MA

Michael ANDERSON

REGULATORY AFFAIRS ENGINEER

Strategic Medical Device Engineer with an extensive background in regulatory affairs and compliance within the medical technology sector. Recognized for a meticulous approach to ensuring that products meet all regulatory requirements while maintaining high standards of quality and safety. Proven expertise in navigating complex regulatory landscapes, including FDA and CE marking processes.

CONTACT

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San Francisco, CA

SKILLS

- regulatory compliance
- quality management
- risk assessment
- project management
- internal auditing
- training

LANGUAGES

- English
- Spanish
- French

EDUCATION

MASTER OF SCIENCE IN REGULATORY AFFAIRS, UNIVERSITY OF SOUTHERN CALIFORNIA

ACHIEVEMENTS

- Streamlined regulatory submission processes, reducing approval timelines by 20%.
- Received the 'Excellence in Compliance' award for outstanding contributions to regulatory affairs.
- Authored multiple guidelines that became standard practice within the organization.

WORK EXPERIENCE

REGULATORY AFFAIRS ENGINEER

Global MedTech Corp

2020 - 2025

- Managed regulatory submissions for over 20 medical devices, achieving a 95% approval rate.
- Developed and maintained quality management systems in compliance with ISO 9001 standards.
- Conducted internal audits to identify areas for improvement in compliance processes.
- Collaborated with R&D teams to ensure designs met regulatory requirements from inception.
- Provided training to staff on regulatory compliance and quality assurance practices.
- Engaged with regulatory agencies to facilitate timely product approvals.

QUALITY ASSURANCE ENGINEER

MedTech Solutions

2015 - 2020

- Implemented quality control protocols that reduced product defects by 15%.
- Conducted risk assessments and developed mitigation strategies for device development.
- Collaborated with cross-functional teams to enhance product safety and efficacy.
- Maintained comprehensive documentation for regulatory compliance and quality audits.
- Participated in the design validation process to ensure product reliability.
- Trained new employees on quality management systems and regulatory requirements.