

Curriculum Vitae



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CAREER SUMMARY

Accomplished professional with extensive experience in US and international healthcare regulatory affairs, product risk management, new product design/development regulation, servicing, standards development, and product liability management. Leadership experience with both internal and external (domestic and international) project teams. Creative in accomplishing organizational goals, within a context of comprehensive customer/market knowledge and deep personal integrity. Solid developer of others, capable trainer and interactive public speaker. International team experience in development of standards and processes. Solid computer skills.

Product Risk Management

- Risk Management Team Leadership
- Product Liability Expert Witness
- Product Safety Program Management
- ISO 14971 Standard Development Team Member

Regulatory Affairs

- Provide regulatory leadership
- Participate in product development
- Develop Regulatory Submissions
- International regulatory experience

Quality Systems

- Develop quality systems
- Improve quality systems
- Supplier quality development
- Cross-functional Team Leadership

PROFESSIONAL EXPERIENCE**VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY-Blacksburg, VA****2010 -Present**

University provides undergraduate and graduate education programs. The Healthcare Risk Management program is part of the Food Science and Technology Department.

Adjunct Professor in Healthcare Risk Management graduate on-line program. Co-teach FST-5144 Medical Device Risk Management and Co-teach FST 5174 Risk Management Lifecycle courses leading to certificate or Masters degree on completion of requirements in the program.

BILANX CONSULTING LLC-Sumter, SC**2002 -Present**

Firm provides consulting services to medical device firms in the area of regulatory affairs, product risk management, product litigation and quality systems.

Principal Consultant and Vice President providing training, auditing and consulting services in the area of quality systems, regulatory affairs, and product risk management, including litigation, for over 40 US and international medical device and pharmaceutical manufacturers, including over 5 Fortune 500 companies. Manage training seminars and workshops, and present in a variety of settings from internal company settings to public seminars and college graduate courses. Assist medical device companies in the development of quality systems and risk management processes that comply with all applicable regulations and standards for the markets served by the manufacturer. Provided quality system and product risk management training in US and internationally to industry and regulatory agency personnel.

Member of FDA Hospital Bed Safety Workgroup. Assisted in the research and development of a US FDA Guidance document on Hospital Bed Safety based on human factors and product risk management. The project lasted 7 years after initial research phase of 5 years. As a result of this experience, currently provide expert witness testimony and depositions in product liability cases involving hospital beds.

Member of AAMI/QM/WG01 on Quality System standards, AAMI/QM/WG04 on Application of Risk Management, IEC SC62D MT30 Medical electrical equipment-General requirements for safety, and Liaison from IEC 62A committee on Medical electrical equipment to ISO TC 198 committee on sterilization of healthcare products. As a member of these standards committees assist in the development of national and international standards guiding the design of safe and effective healthcare products. Represent the position of the United States industry in guiding the standards to present the state-of-the-art in safe and effective healthcare products.

4MED CONSULTING-Charleston, SC**2005 -Present**

Firm provides market research, human factors, and full product development services for the medical device industry. Specializes in wound treatment and patient support products.

Participating partner in medical device risk management firm that develops medical devices in area of patient support and wound treatment. Perform risk management, quality system and regulatory affairs functions for the firm. Have successfully developed products for larger firms that have insufficient resources to meet all product needs, as well as smaller firms without their own development resources.

Hill-Rom, Inc.**1988 - 2003**

Held a number of positions with a major medical device manufacturer of long term care, home care, hospital equipment, software systems, and patient room furnishings.

Director – Americas Service Quality**November 2002-May 2003**

Responsible for developing quality plan for the service organization with 168 locations in the United States and Canada. Supported the development of a new quality organization and the quality system. Continued participation in a number of committees and organizations including ISO/IEC TC 210 JWG1 on Risk Management, AdvaMed Technical and Regulatory Committee, IEC SC 62 Liaison with ISO TC 198 and FDA Hospital Bed Safety Workgroup. 2002-2003 Vice-Chair of ASQ Lowcountry Section. Individual contributor reporting to Corporate VP of Quality.

