MA

Michael ANDERSON

REGULATORY AFFAIRS MANAGER

Visionary Clinical Regulatory Affairs Manager with extensive experience in the medical device industry, specializing in regulatory strategy and compliance. Demonstrated ability to effectively navigate complex regulatory frameworks to achieve timely approvals for innovative products. A proactive leader with a strong focus on quality assurance and risk management, ensuring that all regulatory submissions meet or exceed industry standards.

CONTACT

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San Francisco, CA

SKILLS

- Medical Device Regulations
- Risk Management
- Quality Assurance
- Compliance Training
- Cross-Functional Leadership
- Strategic Development

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOMEDICAL ENGINEERING, GEORGIA TECH

ACHIEVEMENTS

- Achieved a 20% reduction in time-to-market for new device approvals.
- Recognized for outstanding performance in regulatory submissions with a company award.
- Implemented a new compliance tracking system that improved efficiency by 35%.

WORK EXPERIENCE

REGULATORY AFFAIRS MANAGER

Device Innovations Group

2020 - 2025

- Led regulatory strategy development for a diverse portfolio of Class II and III medical devices.
- Managed the preparation and submission of 510(k) applications and PMAs.
- Collaborated with R&D to ensure compliance from concept through product launch.
- Conducted risk assessments to identify potential regulatory challenges.
- Engaged with regulatory bodies to clarify requirements and expectations.
- Trained teams on regulatory compliance and best practices for submissions.

SENIOR REGULATORY AFFAIRS SPECIALIST

MedDevices LLC

2015 - 2020

- Supported regulatory submissions for new medical devices and product modifications.
- Maintained regulatory documentation and ensured compliance with global standards.
- Conducted training sessions on regulatory requirements for product development teams.
- Assisted in post-market surveillance activities to monitor product safety.
- Collaborated with quality teams to ensure adherence to ISO standards.
- Provided regulatory support for clinical trial applications.