

ERIC K. HOESCHLE

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QUALITY ENGINEER

QUALITY ENGINEERING YOU CAN COUNT ON...WINNING BUY-IN ACROSS DEPARTMENTS & PROJECT TEAMS

Quality Engineer with proven experience in internal auditing, quality systems regulations QSR, testing and calibration, and quality assurance for electronic, mechanical and medical device manufacturing. Delivered efficiency improvements, cost reductions, and quality enhancements. Trained in **Lean Six Sigma Green Belt**. Background in field sales and applications engineering. **Bachelor's Degree** in Mechanical Engineering.

Collaborative project leader and internal auditor who champions quality and motivates regulatory compliance with internal and external stakeholders. Recognized strengths in relating to and communicating with others, building trust and respect, and dependable problem-solving. Member of American Society for Quality ASQ.

KEY VALUE OFFERED

- QMS Upgrade & Maintenance
- ISO / cGMP FDA Regulations
- Testing & Quality Assurance
- Continuous Improvement
- Quality Management System QMS Processes
- Six Sigma Design of Experiments DOE
- FDA QSR / ISO 13485 Quality Systems
- Supplier Quality Management & Risk Analysis
- Internal Auditing
- Root Cause Analysis
- Quality Architecture
- Project Management

CAREER TIMELINE

Contract Quality Engineer – McCormack & Masher, Inc., Boston, MA	4/08 - 6/08
Quality Engineer – Topnotch Systems, Microelectronics Div., New York, NY	11/06 - 8/07
Regulatory Affairs Associate – Dennison Manufacturing, Inc., Cambridge, MA	5/06 - 10/06
Med-equipment Design, Inc. (MED), Cambridge, MA	9/99 - 4/06
Promoted to Quality Engineer, Calibration Coordinator, and Lead Internal Auditor ISO 13485/QSR	

PROFESSIONAL HIGHLIGHTS

MED-EQUIPMENT DESIGN, INC.

Manufacturer of electronic medical devices with annual sales of \$14 million (2006) and 145 employees.

Quality Engineer (7/03 - 4/06), Calibration Coordinator (10/02 - 7/03), Lead Internal Auditor / Internal Auditor ISO 13485/QSR (4/02 - 4/06), Electronic Service Technician (9/99 - 10/02)

- **Quality Management System (QMS):** Upgraded QMS in 2005 to comply with ISO 13485 and FDA QSR. Trained and scheduled 3 assistant auditors who conducted 30 internal audits (ISO / FDA QSR) in 9 months.
- **Quality Improvements:** Consistently monitored return product history and sought continuous improvements through root cause analysis, design of experiments (DOE), and supplier quality management. Trained cell operators on work instruction changes and use of manufacturing equipment after product improvements.
 - **Medical Diagnosis Screener:** Saved \$432,000 over 5 years (\$7200 per month) and decreased service repair time 10% by eliminating 15% return rate of largest customer.
 - **Equipment Controller:** Decreased assembly time 25% and saved \$10,000 annually by identifying non-conforming part that slowed production, wasted inventory and potentially damaged PCB assembly.
 - **Device Activator:** Reduced failure rate by 25%, shaved 15% off assembly time, and boosted customer satisfaction. Investigated, performed DOE, tested new component, and changed work instructions.
- **Auditing:** Managed internal audit system and supplier quality audits (ISO / FDA QSR) to maintain product integrity; reported directly to Executive Committee as Lead Internal Auditor. Resolved and closed 100% of preventive corrective action requests (PCARs) for non-conformance (2002-2005).
- **QMS Maintenance:** Led Correction Action / Preventive Action (CAPA) system (2005-2006) and inspection of non-conforming Material Review Board (MRB) activities as Quality Engineer (2003-2006). Resolved and closed 100% of 80 PCARs after 2005 QMS upgrade within 1 day to 5 months.

PROFESSIONAL EXPERIENCE

DENNISON MANUFACTURING, INC.

Privately held manufacturer of medical devices. Key clients included Travenol, Cheeseborough-Ponds, Sherwood Medical, Stryker, B. Braun Medical, and Boston Scientific.

Regulatory Affairs Associate

- **Quality Architecture / ISO 13485:2003 Certification:** Enabled \$2 million in sales through upgrade of FDA QSR-compliant QMS to ISO 13485:2003 and Canada Medical Device Regulations CMDR compliance. Led internal auditing of QMS procedures and prepared QMS documentation and audit schedule.
- **Quality Auditing:** Served as lead quality interface in customer audits, which resulted in minor findings. Maintained regulatory compliance with ISO 13485, ISO 14971 risk management, FDA QSR, and CMDR.

TOPNOTCH SYSTEMS

Manufacturer and ISO 9001 certified supplier of modular circuitry for electronics RF and microwave applications. Primary customer: military contracts. Annual sales (2007) of \$25 million and 150 employees.

Quality Engineer – Integrated Products Division

Sole Quality Engineer for this division and Resistor group. Lead Supplier Quality Engineer and Auditor.

- **QMS Maintenance:** Oversaw non-conforming Material Review Board (MRB) process from all inspection points (receiving, in-process, and final inspection). Led investigation, problem resolution, and corrective action. Successfully dispositioned \$25,000 in inventory (25 lots) per week.
 - Collaborated with process and design engineers, generated rework instructions, and obtained sign-offs.
 - Scheduled and completed source inspections with Raytheon, Lockheed-Martin, Northrup Grumman, BAE, Telephonics, and DFCAS, which fulfilled \$2 million in contractual requirements per month.
 - Facilitated flow of products through inspection process, which minimized bottlenecks and delays.
- **Supplier Quality:** Defined yield and quality improvement goals and consulted with 21 suppliers. Partnered with Director of Quality and Purchasing Manager in supplier quality improvement initiative.
- **Project Management:** Led installation, calibration, testing, and maintenance of \$3,000 ionograph standard test module to assess cleanliness of printed circuit board assemblies, which enabled \$100,000 in sales to Telephonics. Developed and delivered equipment training for 10 staff (engineers and inspector).
- **Quality Assurance:** Championed focus on quality standards and best practices at operator level that led to continuous process improvements. Ensured regulatory compliance with ISO 9001 and MIL-Q-9858, as well as specific military contract compliance requirements.

MacCORMACK & MASHER, INC.

Private manufacturer of fluid control systems for military and aerospace applications. Facilities in MA and India.

Contract Quality Engineer – Quality Group

- **HPACS Project:** Spearheaded completion of AS9102 First Article Inspection Report, which fulfilled contractual requirements of \$3 million project. Met with client representatives and collaborated with design engineering, production, purchasing, and quality in materials review and assembly specs validation.

EDUCATION, CERTIFICATION & TRAINING

Bachelor of Science, Mechanical Engineering – University of Massachusetts, Boston, MA

Certificate, Computer Electronics Technology – New Hampshire Business College, Peterborough, NH

Lean Six Sigma Green Belt Certification (in progress) – American Society for Quality (ASQ) provider

IPC-A-610 Certified – 2007

RAB QSA Certified – ISO 13485:2003 Lead Auditor Training – 2006

Computer Skills: MS Office, Word, Excel, Access, PowerPoint, MS Visio, ManFact and CATSWEB (inventory control and tracking proprietary software applications), Internet research