



MICHAEL ANDERSON

REGULATORY AFFAIRS MANAGER

CONTACT

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-  San Francisco, CA

SKILLS

- Regulatory compliance
- Quality assurance
- Risk management
- Clinical trials
- Stakeholder engagement
- Market analysis

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOMEDICAL ENGINEERING, MASSACHUSETTS INSTITUTE OF TECHNOLOGY

ACHIEVEMENTS

- Achieved market access for over 15 medical devices in the EU and US.
- Improved submission quality, resulting in a 25% increase in approval rates.
- Recognized for outstanding leadership in regulatory compliance initiatives.

PROFILE

Strategic Medical Devices Regulatory Specialist with a robust background in regulatory compliance and quality assurance within the healthcare industry. Recognized for adeptly managing complex regulatory submissions and fostering strong relationships with regulatory agencies. Expertise in risk management and post-market surveillance, ensuring that products meet the highest safety and efficacy standards. Demonstrated success in leading regulatory affairs initiatives, resulting in expedited product approvals and market access.

EXPERIENCE

REGULATORY AFFAIRS MANAGER

BiInnovate Corp

2016 - Present

- Oversaw regulatory submissions for a portfolio of medical devices across multiple jurisdictions.
- Developed regulatory strategies aligned with business goals and market needs.
- Led cross-functional teams in preparing for regulatory inspections.
- Established and maintained relationships with key regulatory agencies.
- Monitored changes in regulations and communicated impacts to stakeholders.
- Coordinated training sessions on regulatory practices for staff.

REGULATORY AFFAIRS SPECIALIST

MedTech Innovations

2014 - 2016

- Prepared regulatory submissions including IDE and PMA applications.
- Conducted product risk assessments and developed mitigation strategies.
- Collaborated with manufacturing teams to ensure compliance with quality standards.
- Reviewed and approved technical documentation for accuracy.
- Participated in clinical trial design and regulatory oversight.
- Engaged in market research to inform regulatory strategies.