Director – Product Risk**March-November 2001**

Responsible for the direction of all Product Risk Manager obligations. Developed integrated Risk Management process for product development and product maintenance. Managed cross-functional team in this activity and reported to Corporate VP of Quality while awaiting identification of permanent staff.

- Initiated and participated in multi-organization Issue Group, sponsored by the Food and Drug Administration's Office of Surveillance and Biometrics, to produce equipment design guidance, installed equipment assessment methodology and hazard mitigation strategies for at-risk patient populations in Acute and Long Term care environments (Hospital Bed Safety Workgroup).
- Updated product safety and risk management program.
- Provided depositions and supporting documentation for product liability cases.
- Held this position on a temporary basis concurrently with Director, Quality and Regulatory position below

Director, Quality and Regulatory**January 1998 – November 2002**

Responsible for all quality, regulatory, reliability, document control, and code compliance activities for four sites. Responsible for US FDA regulatory compliance and pre-market notification submissions with a variety of Class II products, including software, over three year period. Also responsible for international product approvals, including EC and other countries in Europe, South America, and Asia. Manage staff of ten in leading these activities. Personally perform FDA functions and act as team member in international product approvals. Led team on JCAHO certification project for 167 US home care service locations. Responsible for corporate-wide infection control activities. Member of company global regulatory team, with international meetings on regulatory issues to set company policy. Participated in local ASQ Section activities including participating in examination teams for Trident Quality Award based on Malcom Baldrige Award. Participated in AdvaMed Technical and Regulatory Committee. Reported to Corporate Executive Director of Quality and Regulatory Affairs. Supervised staff of 10 people.

- Appointed US TAG to ISO/IEC JWG1, Risk Management for Medical Devices.
- Appointed Sterilization Liaison IEC SC 62D to ISO TC 198
- Assigned to multiple sites to assist with merged and acquired facility integration
- Examiner for Trident Area Quality Award sponsored by ASQ Section
- Founding member of FDA Hospital Bed Safety Workgroup

Manager, Quality and Regulatory**1994-1998**

Assigned to Charleston, SC facility to integrate the facility into the company after a merger. First employee of new corporate parent company after a merger, responsible for integration of quality system. Led facility in obtaining first North American EN ISO 9001, EN 46001 and Medical Device Directive certification within the company. This facility manufactured US Class I and Class II and European Class IIa and IIb medical devices. Reported to Corporate Executive Director of Quality and Regulatory Affairs. Supervised staff of five people.

- Developed team approach to quality system development and integration
- Established quality system performance model later used across company
- Responsible for all FDA-related activities including submissions and inspections

Manager, Supplier Quality**1992- 1994**

Developed supplier certification process at corporate offices, leading staff of four persons. Responsible for component acceptance activities. Assisted in development of component acceptance and non-conforming material mainframe software system. Adjunct faculty, Purdue University Southeast, teaching third and fourth year quality courses during this period. Worked with company team assessing impact of ISO 9000, European Medical Device Directive and proposed revisions to FDA GMPs. Attended many industry meetings on the proposed regulatory climate changes.

- Member of Management Team developing new model for Purchasing with Supplier Quality as a key component reporting to Purchasing Director.

Supplier Quality Engineer**1988 - 1992**

Responsible for supplier quality program for 400 suppliers. Set up first local area network system in the company, consisting of 64 Quality Department personal computers located in several buildings. Performed Supplier Quality Audits in over 200 supplier facilities. Established Supplier Certification program, and performance measurement system for suppliers. Used computer skills to develop supplier rating system, used to select key suppliers. Reported to Executive Director of Quality and Regulatory Affairs.

EDUCATION

Bachelor of Science –Secondary Science Education
 University of Cincinnati – Cincinnati, Ohio
 Master of Education-Vocational Education Administration
 University of Cincinnati – Cincinnati, Ohio
 Ohio Vocational Education Intern Program
 Kent State University

Also attended various seminars on quality management (including Juran Management of Quality) and statistical quality control (Deming Philosophy), Design of Experiments by Dorian Shainin and many subsequent courses from 1982 to present. Attended various regulatory seminars with AdvaMed, AAMI, and RAPS annually since 1993.

