MICHAEL ANDERSON

QUALITY ASSURANCE SPECIALIST

CONTACT

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San Francisco, CA

SKILLS

- Quality Assurance
- Regulatory Affairs
- ISO Standards
- Audit Management
- Validation
- Cross-Functional Collaboration

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOMEDICAL ENGINEERING, TECH UNIVERSITY, 2013

ACHIEVEMENTS

- Implemented a new quality tracking system that increased audit readiness and reduced response time by 40%.
- Recognized as 'Employee of the Year' for outstanding contributions to quality initiatives.
- Contributed to a project that achieved a 95% customer satisfaction rating on product quality surveys.

PROFILE

Results-oriented Life Sciences Quality Specialist with over 8 years in the medical device industry. Expertise in quality assurance, compliance, and regulatory affairs with a focus on ISO standards. Proven ability to conduct audits, manage quality control processes, and implement corrective actions to ensure product safety and efficacy. Strong communication skills with a demonstrated ability to work effectively with multidisciplinary teams.

EXPERIENCE

QUALITY ASSURANCE SPECIALIST

MedTech Solutions

2016 - Present

- Managed quality assurance processes for multiple medical device projects from conception through market release.
- Conducted ISO 13485 compliance audits, ensuring adherence to international quality standards.
- Developed and executed validation protocols for manufacturing processes, reducing validation time by 15%.
- Collaborated with product development teams to address quality concerns early in the design phase.
- Monitored and reported on product quality KPIs, facilitating data-driven decision-making.
- Coordinated training sessions on quality management principles for over 50 employees.

REGULATORY AFFAIRS COORDINATOR

Device Innovations Corp.

2014 - 2016

- Assisted in the preparation and submission of regulatory documentation for CE marking and FDA approvals.
- Maintained up-to-date knowledge of regulatory requirements, guiding the team to ensure compliance.
- Conducted pre-market and post-market surveillance activities to monitor product performance.
- Coordinated with engineering teams to resolve regulatory queries during product development.
- Developed training materials on regulatory compliance for internal stakeholders.
- Participated in cross-functional teams to assess and mitigate quality risks associated with new product launches.