

Sue Jacobs

QMS CONSULTING, INC.
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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 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

- Chapter 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, ISO/EN Standards, and European Medical Device Directives
- Provide Quality Assurance outsourcing alternative for medical device manufacturers (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, 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/EN46001 in December 1994
- Coordinated company-wide CAPA efforts that established the QA program, compliant with FDA's Good Manufacturing Practice Regulations and ISO 9001/EN46001
- Served as faculty for the AAMI course, GMP and Industry Practice, providing industry perspective for implementation of FDA's Quality System Regulation
- Established and implemented the internal audit program including: administration, scheduling, training, and conducting audits. Program recognized as 'best practice' for Siemens Medical Systems, Inc.
- Established and implemented the Quality System Software Validation Program
- Participated on Corporate Quality Improvement Teams to establish Siemens-wide corporate policy and training materials for Process Validation, Design Control and Reliability, and Quality System Training
- 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 Engineering Change Notice (ECN) process, prepared training materials and conducted company-wide training
- Implemented MRP II systems (AMAPS & J.D. Edwards), trained employees, established and implemented written procedures

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

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

PRESENTATIONS

2008

- Oct 2008 MD&M East – New York City, NY
Managing the Supply Chain
CAPA Best Practices
- Jun 2008 MD&M East – New York City, NY
CAPA Best Practices
- Apr 2008 Management Forum - London UK
US FDA Medical Device Inspections – Is Your Firm Ready?
- Apr 2008 Thompson Interactive – Audio Conference
CAPA: 8 Steps to Develop and Implement an Effective Program
- Mar 2008 Biomedical Consortium, MN
Designing CAPA and FDA Trends
- Feb 2008 MD&M West – Anaheim, CA
CAPA, A Practical Perspective, Document Control
- Jan 2008 AdvaMed – Orlando, FL
Complaints, MDRs, Reports of Corrections and Removals and Recalls, Integrating Complaint Handling and CAPA

2007

- Nov 2007 AdvaMed – Irvine, DC
A New Direction For CAPA
- Sep 2007 Management Forum - London UK
US FDA Quality System Requirements for Medical Devices / CAPA for Medical Devices
- Jun 2007 MD&M East – New York City, NY
Today's Best Practices in CAPA Systems
- Apr 2007 Management Forum - London UK
US FDA Medical Device Inspections
- Mar 2007 Medical Device Congress, Harvard University Cambridge, MA
Medical Device Regulation, Reimbursement, and Compliance Issues
- Mar 2007 AdvaMed – Irvine, CA
A New Direction For CAPA
- Mar 2007 ASQ Biomedical Division–San Diego, CA
Integrating Risk Management and CAPA
- Feb 2007 MD&M West – Anaheim, CA
CAPA, A Practical Perspective, Preparing for FDA Inspections
- Jan 2007 AdvaMed – Orlando, FL
Complaints, MDRs, Reports of Corrections and Removals and Recalls
Integrating Your Complaint Handling System and Your CAPA System

2006

- Dec 2006 Management Forum - London UK
US FDA Requirements for Medical Devices / CAPA for Medical Devices
- Nov 2006 AdvaMed – Bethesda, MD
A New Direction For CAPA
- Jun 2006 MD&M East – New York City, NY
Topics: Today's Best Practices in CAPA Systems, How to prepare for an FDA Inspection
- May 2006 Irish Medical Device Association (IMDA) Galway Bay, Ireland
Global Access Annual Conference, Topics: Benchmarking CAPA, US FDA Inspections -- *Don't Panic Be Prepared*
- Mar 2006 Cannon Communications– Webcast
A Case Study: Implementing CAPA to Fix Problems, Minimize Risk, and Produce Better Products
- Mar 2006 MEDTEC – Stuttgart Germany
Keeping a Device on the Market / US FDA Inspections
- Mar 2006 ASQ Biomedical Division –Irwindale CA
Risk Management Roundtable
- Feb 2006 ASQ Biomedical Division – St. Jude Medical, Sylmar CA
Risk Management Roundtable
- Jan 2006 MD&M West – Anaheim, CA
Best Practices in CAPA

