



Michael ANDERSON

REGULATORY AFFAIRS DIRECTOR

Innovative Regulatory Affairs Consultant with a focus on the medical device sector, recognized for expertise in navigating FDA and international regulatory pathways. Possesses a deep understanding of quality management systems and their integration into regulatory processes. Proven ability to lead cross-functional teams in achieving regulatory compliance and successful product launches. Demonstrates exceptional analytical skills, with a commitment to upholding the highest standards of product safety and efficacy.

CONTACT

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SKILLS

- Medical Device Regulations
- Quality Management
- Submission Strategies
- Cross-Functional Leadership
- Compliance Audits
- Training

LANGUAGES

- English
- Spanish
- French

EDUCATION

**MASTER OF SCIENCE IN BIOMEDICAL
ENGINEERING, JOHNS HOPKINS
UNIVERSITY, 2014**

ACHIEVEMENTS

- Achieved 100% success rate for regulatory submissions during tenure.
- Implemented a quality management system that reduced compliance issues by 50%.
- Recognized for leadership excellence in regulatory affairs by industry peers.

WORK EXPERIENCE

REGULATORY AFFAIRS DIRECTOR

MedTech Solutions

2020 - 2025

- Oversaw regulatory compliance for a diverse range of medical devices.
- Developed and implemented regulatory strategies for product approvals.
- Managed submissions for 510(k) and PMA applications.
- Conducted audits of quality systems to ensure regulatory adherence.
- Trained staff on regulatory requirements and best practices.
- Collaborated with engineering teams to ensure design compliance with regulations.

REGULATORY AFFAIRS SPECIALIST

Device Innovations Corp.

2015 - 2020

- Supported regulatory submissions for innovative medical devices.
- Reviewed technical documentation for compliance with standards.
- Participated in regulatory meetings with FDA representatives.
- Maintained up-to-date knowledge of industry regulations and standards.
- Prepared regulatory documentation for device classifications.
- Assisted in post-market surveillance activities to ensure ongoing compliance.