years

Manager of Software Quality Assurance

Established SQA function. Provided technical and administrative management for a group of Software Engineers who performed Software QA and Configuration Management functions.

Ada Language System Project. Under contract to the US Army, SofTech developed the first Ada Compiler for the DoD. Performed detailed technical reviews of high-level and detailed software design documents for compilers, assemblers, linkers, debuggers, and database management tools designed by SofTech. Developed an overall Test Plan and specific Test Procedures for testing the Ada Compiler using the Ada Compiler Validation Capability Test Suites. Participated in the development of configuration control and regression testing tools.

ITT Telecommunications Switch Project. Responsible for providing an independent technical assessment of telecommunications software developed by ITT. Reviewed and evaluated Program Performance Specs, Program Design Specs, Test Plans and Test Procedures as well as software development practices. Developed and applied a set of software quality metrics to code written by ITT.

Combustion Engineering, Inc. 5 years

Senior Engineer

Developed software for monitoring critical parameters in nuclear power plant control systems. Developed real-time control software for a microprocessor-based in-core neutron flux detector. Prepared requirements for advanced control room designs.

Researched structured software development methodologies appropriate for developing critical software for safety-related functions in nuclear power plant control and protection systems.

Professional Affiliations:

IEEE Life Senior Member
IEEE Computer Society

References:

Will be furnished upon request.

Books:

Software Verification & Validation for Practitioners and Managers, 2nd. ed., Norwood, MA: Artech House Inc., 2001.

Articles:

“What can Software Quality Engineering Contribute to Cybersecurity?” ASQ Software Quality Professional, Vol. 18 No. 2, March 2016

“Networked Medical Devices: Essential Collaboration for Improved Safety”, AAMI *Biomedical Instrumentation & Technology*, vol.43, no. 4, pp. 332-338, July-August 2009.

“Coping with Defective Software in Medical Devices”, IEEE *Computer,* vol. 39, no. 4, pp. 40-45, April 2006.

"Creating Accurate Estimates and Realistic Schedules", ASQ *Software Quality Professional*, vol. 4, no. 2, p. 30-36, March 2002.

"Balancing Time to Market and Quality", ASQ *Software Quality Professional*, vol. 1, no. 3, pp. 54-57, June 1999.

"Revisiting the Software Development Process", *Medical Device & Diagnostic Industry*, vol. 16, no. 5, pp. 232-236, May 1994.

"Experience Performing Software Quality Assurance on the Ada Language System Project", *Proc. IEEE Sixth International Conf. on Software Engineering*; Tokyo, Japan, September 1982.

"Validation of Safety System Software", International Atomic Energy Agency Specialists Meeting on Software Reliability for Computerized Control of Safety Systems in Nuclear Power Plants", Pittsburgh, PA, July 1977

Conference Presentations:

“Requirements Based Estimating & Scheduling Best Practices,” QAI QuEST Conference, Chicago, IL April 21, 2009.

“Management's Role in Achieving Predictable Software Development”, QAI QuEST Conference, Chicago, IL April 22, 2009.

“How Clinicians and Medical Device Manufacturers Can Collaborate to Reduce Risk”, invited keynote at Inaugural Medical Device Connectivity Conference, Harvard Medical School, Boston MA, September 10, 2009

“Software Verification and Validation for Practitioners and Managers”, Northeast Quality Council 57th Annual Conference, Marlboro, MA, October, 13, 2008

“Improving Software Reliability”, Northeast Quality Council 57th Annual Conference, Marlboro, MA, October, 15, 2008

“Requirements based Estimating and Scheduling Best Practices”, QAI QuEST Conference, Toronto, ON, September 22, 2008

“Managing a Software Quality and Testing Group”, QAI QuEST Conference, Toronto, ON, September 25, 2008

“Managing a Software Quality and Testing Group”, QAI QuEST Conference, Chicago, IL, April 30, 2008

“Software Verification and Validation for Practitioners and Managers”, QAI QuEST Conference, Chicago, IL, April 29, 2008

