

Sue Jacobs

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CURRICULUM VITAE

EDUCATION

AAMI Faculty Staff - GMP and Industry Practices, 1997
ASQ Certified Quality Auditor (CQA) #11824, 1994
Harper College, Palatine, Illinois, Materials Management, 1979
Curry College, Milton, Massachusetts, Business, 1976

PROFESSIONAL TRAINING

Medical Device cGMP Compliance, ISO Quality Management Systems, ISO Lead Assessor Training, MDD, CE Marking, Quality Planning, Corrective and Preventive Action (CAPA), Risk Management, ISO14971, Design Control, FDA Inspections (QSIT), FDA Enforcement, Medical Device Law, MDR Regulations, ISO13485, Process Validation, Quality System Software Validation Techniques, Documentation and Change Control, Quality Auditing, Supplier Chain Management, ERP Systems, Quality Tools, Root Cause Analysis, and Problem Solving

PUBLICATIONS

The Biomedical Quality Auditor Handbook, Published 2003

American Society for Quality, Quality Press, Milwaukee

- Chapters authored include Preamble to the Quality System Regulation, various Quality System Regulation elements, other 21 CFR regulations and the Quality System Inspection Technique (QSIT).

US FDA Medical Device Inspections - Don't Panic, Be Prepared

- *In development*

EXPERIENCE

2001 - Present

QMS Consulting, Inc.

President and Principal Consultant

QMS Consulting, Inc. provides worldwide consulting services to medical device manufacturers seeking to *establish, implement, or improve* Quality System and Regulatory Compliance to US FDA Regulations, ISO Standards, and European Medical Device Directives

- Perform Quality System assessments for compliance to US FDA Regulation Requirements for Medical Devices, ISO13485 Medical Device Quality Management Systems, European MDD Annex II, JPAL (Japan MHLW Ordinances 135, 136, 169, 180), CMDCAS:SOR/98-282 Canadian Medical Device Directive,
- Outsourcing alternative (Interim Management, Short-term Staffing, Supplier Audits, Internal Quality System Audits, Procedure Development and Implementation)
- Assist firms in resolving US FDA Regulatory Enforcement Action; FDA 483 observations, Warning Letters, FDA Certification Audits
- Quality Systems Expert Witness on behalf of the US Food & Drug Administration
- Design and conduct customized in-house training covering US FDA Medical Device Quality System Regulation, US FDA Inspection Readiness Training (QSIT), Corrective & Preventive Action (CAPA), Quality Auditing, and ISO 9000 / ISO13485
- Provide hands-on assistance to develop or re-engineer the CAPA Process and implementing metrics to monitor effectiveness
- Conduct Organizational Assessments to identify opportunities for improved operating efficiency
- Provide customized in-house Train-the-Trainer courses to enable firms to develop internal core competencies
- Developed the AdvaMed MTLI Course: "CAPA, A New Direction Course" in collaboration with FDA CDRH and Medtronic

1997 – 2001

MEDICAL DEVICE CONSULTANTS, INC. (MDCI)

Senior Quality Systems Specialist

- Perform Quality System audits and assessments for compliance to US FDA regulations, ISO/EN Standards, and EU Directives
- Assist manufacturers and suppliers in developing, implementing, and maintaining Quality System compliance programs and procedures
- Conduct US FDA Medical Device requirements (GMP) and Quality System-related training seminars including FDA Inspection Readiness Training (QSIT)
- Assist manufacturers in developing, implementing, and maintaining compliance programs for MDR and recall regulations
- Manage client relations including meeting with prospective clients to determine their compliance and quality needs

1985 - 1997

Siemens Medical Solutions - Nuclear Medicine Group

Manager, Quality Assurance (1995-1997), Senior Quality Assurance Compliance Specialist (1992-1995), Manufacturing Quality Assurance Specialist (1991-1992), Consultant, Production and Material Planning (1989-1991), Supervisor, Production and Inventory Control (1985-1988)

