



# Michael ANDERSON

## REGULATORY AFFAIRS OFFICER

Innovative Medical Devices Regulatory Specialist with extensive experience in regulatory compliance and quality assurance across a variety of medical device sectors. Expertise in developing and executing regulatory strategies that align with corporate objectives while ensuring adherence to strict regulatory requirements. Proven track record in managing submissions for new products and modifications, resulting in successful market entry.

### CONTACT

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### SKILLS

- Regulatory compliance
- Quality assurance
- Risk management
- Document control
- Cross-functional collaboration
- Training

### LANGUAGES

- English
- Spanish
- French

### EDUCATION

**BACHELOR OF SCIENCE IN LIFE  
SCIENCES, UNIVERSITY OF TORONTO**

### ACHIEVEMENTS

- Successfully led multiple product submissions resulting in timely approvals.
- Improved internal regulatory processes, enhancing efficiency by 20%.
- Recognized for excellence in regulatory compliance training initiatives.

### WORK EXPERIENCE

#### REGULATORY AFFAIRS OFFICER

NextGen Medical Devices

2020 - 2025

- Managed the preparation and submission of regulatory documents for new device approvals.
- Conducted regulatory compliance assessments for product lines.
- Collaborated with engineering teams to ensure regulatory considerations are integrated.
- Provided regulatory expertise during product development phases.
- Maintained comprehensive records of regulatory submissions and communications.
- Participated in external audits and inspections.

#### REGULATORY AFFAIRS ASSOCIATE

HealthTech Solutions

2015 - 2020

- Assisted in the regulatory review of product labeling and promotional materials.
- Supported the development of regulatory submissions for international markets.
- Engaged in post-market surveillance and reporting activities.
- Reviewed technical files for compliance with applicable regulations.
- Facilitated communication between the organization and regulatory bodies.
- Contributed to the development of training materials for regulatory compliance.