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KENNETH B. SCHMIDT, MS

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SUMMARY OF QUALIFICATIONS

Senior executive with over 19 years effective leadership and consulting success in FDA regulated medical device, pharmaceutical and healthcare industries: Quality Systems, Regulatory Compliance, Risk Management and Reliability. Experienced subject matter expert (SME) in research and development, risk management, design and process validation, manufacturing operations, calibration, analytical laboratories, product test laboratories and post-market surveillance systems / processes. Demonstrated ability to implement and lead effective cross-functional solutions to meet regulatory requirements and critical deadlines proactively and in response to FDA Regulatory Actions: 483's, Warning Letters, Consent Decree, and Import Detentions.

AREAS OF CORE COMPETENCIES

- Quality Systems Development / Remediation
- Regulatory Compliance
- Risk Management
- Risk-Based Planning & Analysis
- Design Controls
- New Product Development
- SDLC
- Product Verification & Validation
- Management Controls
- Training
- CAPA
- Production and Process Controls
- Quality Assurance & Validation
- Complaints, Recalls, & MDR's
- Documentation & Change Controls
- Training
- Business Process Re-engineering
- Project / Program Management

PROFESSIONAL EXPERIENCE

PRINCIPAL QUALITY / REGULATORY CONSULTANT, OPTIM ASSOCIATES, INC. 2002 TO CURRENT

Engagements with Fortune 1000 companies to provide Quality Systems and detailed regulatory / engineering guidance for Class II and Class III medical device designers and manufacturers. Lead multi-site QSR Audits, Perform Gap Analysis, Implement QSR and Product Remediation Plans, Coordinate cross-functional projects in response to FDA Regulatory Actions: 483's, Warning Letters, Import Detentions, Consent Decrees. Specific expertise—Management Controls, Training, CAPA, Hardware / Software Design / Development, Risk Management, Design Validations, Process Qualification and Validations, Production and Process Controls, Computer System Validations, and Post Market Surveillance and Support Systems, including Complaints / MDR's.

REPRESENTATIVE ENGAGEMENTS / CLIENT LIST:

- **Dental Implant Design / Mfg.**, (Palm Beach Gardens, FL, 2014-present): Pro-Active FDA Warning Letter Remediation Response. Design Controls / Risk Management Remediation. Develop Interim Controls, Corrections and Containment Plans. Address external and FDA audits.
- **Infusion Pump Design / Mfg.**, (Lake Forest, IL, 2013-2014): FDA Warning Letter / Import Detention. CAPA Remediation. Develop Interim Controls, Corrections and Containment Plans. Address external and FDA audits.
- **Sterilization Products Design / Mfg.**, (Irvine, CA, 2012-2013): FDA Warning Letters. Product Risk Management File correction and Design History File assessments. Preparation for external audit readiness.
- **Infusion Pump Design / Mfg.**, (Buffalo, NY, 2012): FDA Warning Letter. Complaints Management, MDR and Risk Management System Remediation. Perform Assessment and gap analysis, develop and implement detailed implementation plan and act as interim Complaints Manager.
- **Heart-Lung Design / Mfg.**, (Ann Arbor, MI, 2011-2012): FDA Consent Decree. Risk Management and Design Control Remediation. Perform Gap Analysis, establish integrated Risk Management program and train company personnel. Remediate on-market products.

