



MICHAEL ANDERSON

REGULATORY AFFAIRS MANAGER

CONTACT

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-  San Francisco, CA

SKILLS

- Regulatory submissions
- Biotechnology
- Compliance training
- Strategic planning
- Risk assessment
- Market research

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOLOGY,
UNIVERSITY OF MICHIGAN

ACHIEVEMENTS

- Successfully led a project that reduced regulatory submission timelines by 20%.
- Recipient of the 'Regulatory Excellence Award' in 2021.
- Authored a comprehensive regulatory guidelines document adopted company-wide.

PROFILE

Highly skilled Regulatory Affairs Specialist with a robust background in biotechnology and over 8 years of relevant experience. Renowned for expertise in managing regulatory submissions and ensuring compliance with international regulations. Demonstrates exceptional ability to interpret complex regulatory frameworks and provide strategic guidance to product development teams. Proven success in facilitating timely approvals through effective communication with regulatory bodies.

EXPERIENCE

REGULATORY AFFAIRS MANAGER

Biotech Innovations

2016 - Present

- Directed regulatory submission strategies for biologics, enhancing approval timelines by 25%.
- Evaluated regulatory implications of clinical data, providing critical insights to project teams.
- Established and maintained relationships with key regulatory stakeholders.
- Developed internal compliance training programs for staff and stakeholders.
- Oversaw the preparation of regulatory submissions, ensuring accuracy and completeness.
- Conducted regulatory risk assessments for product development initiatives.

REGULATORY AFFAIRS ASSOCIATE

Innovative Health Corp.

2014 - 2016

- Assisted in the compilation of regulatory submissions for new and existing products.
- Conducted market research to align product development with regulatory requirements.
- Supported the creation of regulatory documentation for clinical trials.
- Monitored industry trends and regulatory changes, providing updates to teams.
- Facilitated meetings with cross-functional teams to discuss regulatory strategies.
- Prepared responses to regulatory inquiries and deficiencies from agencies.