Director of Quality and Compliance

AREAS OF EXPERTISE

- **High Purity Water Qualification**
- **Clean Room Qualification**
- **Training & Presentation**
- **Process Improvement**
- **Root Cause Analysis**
- **Cleaning Validation**
- **Quality Assurance**
- **Proces Validation**
- **Benchmarking**
- **Aseptic Fill**
- **Regulatory**
- **ISO 13485**
- **Author**
- **CMQ/QE, CQA, CBA, CSSBB, CPGP, QSR, cGMP, CIP, SIP, SPC, TQM, COQ**
- **Sterilization – EO, Gamma, E-Beam, Steam**
- **Microbiology, Biocompatibility**
- **Quality System Auditor**
- **Failure Investigation**
- **ASQ Fellow**
- **Biomedical**
- **Six Sigma**
- **CAPA**
- **Lean**
- **SOP**
- **MS**

INTRODUCTION

As Director of Quality and Compliance, Quality Manager, Quality Systems Manager and QA Laboratory Manager with more than 25 years in manufacturing, Consultant has extensive experience in applying GMPs and Quality System standards to IVDs, Medical Devices, Biologicals and Sterile Packaging. Consultant also has specific experience in material biocompatibility, controlled environments, sterilization validation, aseptic filtration, cleaning validation, SIP and related microbiological quality issues, and he was a participating author for several related industry and international standards. As Management Representative for four facilities, Consultant developed and revised Quality System procedures to assure GMP (21CFR 820) compliance and achieve certification to ISO 9001 and 13485 standards. Consultant also hosted 20 ISO audits, 32 important customer audits and 9 FDA inspections. Where necessary, Consultant has developed appropriate corrective and preventive actions and verified they were effective. Consultant also managed programs for internal and supplier audits and served as lead auditor for all critical and technical areas and suppliers. Consultant trained audit teams in Value-Added Auditing and Lean/6 Sigma improvement methods yielding significant savings, and as an instructor and frequent speaker for ASQ for more than 20 years, he am experienced in live and web-based presentation formats. Consultant is recognized by the American Society for Quality as a Fellow and Quality Leader, and in addition, he also holds ASQ certifications for Quality Auditor, Biomedical Auditor, Six-Sigma Black Belt, Pharmaceutical GMP Professional, and Manager of Quality and Organizational Excellence.

WORK EXPERIENCE

1998 – Present
Industry Consultant
Duties:

- Client list includes Fresenius, Ethicon, EKOS, Alphatec, Amgen, Ximedica, and Delsys. cGMP Compliance, Cleaning, Cell Culture & Environmental Control at Multicell Biotechnology Training & Team Facilitation in Process Improvement at Tiffany (saving over $300,000). Training in Root Cause Analysis (RCA) at Lavigne, Stanley, Hexagon, Interplex and Banneker: Training in Value Added Auditing, Systems Thinking, Quality Function Deployment (QFD), RCA, Failure Investigation, Measurement and Calobration, Lean/Six Sigma Process Improvement, FMEA, CAPA, Supply Chain Management, and Quality Management Principles for ASQ, Compliance On-Line, MSMRG, and APICS.

1993 – Present
American Society for Quality
Instructor
Duties:

- Certified Quality Manager (CMQOE) and Quality Auditor Refresher courses. Cost of Quality and Root Cause Analysis and Failure Investigation seminars. Quality Press Editorial Review Board, Content Author for training programs and certification exams.

02/2008 – 2013
Tunstall Americas, Pawtucket, RI
Director of Quality and Regulatory Compliance
Duties:

- Electronic Patient Monitoring Devices.

2010 – 2013
Sealed Air Corp., Cranston, RI
Medical Packaging Quality Manager/Management Representative
Duties:

- Facility Head of QA/QC, 11 direct reports upgraded to ISO 13485 Certification in 6 months, Developed protocols. SOPs and Training to qualify new Class 8 Clean Rooms, develop FMEAs, and manage Supplier QA, CAPAs and audits.

1990 – 2010
DAVOL Inc., Division of C.R. Bard, Warwick, RI
Medical Device Quality Systems Manager, (1997 – 2010)
Duties:

- CAPAs, Quality Metrics, Audits, Compliance

QA Laboratory Manager, (1995 – 1997)
Duties:

- Validation of Test Methods for Product Release.

Manager of Sterilization Operations, (1990 – 1995)
Duties:

- EO Sterilization and product

SCOTT Laboratories, Inc., West Warwick, RI
Director of QA/RA – Micro Media (IVD)

National Institutes of Health (NIH/NCI) Bethesda, MD
Senior Research Microbiologist

EDUCATION

Anna Maria College, Paxton, MA
Master: Total Quality Management

Pennsylvania State University
Bachelor: Microbiology & Biology

AMERICAN SOCIETY FOR QUALITY CERTIFICATIONS AND AWARDS

- Certified Manager of Quality/Organizational Excellence, #717
- Certified Pharmaceutical GMP Professional, #372
- Certified Six Sigma Black Belt, #11132
- Certified Quality Auditor, #904
- Certified Biomedical Auditor, #41
- ASQ Fellow Status, Nov 2011