CURRICULUM VITAE: **Sue Jacobs**

2005

- Dec 2005 Management Forum - London UK
US FDA Requirements for Medical Devices / CAPA for Medical Devices
- Nov 2005 ASQ Biomedical Division – St. Jude Medical, Sylmar CA
CAPA – A Practical Perspective
- Jul 2005 FOI Services – Audio Conference
Getting the Most from Your Internal Audits
- Jun 2005 MD&M East – New York City, NY
Integrating Complaint Handling & CAPA
- Jun 2005 Management Forum - London UK
Preparing for US FDA Inspections
- Apr 2005 ASQ Biomedical Division – Ft. Lauderdale, FL
CAPA – A Practical Perspective
- Feb 2005 AdvaMed – Orlando, FL
Complaints, MDRs, Reports of Corrections and Removals and Recalls
Integrating Your Complaint Handling System and Your CAPA System
- Jan 2005 Management Forum - London UK
US FDA Requirements for Medical Devices...
“Is Your Quality System Ready?”

2004

- Dec 2004 FOI Services – Audio Conference
Getting the Most from Your Internal Audits
- Oct 2004 AAMI - GMP Requirements and Industry Practice - Washington DC
Association for the Advancement of Medical Instrumentation (AAMI)
- Sep 2004 RAPS Chicago Chapter, IL
CAPA - A Practical Perspective
- Jul 2004 AdvaMed – Chicago, IL
Topics: Setting Up an Effective Complaint Management System, Managing Product Problems
- Jun 2004 AAMI - GMP Requirements and Industry Practice
Association for the Advancement of Medical Instrumentation (AAMI), San Francisco, CA
- May 2004 Irish Medical Device Association (IMDA)
Global Regulatory Issues for Medical Device Manufacturers, Galway Bay, Ireland
- Apr 2004 AdvaMed – Boston, MA
How FDA Regulates Medical Devices
- Jan 2004 Management Forum - London UK
QS Regulation Requirements 21 CFR Part 820, US FDA Inspections vs. Notified Body Audits

2003

- Sep 2003 Institute of Quality (Medical Device Quality Group) - London UK
Implications of ISO13485 on US FDA Regulations
- Jun 2003 AdvaMed – Newport Beach CA
Integrating Your Complaint Handling System and Your CAPA System
- Jun 2003 AdvaMed – Alexandria, VA
Setting Up an Effective Complaint Management System, Conducting Effectiveness Checks
- Apr 2003 AdvaMed – Arlington, VA & Irvine CA
Setting Up an Effective Complaint Management System, Conducting Effectiveness Checks
- Mar 2003 ASQ Biomedical Division Palo Alto, CA
Corrective and Preventive Action
- Jan 2003 Management Forum - London UK
QS Regulation Requirements 21 CFR Part 820, US FDA Inspections vs. Notified Body Audits

2002-1997

- May 2002 AdvaMed – Irvine CA
Complaints, MDR's, Reports of Corrections and Removals and Recalls
- Apr 2002 AdvaMed – Arlington, VA
Complaints, MDR's, Reports of Corrections and Removals and Recalls
- Jan 2002 Management Forum - London UK
US FDA Quality System Requirements 21 CFR Part 820
- Jul 2001 Management Forum - London UK
- Apr 2001 Management Forum - London UK
- Apr 2001 AdvaMed – Washington DC and Temecula CA
- Dec 2000 5th National Conference, ASQ FD&C and Biomedical Divisions–AZ
- Oct 2000 ASQ/Irish Medical Device Association (IMDA)
- May 2000 ASQ Quality Congress
- Jan 2000 Management Forum - London UK
- Mar 1999 RAPS Medical Devices Today
- Apr 1998 AAMI GMP Requirements and Industry Practice - Minneapolis, MN
- Aug 1997 AAMI GMP Requirements and Industry Practice - Chicago, IL