- **LASIK, Intra-Ocular Products Design / Mfg.**, (USA, Spain, 2009-2011): QSR Audit and Remediation. Lead QSR Auditor (3 sites), perform site Gap Analysis and implement Quality System and Product Remediation Plans.
- **AED / Clinical Defibrillator Design / Mfg.**, (Andover, MA, 2010): Reliability Program / Product Assessment. Perform reliability program and product assessments.
- **Orthopedic Implant Mfg.**, (Ohio, 2009): FDA Warning Letter QSR Follow up Audit. Executive Management Education.
- **Blood Pressure Design / Mfg.**, (Michigan, Taiwan, China, 2008-2010): FDA Import Detention. Quality System and Device Gap Analysis and Remediation—Design Controls, Risk Management, Documentation Control, and Training systems.
- **IVD, Glucose/Ketone/Cholesterol Analyzer Design / Mfg.**, (Indianapolis, IN, 2008): FDA Warning Letter. Quality Systems and Device Remediation—Design Controls, Risk Management, Documentation Controls, and Project Management.
- **Telemedicine Design / Mfg.**, (McLean, VA, 2008): BSI Audit Preparation. QSR / ISO Audit. Quality System and Device records preparation for BSI Audit.
- **Infusion Pump Design / Mfg.**, (San Diego, CA, 2007): FDA Consent Decree. Quality System and Device Remediation implementation—Design Controls, Risk Management, Product Root Cause Investigations and product corrections.
- **Mobile Fluoroscopy System Design / Mfg.**, (Salt Lake City, UT, 2007-08): FDA Consent Decree. Quality System and Device Remediation—Design Controls, Risk Management, and Reliability.
- **Hemodialysis Design / Mfg.**, (Modena, Italy, 2006): FDA Import Detention. Quality System and Device Remediation—Design Controls, Risk Management, Product Validation (HW/SW), DHF Remediation, HACCP, Product Root Cause Investigations and product corrections, and Interim Quality Management.
- **Tissue Oximeter**, (Champaign, IL, 2006): 510(k) Traditional Pre-Market Notification.
- **US Army Vehicle Weapons System**, (Sterling Heights, MI, 2004-05): Management and Technical Reliability Liaison between US Government Program Office and System Developer for Stryker MGS and Expeditionary Fighting Vehicle government programs.
- **Legal Consultation**, (Chicago, IL, 2005): Research Expert Witness for Class III medical device personal injury claim.
- **AED / Clinical Defibrillator Design / Mfg.**, (Chelmsford, MA, 2004-06): Reliability Assessments and Program Development. Program development, implementation and execution for three new product development projects.
- **Pharmaceutical / Medical Device Design / Mfg.**, (N. Chicago, IL, 2003-04): FDA Inspection Readiness. Corporate Metrology/Calibration Laboratory Validation remediation: hardware, software, utilities, facilities, processes, and methods. Develop and execute remediation plans and procedures for Laboratory IQ/OQ/PQ—integrate into existing Quality System.
- **Dental Device Design / Mfg.**, (Franklin Park, IL, 2003): FDA Inspection Readiness. Quality Systems Remediation. Gap Analysis, Root Cause Analysis, Risk Assessments, CAPA Plans, Master Validation Plans, IQ, OQ, and PQ development and execution.
- **Urology Stent Design / Mfg.**, (Racine, WI, 2003): Complaint and Field Failure Remediation. Root Cause Analysis and Process / Yield Improvement for manufacturing processes.

CORPORATE QUALITY & RELIABILITY MANAGER, BAXTER HEALTHCARE, ILLINOIS 2001 to 2002

Provide strategic quality and reliability leadership, mentoring and training for Renal, Fenwal, and Medication Delivery divisions. Define and develop corporate Reliability Best Practices. Integrate reliability and design control best practices into Product Development Processes. Develop and execute program implementation strategy, charter, budget, schedule and coordinate detailed project execution.

- Mitigate $50 million Colleague Infusion Pump recall. Develop and communicate post-recall reliability strategic path. Conduct engineering consultations to improve engineering design and process efficiencies. Address multiple FDA 483 findings and divisional warning letters. Lead Corporate Reliability HW/SW Competency team. Perform Reliability Assessment Survey and Gap Analysis.
- Develop corporate strategy and direct efforts to overhaul corporate R&M design practices and field metrics.

