

Karen Kenney

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Professional Summary

Experienced Quality manager within the medical device, aerospace, automotive and general industries. Having built and maintained quality systems from scratch, I offer a wealth of knowledge to enhance any ISO certified facility.

#readytowork

Authorized to work in the US for any employer

Work Experience

Quality Manager

Eclipse Engineering Inc-Erie, CO

June 2020 to Present

Quality Manager: responsibilities management representative for ISO 9001 / AS9100D, responsible for all facets of the QMS, customer quality concerns, vendor management. Eclipse is a mid size seal manufacture I was able to upgrade the QMS and have guided them through multiple audits with no findings.

Quality Manager

Relucent Plastics Solutions-Erie, CO

December 2018 to January 2020

- Developed ISO9001 and ISO13485 quality management system
- Implemented in-line inspection protocols for quality inspection
- Sponsorship of employee Safety Committee
- Created Document Control processes
- Oversaw implementation of MSDSOnline tool to increase chemical compliance capabilities
- Managed CAPA, NCMR, MRB and Audits

Quality Manager

ARC Group Worldwide-Frederick, CO

October 2016 to December 2018

- Managed AS9100 Quality System implementation
- Enhanced supplier quality management capabilities
- Leadership of Material Review Board and Material Rejection Report teams
- Managed Quality Inspection staff of 18 people running a 24/6 schedule
- Identified process improvement areas by analysis of scrap report

Quality Supervisor

PAC Worldwide-Phoenix, AZ

December 2015 to August 2016

- Originated all rework instructions according to document control process
- Conducted lab testing of raw materials and final inspection of finished goods
- Lead internal auditor for site
- Managed Quality system training for all employees

File Room Supervisor

CVS Caremark-Phoenix, AZ
October 2014 to December 2015

- Developed HIPPA Compliance training procedures and tools
- Managed mail room staff and implemented training processes for the team
- Ensured compliance and on-time delivery of products and services within Medicare guidelines

File Room Supervisor

Express Scripts-Phoenix, AZ
October 2010 to October 2014

- Increased Data Entry team productivity by 25% through coaching and mentoring programs
- Reduced mailroom FTE by 50% while increasing throughput and decreasing TAT to less than one day
- Managed mail room team during company merger
- Implement On-the-job training programs for new hires resulting in retention rates increasing 30%

Education

Medical Assistant Degree

Parks College-Denver, CO
1983

Skills

- Six Sigma
- FIFO
- Document Control
- ECR/ECN
- Corrective Action
- Non-conforming material disposition
- Visual controls
- 5S/Lean
- Continuous Improvement
- Team building and management
- ISO9001, ISO13485, AS9100, IATF16949
- Internal Audit
- Project management
- Process improvement
- Learning and Development

- FDA Experience
- REACH and RoHS oversight
- SPC
- Risk Mitigation
- FMEA and Control Plans
- Quality Assurance
- training
- ISO
- Microsoft Office
- Quality Systems
- Plastics Injection Molding
- Quality Management
- Lean Manufacturing
- Manufacturing
- ERP Systems
- Micrometer
- Quality Inspection
- Senior leadership
- Overseeing audit functions
- Leadership
- Data-driven decision making
- Compliance audits & assessments
- Manufacturing management
- Aviation
- Analysis skills
- Team management
- Regulatory compliance
- Manufacturing company experience
- Management
- Pharmaceutical regulatory compliance
- Accreditation standards (regulatory compliance area)
- Supervising experience
- Project implementation
- Microsoft Word
- Microsoft PowerPoint
- Microsoft Outlook
- Microsoft Excel
- Communication skills
- Driving
- Windows

- Productivity software
- Computer operation