“Software Verification and Validation for Practitioners and Managers”, Software Process Improvement Symposium, Edison, NJ, October 29, 2007

“Software Reliability Basics for Embedded Systems”, Embedded Systems Conference, Boston, MA, September 19, 2007

“Software Verification and Validation for Practitioners and Managers”, presented at Embedded Systems Conference, Boston, MA, September 18, 2007

"Improving the Effectiveness of Software Testing", QAI Quality Assurance Association of Maryland Conference, Baltimore, MD, September 14, 2007

"Software Verification and Validation", Association for Advancement of Medical Instrumentation Annual Conference, Boston MA, June 18-19, 2007

"Software Validation Revisited", ASQ New England Biomedical Division Discussion Group, Dedham, MA, January 26, 2006.

"Assessing the Effectiveness of Software Validation Testing", Invited tutorial, 4th Annual Best Practices in Software Design for Medical Devices Conference, IQPC, Boston, MA, March 21, 2005.

"Effective Risk Management Techniques for Software-based Medical Devices", BOSCON 2005, ASQ Boston Section's Annual Quality Conference, Burlington, MA, April 7, 2005.

"Improving the Effectiveness of Medical Device Software Validation", 2005 Annual Meeting of the Association for the Advancement of Medical Instrumentation (AAMI), Tampa, FL, May 16, 2005.

"Improving the Effectiveness of Medical Device Software Validation", 55th Annual ASQ North East Quality Council Conference, Marlboro, MA, October 20, 2004.

"Assessing the Effectiveness of Software Validation Testing", Invited tutorial, 3rd Annual Best Practices in Software Design for Medical Devices Conference, IQPC, Chicago, IL, September 27, 2004

"Utilizing Risk Management Techniques for Software Based Medical Devices", Invited tutorial, 3rd Annual Best Practices in Software Design for Medical Devices Conference, IQPC, Chicago, IL, September 27, 2004

"How Effective is your Software Testing Efforts?", BOSCON 2004, ASQ Boston Section's Annual Quality Conference, Burlington, MA, April 8, 2004.

"Assessing the Effectiveness of Software Testing", ASQ 58th Annual Quality Conference (AQC), Toronto, ON, Canada, May 25, 2004.

"Software Development for Medical Device Manufacturers", Invited tutorial BOSCON 2003, ASQ Boston Section's Annual Quality Conference, Burlington, MA, April 10, 2003.

"An Overview of Software Verification and Validation", 56th ASQ Annual Quality Congress, Denver, CO, May 2002.

"A Holistic Approach to Software Quality", BOSCON 2002, ASQ Boston Section's Annual Quality Conference, Burlington MA, April 11, 2002.

"Software Development for Medical Device Manufacturers", Invited tutorial. BOSCON 2001, ASQ Boston Section's Annual Quality Conference, Burlington, MA, March 16, 2001.

"Software Verification & Validation – An Overview for Practitioners", Invited tutorial. 17th Annual Pacific Northwest Software Quality Conference, Portland OR, October 11, 1999.

"Software Verification & Validation – An Overview for Practitioners", Invited tutorial. 1999 Annual Meeting of the Association for the Advancement of Medical Instrumentation (AAMI), Boston, MA, June 5, 1999.

"Software Verification & Validation – An Overview for Practitioners", Invited tutorial. 15th Annual Pacific Northwest Software Quality Conference, Portland OR, October 27, 1997.

"The Economics of Software Process Improvement", Health Industry Manufacturers Assoc. (HIMA) Conference on Medical Device Software, Washington DC, May 1994.

"Practical Methods for Cost-effective Verification and Validation of Medical Device Software", Health Industry Manufacturer's Assoc. (HIMA) Conference on Medical Device Software Development and Product Submissions, Washington DC, December 1992.

"Factors Influencing the Software Development Process for In-vitro Diagnostic Instruments", Assoc. for the Advancement of Medical Instrumentation (AAMI) 27th Annual Conference; Anaheim, CA, June 1992.