- Provide leadership for three (3) divisions on five (5) distinct projects. Leadership areas include: FDA/QSR interpretation, reliability, risk management, design trade-offs, technical oversight, project management, and core team development. Implement Reliability plans, requirements, and validation tests.
- Extensive cross-functional interface with Marketing, Finance, Regulatory Affairs, Engineering (SW/HW), Manufacturing, Field Service and Product Surveillance.

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SR. QUALITY MANAGER, CR BARD, UTAH 2000 to 2001

Developed new product development process and trained site personnel on FDA Design Control requirements. Managed hardware and systems software QA Engineering functions.

PROCESS CONSULTANT, ELI-LILLY, INDIANA 1998 to 2000

Implemented Reliability Centered Maintenance (RCM) program for manufacturing facilities in Terra-Haute, Lafayette and Indianapolis. Perform detailed Gap Analysis, resolution plans and developed business process maps. Train, coach and mentor maintenance crafts, schedulers, maintenance engineers and management. Implement and perform Global Reliability Training Program, including: Incident Investigation, Root Cause Failure Analysis, FMEA, Maintenance Planning, Equipment Identification, Equipment Criticality and Mechanical Integrity. Perform job-task analysis. Coordinate and develop design requirements, detail equipment specifications, commission manufacturing equipment and processes--P&ID's, equipment lists, qualification / validation (IQ/OQ/PQ), maintenance procedures, SOP's--de-commissioning activities and scrap.

- Implement multiple Incident Investigations / Root Cause Analysis. Documented saving exceeding $750,000.
- Develop and execute RCM audit program.
- Restructure and manage $420,000 FMEA development project.

QUALITY / RELIABILITY MANAGER, NELLCOR PURITAN BENNET, KANSAS 1996 to 1998

Managed product test laboratory with four (4) test technicians and three (3) engineers of a $1.9 billion medical device and specialty chemical company: Pulse Oximetry Monitoring Systems R & D. Developed and directed implementation of Environmental / EMC laboratory revitalization program. Initiated equipment, procedural, and personnel upgrades per ISO Guide 25. Coordinated verification and validation tests at two remote sites for five (5) business units. Harmonized local procedures with corporate verification and validation test procedures. Directed metrology / calibration efforts.

- Saved $182,000 in prototype development costs and reduced test schedule 3 months by initiating alternate test strategy. Strategy allowed achievement of 12-month Time-To-Market project development goal.
- Recovered 2 month, $512,000 design project slip without neglecting management responsibilities when chosen as lead reliability engineer on four projects. Within one month, optimized design-to-test requirements and reduced document inefficiencies while maintaining traceability requirements.
- Lead Quality and Reliability design efforts. Trained and mentored design team on QSR Design Controls, ISO, IEC and vendor / component selection requirements. Implemented proactive verification and validation techniques based on historical data and HALT / HASS testing to augment traditional testing activities. Functional interface with SW QA and SW Engineering Development departments.
- Twice selected by corporate office to develop project assessment and recovery plans for alternate business unit critical project significantly behind schedule.

RELIABILITY ENGINEER / PROGRAM MANAGER, OEC MEDICAL SYSTEMS, UTAH 1993 to 1996

Report to VP of Quality & Regulatory Affairs of $128 million world sales leader in the interventional digital X-ray C-arm imaging market for general, orthopedic, vascular, neurovascular, urological and cardiac procedures. Implemented corporate Reliability Engineering program. Integrated with Engineering, Manufacturing, Field Service and Regulatory Affairs per FDA requirements and international standards. Developed corporate procedures and conducted training at all management and staff levels. Implemented and tracked strategic Reliability corporate metrics. Presented executive staff with metrics on install base and critical equipment.

- Improved annual corporate efficiencies $270,000 by implementing Elapsed Time Indicators and defining reliability feedback metrics for all future products.
- Developed comprehensive reliability assessment of existing install base and restructured FRACAS to emphasize failure analysis, corrective action and corrective action effectiveness tracking.
- Saved $60,000 annually and reduced early device failures 10% by designing, constructing and implementing system-level Burn-In Chamber.
- Specified system-level reliability requirements, designed verification and validation test protocols and conducted tests for three developmental projects.
- Provided guidance to SW Development and Test for bug 'finds and fixes', tracking, and effectiveness monitoring. Validated COTS analysis SW.

