# Michelle Cooley

**Manager/Supervisor, Quality**
Parker, CO
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Highly motivated, detail-oriented, administrative, organized, and reliable professional offering over 8 years of education and more than 15 years of experience in quality management systems, document and record management, and change management. Provided statements, analysis, and other key performance reporting to make informed business decisions. Focused on analyzing, developing, implementing, and supporting various objectives while task prioritizing and meeting projected deadlines. Highly skilled at evaluating and resolving complex problems and making sound decisions. Possess strong effective communication skills.

Authorized to work in the US for any employer

## Work Experience

### Supervisor, Quality

West Pharmaceuticals (Medical)
2017 to 2019

• Supervised direct reports in change management, document control, records management, CAPA, nonconformance, complaint handling, inspection, shipping, and calibrations.
• Conducted performance management, interviews, and development planning.
• Developed and maintained policies, procedures, and programs related to various regulations and standards: ISO 13485, ISO 22301, ISO 14001, and ISO 14971. Assisted in obtaining ISO13485 certification.
• Drove defined projects to closure while maintaining compliance will regulations and standards.
• Collaborated with cross-functional departments to ensure timely implementation of change management requirements (review, approval, change, implementation, release, and notification).
• Conducted root cause analysis, investigations, containment, effectiveness checks, and implemented sound solutions for nonconformance, CAPAs, and complaints.
• Analyzed deviations, sampling procedures, engineering studies/protocols, and validations to include statistical analysis and metrics.
• Reviewed and updated customer drawings, specifications, and/or requirements.
• Conducted quality inspections on product requirements to include quality planning of control plans and inspection documentation.
• Analyzed quality data and trends to determine areas/process for improvement.
• Coordinated and performed audits (internal and external).
• Assisted in the development of the quality management system for ISO13485 certification.

### Analyst, Quality

Eaton (Manufacturing)
2015 to 2017

• Developed, implemented, and maintained a system for document control, record management, change management, and training requirements.

• Executed and maintained corrective actions, preventive actions, complaints, deviations, and nonconformance to determine root cause and required solutions.
• Conducted quality problem investigation, defect containment, determination of root cause, development and implementation of countermeasures, and follow up to confirm effectiveness.
• Conducted internal audits and supported various external audits.
• Performed problem identification, resolution, loss reporting, and continuous improvement.
• Designed and implemented methods for process control and process improvement.
• Established policies, procedures, forms, and work instructions for the Quality Management System.
• Expertise in ISO, Internal 8D, DMAIC, Database Administration, software integration, and etc.
• Established ISO 9001:2015 certification within 1 year.

### Analyst, Quality

CWS (Oil and Gas)
2012 to 2015

• Assisted in developing a quality management system aimed at business processes and procedures at the operational and corporate level.
• Worked with operational, HSE, and corporate groups in Canada and the USA to ensure documents and records are captured, organized, edited and formatted, made available and controlled in accordance with ISO 9001 and API Q2 requirements.
• Developed and maintained a document and record control process to include corporate document and records map, record retention and retrieval system, standards and specification library/register, and project registry.
• Developed and maintained a risk management process: FMEA, Statistical Analysis, Contingency Planning, Root Cause Analysis, Investigation, etc.
• Developed and administrated change management within the core function of the business.
• Conducted internal document audits and resolved findings and discrepancies with use of a variety of quality techniques to include Nonconformance's, Preventive Actions, Corrective Actions, Risk Managements, or Management of Change Orders.
• Assisted in establishing API Q2 certification.

### Coordinator III, Project

Medtronic (Medical)
2008 to 2011

• Oversaw and managed all manufacturing, engineering, and quality documentation.
• Multiple roles as NCMR / CAPA / ECO coordinator to ensure proper documentation functions.
• Maintained certification in ISO 9001 and FDA regulations.
• Conducted audits (internal and external).
• Maintained databases for all qualifications, validations, engineering change orders, retrieval of documents, issuance of part numbers, and NCMRs.

### Analyst, Quality

Veritek Manufacturing
2007 to 2008

• Oversaw the development, coordination, and maintenance of the document management system in relations to aerospace, defense, medical, and industrial services.
• Established and maintained procedures, policies and automated systems needed to meet the demands of the company and customers.

• Extensive knowledge of regulations and standards: FDA, ISO 14001 / 9001 / 13485, AS9100, IPC, and UL.

## Education

### Master's Degree in Business Administration
University of Phoenix
June 2010

### Bachelors of Science in Computer Information Systems
Arizona State University
May 2004

## Skills

Quality Assurance (10+ years), Quality Control (10+ years), Quality Management (10+ years), Auditing (10+ years), Change Management (10+ years), Document Management (10+ years), Records Management (10+ years), ISO (10+ years), Complaint Handling (8 years), CAPA (10+ years), NCR (10+ years), Validation (10+ years), Process Improvement (8 years), Lean Six Sigma (8 years), GMP, QA

## Additional Information

• Quality Mgmt. Systems • Quality Control/ Processes • Document/Record Mgmt. • Change/Risk Mgmt.

• Process/Project Mgmt. • Technical Writing • CAPA/Nonconformances • Complaint Handling
• Product Lifecycle • Regulations - ISO / FDA • Audits - Internal/External • Customer Service
• Multi-Task/Prioritizing • Key Performance Reports • Self-Starter/ Team • Leadership
Computer Literate with proficiencies in all Microsoft Software applications, Project, SharePoint, LMS (Success Factors), and various Enterprise Content Management Systems (i.e. SAP/Agile/etc.)