CAREER EXPERIENCE AND ACCOMPLISHMENTS

- Responsible for QSR/ISO 13485 Quality System Compliance and improvement activities for over 25 years. Provided technical support for product launches, process improvements and transfer projects, including biocompatibility and sterility assurance programs for synthetic, biological, lyophilized powders, drug coated implants & medical devices.
- Compliance: Develop and author policies & procedures to upgrade Sealed Air to ISO 13485:2003 in 6 months. Chairperson, Davol ISO Council and achieved ISO 13485 upgrade 4 months ahead of schedule. Managed all External Customer, FDA & ISO audits to demonstrate QSR/ISO compliance and maintain ISO certification for Sealed Air & all Davol sites. Used DMAIC to implement improved tracking of open complaints & trending of quality metrics. Compiled and analyzed metrics for Management Review presentations to evaluate performance to goals. Tracking and follow up of all quality action items.
- Auditing: Administer system-wide Internal Audit program 1997-2012. Coordinate schedules, qualify auditors, track and trend results. Audit internal systems and critical suppliers for raw materials, lab testing, biological products & sterilization. Train and mentor internal auditors in Value-Added Auditing. Instructor ASQ-CQA Refresher course since 1993.
- CAPA & Root Cause Analysis: Administered system-wide Corrective/Preventive Action (CAPA) Program 1997-2012 and developed database to keep track of all Customer and Business Concerns, 2011. Survey CAPA user input to improve documentation and address causes of overdue issues. Reduced overdue issues at Davol by 82% and eliminated recurring issues.
- Project Team Leader: To investigate pyrogen failures on bulk processed material in 2008-09. Used DMAIC to analyze process data, develop test protocols and data collection schemes. Revised process FMEA, summarized and presented results to support proposed solutions. Developed body of

knowledge and specific test modules for a comprehensive operator certification program. No failures since solutions were implemented, saving >$500,000 compared to previous year scrap.

- Sterilization Program Manager: Fully validated 11 steam vessels, 5 EO vessels, 1 Dry Heat oven and 7 contract sterilizers (EO & Gamma). Increased capacity for "bottleneck" process over 170% to eliminate related back-orders. Optimized sterilization cycles to reduce EO gas consumption 20-40% and improved product aeration to decrease quarantine time by 40%. Savings over $400,000 per year 1991-2000. Sterilization and Packaging Subject Matter Expert. Served on AAMI Sterilization Working Groups to develop current industry standards & best practices. Member of writing committees for AAMI TIR 28:2001 Product Adoption & ST 63:2002 Dry Heat Sterilization.
- Project Team Leader: For upgrading two 1000 ft3 sterilizers from EO/Freon to Carboxide (EO/CO2) including software validation 1991. Completed on time and under budget with no service interruption and annual savings over $2,000,000.
- Project Team Leader: For EO Sterilization Facility Upgrade 1992-1994, cost over $1.5 million to improve process control and meet emission requirements. Conducted investigation using complex data collection and analysis to show increased failure incidents were caused by insufficient preconditioning. Established standard operating procedures and SPC to improve process reliability by 97% and reduce process reject rate to < 0.02%. Also saved > $100,000/yr in utility costs.
- Lab Manager: For Microbiology, Analytical Chemistry and Physical QC Test Laboratories (staff of 11 with annual budget >$1M). Supervised QC testing for sterility release, biocompatibility (ISO 10993), cytotoxicity, bioburden, LAL, particulate contamination, heavy metals, FTIR, GC, AA, etc. Implemented SPC charts, smart forms and on-line reporting to improve test turnaround time (>50%), reduce errors (>82%) and facilitate review and retrieval of lab results. Eliminated need lot release testing for transfusion products through process validation, and brought new testing in-house for faster turnaround and savings of over $150,000/yr. Closed local labs and transferred testing for all Davol products to other Bard facilities, savings over $500,000/yr. Chairperson C.R.Bard Laboratory Steering Committee 1997-2002. Establish policies & best practices to maintain testing & compliance goals. Committee initiatives for test reduction resulted in annual savings over $1,000,000.
- Project Team Leader: To qualify self-contained biological indicator system for use at KS sterilization facility to enable on-site sterility testing without a Micro Lab in 1997. Expedited product release 3-5 days to improve customer service and save over $160 K/yr in inventory charges. Eliminated need for new warehouse ($2,000,000 cost avoidance).
- Controlled Environment (Class 8): Qualifications 2008 & 2012. Developed and implemented IQ/OQ/PQ. Analyzed and investigated particulate and bioburden excursions. Revised all related SOPs and conducted training on contamination control.
- Training: Developed Body of Knowledge & competency tests for Operator Certification Programs at Davol and Sealed Air. Developed and conducted technical presentations for training managers, engineers and hourly employees. Also developed web-based versions to deliver on-line, with 24/7 flexibility, tracking and documentation. Instructor for ASQ CQA & CMQ/OE refresher courses since 1993. Implemented computer tracking of training requirements and records to improve compliance from less than 50% to greater than 99%. Topics included: Cost of Quality, Process Improvement, Lean, 6 Sigma, SPC, QFD, Failure Investigation and Root Cause Analysis, ISO/GMP Compliance, Internal Auditing, FMEAs, Supplier Management, Measurement & Calibration Awareness, Cleaning & Sterilization Validation, General Safety Awareness (HazCom and Blood Borne Pathogens) and other issues as needed.