PROFESSIONAL AFFILIATIONS

Association for the Advancement of Medical Instrumentation (AAMI)
 American Society for Quality (ASQ) Senior Member, past Vice-Chair Lowcountry Section 1122, Charleston, SC
 Member, Regulatory Affairs Professional Society (RAPS)

CERTIFICATIONS AND APPOINTMENTS**American Society for Quality****ASQ Fellow**

Certified Quality Engineer, Certificate 18531; Certified Quality Auditor, Certificate 02559;
 Certified Manager of Quality/Organizational Excellence, Certificate 00690



2010
 Certified Manager of Quality/
 Organizational Excellence



2010
 Certified
 Quality Engineer



2010
 Certified
 Quality Auditor

Regulatory Affairs Professional Society

Regulatory Affairs Certified, Certificate 847

Member, **US Food and Drug Administration Hospital Bed Safety Workgroup**

Association for the Advancement of Medical Instrumentation (AAMI)

Appointed, AAMI/EV/WG05, Hospital beds (US national standards committee)

Appointed, AAMI/QM/WG01, Application of quality systems to medical devices (US national standards committee)

Appointed, AAMI/QM/WG04, Application of risk management for medical devices (US national standards committee)

International Electrotechnical Commission (IEC)

Appointed, SC62D, International Liaison to International Organization for Standardization (ISO) TC 198 (Sterilization)

Appointed IEC, SC62D, MT30 (Oxygen and Temperature Hazards)

Miscellaneous

Examiner, Trident Area Quality Award, 1996, 1997

Past Member of Technical and Regulatory Committee, AdvaMed

Past Member of AdvaMed's MTLI Advisory Board

Federal Communications Commission General Radiotelephone License with Radar Endorsement, and Amateur Extra Class Radio License. ARRL

Amateur Radio License Volunteer Examiner.

American Red Cross National Volunteer, Disaster Services Technology Team

Biography listed in *Who's Who in the Midwest, Eighteenth Edition*

Past Board Member, National Alumni Association College of Education, University of Cincinnati.

PUBLICATIONS AND PRESENTATIONS*

Course Development, Medical Device Risk Management, RAPS, August-September 2010.

Course Development, Supplier Management, American Society for Quality, August-September, 2010.

Presenter, *Integrating Risk Management into the Device Quality System*, International Pharmaceutical Academy, Quality Risk Management Conference, Montreal, Quebec, Canada, June 8-9, 2010.

Conference Co-host, *Seventh Annual Medical Device Quality Congress: From Risk Management to Postmarket Surveillance*, FDA News, Bethesda, MD, June 2-4, 2010.

Course Development, Medical Product Risk Management, Round Lake, IL, July 13-15, 2009.

Presenter, *Document Control and Records Management for Medical Devices*, AAMI, San Francisco, April 29-May 1, 2009

Author, *The Commonalities Between Risk Management, Verification and Validation*, PathWise October Newsletter, October 2009

Co-author, *Integrating Risk Management into the CAPA Process*, Biomedical Instrumentation and Technology, November/December 2008.

Presenter, *Understanding and implementing a risk management plan, and Creating a risk assessment that meets requirements of IEC 60601-1 3rd edition*, Informa Life Sciences Conference, Electro-Medical Devices: Design, Regulations and Safety, December 2, 2008, Brussels, Belgium.

Presenter, *Risk Management for Medical Device Manufacturers*, Pathwise, Chattanooga, TN, October, 28-29, 2008, Galway, Ireland, February 25-26, 2010

Presenter, *Risk Management for FDA Regulated Industries*, Pathwise and Master-Control, Chicago, October 9-10, 2008.

Presenter, *Risk Management for FDA Regulated Industries*, Pathwise and Master-Control, Webinar, July 29, 2008.

Presenter, *Product Risk Management for Medical Device and Pharmaceutical Manufacturers*, Hyderabad, India, February 5, 2008 and February 7, Ahmadabad, India; Sponsored by Compliance On-line.

Co-Presenter AAMI Webinar, *Implementing Risk Management into Design of Electrical Medical Devices*, November 6-7, 2007.

