



MICHAEL ANDERSON

DIRECTOR OF REGULATORY AFFAIRS

CONTACT

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SKILLS

- regulatory compliance
- project management
- risk assessment
- stakeholder management
- training and development
- process optimization

LANGUAGES

- English
- Spanish
- French

EDUCATION

**MASTER OF BUSINESS
ADMINISTRATION, REGULATORY
AFFAIRS, HARVARD UNIVERSITY**

ACHIEVEMENTS

- Achieved a 100% compliance rate during regulatory inspections.
- Received the 'Regulatory Excellence Award' for innovative process improvements.
- Successfully led a project that resulted in the launch of three new products in one year.

PROFILE

Highly accomplished Regulatory Affairs Executive with a decade-long career in the biotechnology industry, recognized for strategic vision and operational excellence. Expertise in regulatory compliance and product registration in both domestic and international markets. Proven ability to manage complex projects, ensuring alignment with regulatory requirements and corporate objectives. Skilled in risk assessment and mitigation strategies, enhancing the overall compliance framework.

EXPERIENCE

DIRECTOR OF REGULATORY AFFAIRS

BioTech Global

2016 - Present

- Directed regulatory strategy for a portfolio of biologics and biosimilars.
- Oversaw the preparation and submission of regulatory documents to health authorities.
- Established and maintained relationships with key regulatory stakeholders.
- Led initiatives to streamline regulatory processes, achieving 20% faster approvals.
- Conducted training sessions on regulatory compliance for cross-departmental teams.
- Monitored regulatory trends to inform strategic business decisions.

REGULATORY AFFAIRS MANAGER

Innovative Biologics Inc.

2014 - 2016

- Managed the regulatory submission process for clinical trials and marketing applications.
- Coordinated with clinical teams to ensure adherence to regulatory requirements.
- Prepared detailed regulatory reports and documentation for submission.
- Assisted in developing regulatory strategies for product lifecycle management.
- Facilitated interactions with regulatory agencies to resolve issues promptly.
- Maintained comprehensive knowledge of applicable regulations and guidelines.