Michael ANDERSON

REGULATORY COMPLIANCE OFFICER

Detail-oriented Biomedical Regulatory Scientist with 6 years of experience in the medical device industry. Strong familiarity with the regulatory landscape, including 510(k) submissions and CE marking processes. Proven ability to navigate complex regulatory frameworks and ensure compliance with applicable standards. Experienced in cross-functional collaboration with engineering, quality assurance, and clinical teams to ensure product safety and efficacy.

CONTACT

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San Francisco, CA

SKILLS

- Medical device regulation
- 510(k) submissions
- Compliance auditing
- Quality control
- Cross-functional collaboration
- Documentation

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOMEDICAL ENGINEERING, UNIVERSITY OF MICHIGAN, 2014

ACHIEVEMENTS

- Achieved a 30% reduction in submission timelines through process improvements.
- Recognized for exceptional performance during FDA inspections with zero observations.
- Developed and implemented a training program that improved compliance rates across the organization.

WORK EXPERIENCE

REGULATORY COMPLIANCE OFFICER

MedTech Innovations

2020 - 2025

- Managed 510(k) submissions for multiple medical devices, achieving timely approvals.
- Collaborated with engineering teams to ensure product designs met regulatory requirements.
- Conducted internal audits to identify compliance risks and implement corrective actions.
- Maintained up-to-date knowledge of regulatory changes affecting the medical device industry.
- Documented and reported post-market surveillance findings to regulatory authorities.
- Trained staff on compliance protocols and regulatory updates, enhancing organizational knowledge.

QUALITY CONTROL ANALYST

Device Safety Corp.

2015 - 2020

- Performed quality control testing on medical devices, ensuring compliance with FDA standards.
- Assisted in the development of quality assurance processes to enhance product safety.
- Collaborated with regulatory teams to prepare documentation for regulatory submissions.
- Conducted product performance evaluations and reported results to management.
- Participated in root cause analysis for non-conformance issues, implementing corrective actions.
- Supported training initiatives on quality standards and regulatory expectations.