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ADDITIONAL TECHNICAL COMPETENCIES

- TECHNICAL MANAGEMENT: Program Development, Project management. Business process reengineering. Change management.
- FUNCTIONAL MANAGEMENT: Leadership, Mentoring, Budgeting, Clear Communication, Evaluations.
- TRAINING: QSR, Design Controls, Corrections and Removals, CAPA, Root Cause, Risk Management, Risk Analysis, Design for Reliability, Validations, Statistics, Quality and Reliability Methods.
- REGULATIONS AND STANDARDS: FDA, GxP, QSR, 21 CFR Parts 11 / 803 / 820, Design Controls, Design Validation, COTS and Software Validation, Process Validation (IQ/OQ/PQ), 510(k) Submissions, ISO 9001 (2000), ISO 13485, ISO 14971, IEC 60601-1, IEC 62304, OSHA, Mil-Stds, Mil-Hdbks.
- AUDITING AND ASSESSMENTS: Investigative, Compliance, Supplier, Quality System, Reliability, QSIT, FDA Inspection Readiness.
- DESIGN REVIEW AND ENHANCEMENTS: Robust Design Techniques, Design for Quality / Reliability / Maintainability / Manufacturability, Design Checklists.
- QUALITY AND SYSTEMS ANALYSIS: Incident Investigation, Root Cause Analysis, CAPA, Field Trending & Monitoring, FRACAS, Procedure Development, Process Optimization.
- RELIABILITY MODELING AND PREDICTION: FMEA, FRACAS, Block Diagrams, Weibull Analysis, Crow-AMSAA Growth, HAZOP, Fault Trees, Risk, Warranty Analysis, Electrical, Mechanical, Software, Disposables, Durables, Field Data Trending.
- STATISTICAL ANALYSIS: Sampling Plans, DOE, SPC, Hypothesis Testing, ANOVA, Linear Regression, Non-linear Regression, Analysis of Means.
- TESTING: Hardware, Software, Environmental Testing, Human Factors, Accelerated Testing, HALT, HASS, ESS, Reliability Demonstration Tests, Production Acceptance Tests, Burn-In, Reliability Growth, Test Protocol Design.
- PROCESS EQUIPMENT MAINTENANCE MANAGEMENT: Life Cycle Costing, Mechanical Integrity Ranking, Criticality Ranking, Overall Equipment Effectiveness (OEE), Total Productive Maintenance (TPM), Reliability Centered Maintenance (RCM).
- TOOLS: Windows NT/XP, MS/Office, MS/Project, MS/Visio, MiniTab, Statgraphics, MathCAD, MiniTab, Weibull Smith, @RISK, FORTRAN, SIMAN, Maximo, AMSAA, ReliaSoft (Weibull++, Block-Sim, X-FMEA, RGA).

CERTIFICATIONS

CERTIFIED RELIABILITY ENGINEER (CRE), American Society for Quality, Milwaukee, Wisconsin (Expired Certification #03525).

CERTIFIED QUALITY AUDITOR (CQA), American Society for Quality, Milwaukee, Wisconsin (Expired Certification #18717).

EDUCATION

M.S. ENGINEERING MGMNT (Operations Research), Wichita State University, Wichita, Kansas.

B.A. MATHEMATICS (Physics), Bethel College, North Newton, Kansas.

PROFESSIONAL AFFILIATIONS

AAMI – Association for the Advancement of Medical Instrumentation	Member #411520
ASQ – American Society for Quality (ASQ), Senior Member	Member #00974463
IEEE – Institute of Electrical and Electronic Engineers	Member #40080863
RAPS – Regulatory Affairs Professionals Society	Member #09238147
ISPE – The Society for Life Science Professionals	Member #243977

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