Presenter, *Integration of Risk Management to IEC 60601-1 3rd Edition*, January 28, 2008, *Risk Management and the IEC 60601-1 Collaterals*, January 29, 2008, Stockholm, Sweden; *Integration of Risk Management to IEC 60601-1 3rd Edition*, January 31, 2008; *Risk Management in IEC 60601-1, 3rd Edition*, and *Risk Management and the IEC 60601-1 Collaterals*, Frankfurt, Germany, February 1, 2008, sponsored by Synergus.

Presenter, *Design Controls*, Copenhagen, Denmark, October, 17, 2007, Bergen, Norway, October 18, 2007, sponsored by Synergus.

Presenter, *Process Validation*, Copenhagen, Denmark, October 15, 2007, Sponsored by Synergus.

Presenter, *Outsourcing Medical Device Design*, Copenhagen, Denmark, October 16, 2007, Sponsored by Synergus.

Presenter, *Overview of ISO 14971:2007*, Intermountain Biomedical Association, Salt Lake City, UT, October 12, 2007.

Speaker, *Setting up an Efficient Corrective Action and Preventative Action Process*, Quality Expo, Chicago, IL, September, 25, 2007.

Web Seminar Presenter, *Integrating Risk Management with CAPA*, July, 25, 2007; *Overview of ISO 14971 Risk Management*, July 25, 2007; *Risk Management Activities During Design Input*, August 2, 2007; *The Use and Misuse of FMEA in Risk Management*, September 4, 2007 and February 20, 2008; *Overall Residual Risk and Risk Acceptability*, October 10, 2007; *Integrating Risk Management with CAPA*, October, 23, 2007 and February 22, 2008 ; *Overview of ISO 14971 Risk Management*, November, 9, 2007; *Conducting and Documenting Proper Risk Analysis in Compliance with ISO 14971*, December 11, 2007; *Quality Risk Management for the Pharmaceutical Industry*, February 27, 2008; *How to create and maintain an ISO 14971-compliant Risk Analysis using other standards*, March 12, 2008; *Medical Device Software Risk Analysis*, June 18, 2008; *Essentials of Food and Drug Administration Medical Device Regulations: A Primer for Manufacturers and Suppliers; Part 1- Quality System Regulation*, June 24, 2008; *Essentials of Food and Drug Administration Medical Device Regulations: A Primer for Manufacturers and Suppliers; Part - Registration, Medical Device Reporting, Corrections and Removals (Recalls)*. And numerous other sessions continuing to present, Sponsored by Compliance On-Line.

Co-author, *Integrating Risk Management into the CAPA Process*, Biomedical Instrumentation and Technology, pp. 466-468, November/ December, 2008.

Co-Presenter AAMI Webinar, *Overview of New Risk Management Standard: ANSI/AAMI/ISO 14971:2007*, May, 2007.

Author, *Preventing Bed Entrapments: A Report from the Hospital Bed Safety Workgroup*, pp. 227-229, Biomedical Instrumentation and Technology, May/June 2007.

Author, *Risk Management for Cleaning, Sterilization, and Biocompatibility*, pp. 390-392, Biomedical Instrumentation and Technology, September/October 2006.

Presenter, *60601-1 Third Edition: Requirements and Practical Applications*, Association for Advancement Medical Instrumentation Conference, Reston, VA, May 22-24, 2006.

Speaker, *Product Risk Management*, University of Washington, Biomedical Regulatory Affairs Certificate Program, February 21, 2006.

Co-Instructor, *Quality Systems Requirements and Industry Practice*, Association for Advancement of Medical Instrumentation, Washington, DC January 31-February 3, 2005; December 5-8, 2005; September 18-21, 2006, Denver, CO; December 11-14, 2006 Sao Paulo, Brazil; February 26-March 1, 2007, Las Vegas, NV; March 12-16, 2007, Nairn, Scotland; May 22-24, 2007, Plymouth, MN; Phoenix, AZ, October 1-4, 2007; Washington, DC November 12-15, 2007; St. Petersburg Beach, FL, March 31-April 4, 2008; Carlsbad, CA, August 18-22, 2008; Dover, OH, November 10-14, 2008; Dover, OH, January 26-30, 2009; Syracuse, NY, November 9-13, 2009; West Lafayette, IN, March 15-19, 2010; Deerfield, WI, April 19-23, 2010.

