



MICHAEL ANDERSON

REGULATORY AFFAIRS MANAGER

CONTACT

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-  San Francisco, CA

SKILLS

- Regulatory Compliance
- Medical Device Regulations
- Submission Management
- Team Leadership
- Risk Assessment
- Training Development

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOMEDICAL
ENGINEERING, MASSACHUSETTS
INSTITUTE OF TECHNOLOGY

ACHIEVEMENTS

- Achieved a 98% success rate for regulatory submissions during tenure.
- Recognized for implementing a new compliance tracking system that improved efficiency.
- Spearheaded a project that reduced regulatory approval timelines by 20%.

PROFILE

Strategic and detail-oriented Regulatory Affairs Officer with a robust background in biotechnology and medical devices. Excels in developing and executing regulatory strategies that enhance product development timelines while ensuring adherence to regulatory standards. Expertise in managing complex regulatory submissions and maintaining compliance with global regulations. Proven ability to lead cross-functional teams and communicate effectively with stakeholders at all levels.

EXPERIENCE

REGULATORY AFFAIRS MANAGER

BioInnovate Corp

2016 - Present

- Oversaw the regulatory submission process for novel medical devices, achieving a 40% increase in approval rates.
- Developed and implemented regulatory training programs for staff.
- Collaborated with quality assurance teams to align product development with regulatory requirements.
- Managed regulatory audits and inspections, ensuring compliance with ISO standards.
- Created comprehensive regulatory documentation for product commercialization.
- Established best practices for regulatory submissions across the organization.

REGULATORY AFFAIRS SPECIALIST

HealthTech Solutions

2014 - 2016

- Assisted in the preparation of 510(k) submissions for multiple medical devices.
- Maintained up-to-date knowledge of global regulatory changes affecting product lifecycle.
- Facilitated communication between engineering and regulatory teams to ensure compliance.
- Participated in risk assessment activities to identify regulatory impacts.
- Developed templates and guidelines for regulatory documentation.
- Supported post-market surveillance by monitoring product performance and adverse events.