- Responsible for Quality System Compliance, Internal Audit Program, Supplier Quality Assurance, and Incoming Inspection; managed staff of 12 employees
- Assisted in the implementation of ISO 9001 quality program successfully achieving certification to ISO9001 in December 1994
- Coordinated company-wide compliance initiative redefining QMS in accordance with FDA and international standards in response to FDA Consent Decree
- Coordinated multi-site Corporate Quality Improvement Teams to establish Siemens-wide corporate policy and training materials for Process Validation, Design Control, and Quality System Training
- Served as industry faculty for the AAMI course, GMP and Industry Practice, providing industry perspective for implementation of FDA's Quality System Regulation
- Established the internal audit program including: administration, scheduling, training, and conducting audits. Program recognized as 'best practice' for Siemens Medical Worldwide
- Established and implemented the Quality System Software Validation Program
- Prepared course materials and conducted various training programs for: GMP, ISO 9001, FDA Inspections, Process Validation, Good Record-Keeping Practices, Quality Audits, Change Control, and Procedure Writing
- Coordinated on-site FDA Inspections, ISO Surveillance Audits, and Corporate Quality Audits, including preparing written responses and implementing corrective actions
- Streamlined Change Control process, prepared training materials and conducted company-wide training

1981 - 1984

Mylstar Electronics

Production Planner

- Implemented ASK MAN/MAN MRP System; maintained 30 inventory commodities at an inventory level of \$2.5 million, 40% of total inventory value

1978 - 1981

Chicago Specialty Manufacturing Co.

Production and Inventory Planning

- Responsible for planning and scheduling purchased parts using MAPICS MRP System; achieved \$1.5 million reduction in raw material inventory (40%) while maintaining a 97% customer service level

PROFESSIONAL AFFILIATIONS

- AdvaMed – Advance Medical Technology Association
- American Society for Quality (ASQ)
 - Senior Member
 - ASQ Biomedical Division Chair 2002-2004, Biomedical Division Chair Elect 2001-2002, Biomedical Division Program Chair 1998-2001
 - ASQ Board of Directors, National Director 2004-06, ASQ Vice-Chair Division Affairs Council 2005-07
- Association for the Advancement of Medical Instrumentation (AAMI)
- Food & Drug Law Institute (FDLI)
- Regulatory Affairs Professional Society (RAPS)
 - Senior Member
- Society of Industry Leaders, Standard & Poor's

PUBLIC SPEAKING

Frequent speaker, routinely invited to present papers and conduct public seminars and workshops

- AAMI – Association for the Advancement of Medical Instrumentation
- AdvaMed – Advance Medical Technology Association
- ASQ – American Society for Quality
- Biomedical Consortium
- Compliance Alliance
- Canon Communications (MD&M-US, MEDTEC-Germany)
- FDANews
- FOI Service
- IMDA Irish Medical Device Association (Ireland)
- Institute of Quality – Medical Device Group (London, UK)
- Management Forum, LTD. (London, UK)
- Medical Device Congress, Harvard University
- Medical Device Summit
- RAPS – Regulatory Affairs Professional Society
- Thompson Publishing, Thompson Interactive

Topics include

- A New Direction For CAPA
- AAMI – GMP and Industry Practices Course
- After the FDA Inspection
- Best Practices in CAPA Systems
- CAPA – A Practical Perspective
- CAPA: 8 Steps to Develop and Implement an Effective Program
- Complaint and MDR Management
- FDA Inspection Readiness – Is Your Team Ready?
- Getting the Most from Your Internal Audits
- Global Challenges for Medical Device Quality Systems
- Integrating Risk Management and CAPA
- Integrating Risk Management into your QMS
- Managing Quality in Your Supply Chain
- Medical Device Auditing
- QSIT – Quality System Inspection Technique
- Responding to FDA Form 483 and Warning Letters
- Setting Up an Effective Complaint Management System