Presenter, American Association of Healthcare Society for the Aging, *Hospital Bed Safety*, sponsored by Huntleigh Healthcare, October 25, 2004.

Presenter, Symposium for Advanced Wound Care, *Hospital Bed Safety*, sponsored by Huntleigh Healthcare, May 3, 2004.

Co-author, *Exploring Postdevelopment Risk Management*, pp. 70-75, Medical Device & Diagnostic Industry, May 2004.

Co-Instructor, Association for Advancement of Medical Instrumentation, *Risk Management for Medical Device Manufacturers*, Washington, DC September, 13-15, 2004; Dallas, TX May, 17-19, 2004; Phoenix, AZ, March 22-24, 2004; October 9-11, 2006, Orlando, FL; January 17-19, 2007, Santa Clara, CA; February 21-23, 2007, Arlington, VA; April 30-May 2, 2007, Denver, CO; Cleveland, OH, June 25-27, 2007; Milan, Italy, April 28-30, 2008; New Orleans, May 12-14, 2008; Arlington, VA, October 1-3, 2008; Arlington, VA, February 9-11, 2009; Brasilia, Brazil, January 27-29, 2010; Arlington, VA, June 21-23, 2010; Tucson, AZ September 13-15, 2010.

Course Manager and Presenter, Advanced Medical Technology Association/American Society for Quality, Biomedical Division seminar, Risk Management (ISO14971): How Medical Device Firms Can Utilize This Standard for the Product Lifecycle, *Overall Risk Evaluation*, Fort Lauderdale, FL February 23-24, 2004.

Guest Speaker, Drug Information Association, *Risk Management Concepts: Application to Medical Products*, Washington, DC January 15, 2004.

Guest Speaker, American Society for Quality, Lowcountry Section 1122, *International Standards Process*, Charleston, SC, October 2003.

Lectures, *Labeling and Advertising: Adverse Event Reporting and Tracking-Implications for Risk Assessment*; University of Southern California, School of Pharmacy, Risk Management Course MPTX 520, Los Angeles, CA, May, 2003 and November 2004.

Course Manager and Presenter, Advanced Medical Technology Association seminar, Risk Management (ISO14971): How Medical Device Firms Can Utilize This Standard for the Product Lifecycle, *Overall Risk Evaluation*, Alexandria, VA, May 2003.

Presenter, Virginia Tech, 1st International Symposium on Risk Management: Implementation for Healthcare Products, *The Heart of the Quality System: Integrating ISO 14971 into ISO 13485*, Temucula, CA, June 2002.

Guest Speaker, 12th Annual AAMI/FDA International Conference on Medical Device Standards and Regulation, *Risk Management in Standards and Regulations: An Update on ISO 14971*, McLean, Virginia March, 2002.

Guest Speaker, SenSym Educational Forum, *Supplier Quality*, Milpitas, CA, June 1994.

Adjunct Faculty, Purdue University, Versailles, IN SPV 484 / SPV 485, Leadership Strategies for Quality, Spring 1991, 1992, 1993, 1994

Adjunct Faculty, Purdue University, Versailles, IN IT 382, Spring 1989, 1990

Presenter, Forest Products Research Society, Fall Meeting, *Vendor Certification and Quality Control*, Jasper, IN October, 1992.

Guest Speaker, American Society for Quality Control, Palmetto Section, *Supplier Quality*, Greenwood, SC, May, 1987.

Guest Speaker, American Society for Quality Control, Lexington, Kentucky Section, *Use of Juran on Quality Improvement Techniques*, Lexington, KY, April, 1987.

Guest Speaker, American Society for Quality Control, Cincinnati Section, *Training-A Key for Quality*, Cincinnati, OH, November, 1987.

Presented Paper, *Supplier Reduction: Road to Improved Quality*, IMPRO 87, Juran Institute at Chicago, Illinois, November 1987.

* Additional private courses in area of product/process risk management and quality systems have been developed for, and presented to various medical device and pharmaceutical clients.

Other Experience

United States Navy Veteran, Electronics Technician, Submarine Qualified