

**Steven R. Rakitin**

**Summary:**

Software Quality Assurance, Verification & Validation, Software Development, Process Improvement, Inspections, Automated Testing, Management, ISO-9000, TickIT, FDA GMP/QSR, Auditing.

**Education:**

- BS Electrical Engineering/Power Systems, Northeastern University, 1973
- MS Computer Science, Rensselaer Polytechnic Institute, 1979
- IEEE Software Reliability Seminar, 1991
- ISO-9000 Lead Auditor Training, 1994
- ASQ Certified Quality Auditor (CQA), 1994
- ASQ Certified Software Quality Engineer (CSQE), 1996
- Introduction to the SEI Capability Maturity Model, 1996

**Experience:**

**Software Quality Consulting Inc.** 1997 - present  
**President**

Established a consulting practice focused on helping clients create Predictable Software Development Processes.

**Viewlogic Systems, Inc.** Jan 1996 - 1997  
**Director of Corporate Quality**

Reporting to the President, I established a corporate Quality function with overall responsibility for improving Viewlogic's Quality System. Primary focus on product and process improvements, Customer Satisfaction, and ISO-9001/TickIT compliance. Coordinated software process improvement initiatives with software development groups working in both Unix and NT environments. Managed program for measuring Customer Satisfaction. Initiated a Supplier Quality program for third party software. Improved software-licensing processes. Provided training to improve effectiveness of internal testing. Established Viewlogic User Group. Frequent customer contact.

**Ciba Corning Diagnostics Corp.** 1990-1996  
**Manager of Regulatory Compliance**

Responsible for assessing compliance with FDA GMP regulations and ISO-9000 standards by performing periodic audits at 5 development and manufacturing facilities. Prepared and submitted 510(k)s for several devices.

**Manager of Software Quality Assurance**

Established SQA function for the R&D organization. Responsible for Software V&V for in-vitro diagnostic medical instruments and data management products. Actively participated in software development activities. Provided technical and administrative management for SQA Group. Developed a Software Engineering Handbook tailored to needs of business. Developed a similar handbook for software used in test equipment. Led a cross-functional team in developing a New Product Development Process encompassing Engineering, Manufacturing, and Service.

**GenRad, Inc.**  
**Manager of Operating Systems Group**

1989-1990

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. 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.**  
**Principal Engineer**

1986-1989

**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.**  
**Principal Engineer**

1985-1986

**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.**  
**Member of Technical Staff**

1983-1985

**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.**  
**Manager of Software Quality Assurance**

1978-1983

Established SQA function. Provided technical and administrative management for a group of 8 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.**  
**Senior Engineer**

1973-1978

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 Computer Society  
American Society for Quality (ASQ) Software Division  
Association for the Advancement of Medical Instrumentation (AAMI)

**Other:**

Editorial Review Board for *Software Quality Professional*, a new journal published by the ASQ Software Division

**References:**

Will be furnished upon request.

## Books:

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

## Articles:

"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, co-author.

## Conference Presentations:

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

"Assessing the Effectiveness of Software Validation Testing", Invited tutorial, 4<sup>th</sup> 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", presented at BOSCON 2005, ASQ Boston Section's Annual Quality Conference, Burlington, MA, April 7, 2005.

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

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

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

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

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

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

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

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

“Software Verification & Validation – An Overview for Practitioners”, Invited tutorial. Presented at the 17<sup>th</sup> Annual Pacific Northwest Software Quality Conference, Portland OR, October 11, 1999.

“Software Verification & Validation – An Overview for Practitioners”, Invited tutorial. Presented at the 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. Presented at the 15<sup>th</sup> Annual Pacific Northwest Software Quality Conference, Portland OR, October 27, 1997.

"The Economics of Software Process Improvement", Presented at 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", Presented at 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", Presented at Assoc. for the Advancement of Medical Instrumentation (AAMI) 27th Annual Conference; Anaheim, CA, June 1992.