



# MICHAEL ANDERSON

## QUALITY SYSTEMS MANAGER

### CONTACT

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### SKILLS

- Regulatory Compliance
- Quality Auditing
- CAPA
- Risk Management
- Team Leadership
- Process Improvement

### LANGUAGES

- English
- Spanish
- French

### EDUCATION

**MASTER OF SCIENCE IN QUALITY ASSURANCE, UNIVERSITY OF SOUTHERN CALIFORNIA**

### ACHIEVEMENTS

- Achieved a 99% pass rate during external FDA inspections over five consecutive years.
- Implemented a quality training program that decreased employee errors by 50%.
- Received the Quality Excellence Award for leading successful quality improvement projects.

### PROFILE

Results-driven Biomedical Quality Specialist with over 10 years of experience in pharmaceuticals and medical devices. Exceptional knowledge of regulatory requirements and quality standards. Proven ability to manage quality audits, risk management, and compliance assessments. Adept at leveraging analytical skills to develop and implement quality improvement initiatives that enhance operational efficiency. Strong leadership and communication skills facilitate effective collaboration with stakeholders across multiple departments.

### EXPERIENCE

#### QUALITY SYSTEMS MANAGER

##### PharmaGen Solutions

2016 - Present

- Directed quality assurance operations, ensuring compliance with FDA and EMA regulations.
- Developed and maintained quality management systems, resulting in a 40% decrease in audit findings.
- Oversaw the training and development of quality assurance personnel on standard operating procedures.
- Implemented CAPA processes that reduced cycle times by 20%.
- Conducted internal and external audits to ensure compliance with regulatory standards.
- Collaborated with product development teams to integrate quality into the design process.

#### QUALITY ASSURANCE SPECIALIST

##### MediTech Corp.

2014 - 2016

- Performed quality checks on incoming materials and finished products to ensure compliance with specifications.
- Facilitated training sessions for staff on quality assurance processes and best practices.
- Managed deviation reports and non-conformance investigations, implementing corrective actions.
- Analyzed quality data to identify trends and areas for improvement.
- Participated in cross-functional teams to enhance product quality and reduce time to market.
- Supported successful ISO 9001 certification audit by maintaining thorough documentation.