



MICHAEL ANDERSON

REGULATORY AFFAIRS MANAGER

CONTACT

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-  San Francisco, CA

SKILLS

- Regulatory Strategy
- Compliance Management
- Clinical Trials
- Documentation Review
- Stakeholder Communication
- Training Development

LANGUAGES

- English
- Spanish
- French

EDUCATION

**BACHELOR OF SCIENCE IN BIOLOGY,
UNIVERSITY OF FLORIDA**

ACHIEVEMENTS

- Successfully led the regulatory submission for a breakthrough drug, achieving approval ahead of schedule.
- Received the Compliance Excellence Award for outstanding performance in regulatory affairs.
- Implemented a new regulatory tracking system that reduced submission errors by 40%.

PROFILE

Diligent Regulatory Manager with extensive experience in the biotechnology sector, specializing in compliance with federal and international regulations. Exceptional knowledge of drug development processes, from preclinical to post-market phases. Proven ability to develop and implement regulatory strategies that align with corporate goals while minimizing risk. Strong analytical skills facilitate thorough evaluation of regulatory submissions and documentation.

EXPERIENCE

REGULATORY AFFAIRS MANAGER

Biotech Innovations LLC

2016 - Present

- Oversaw regulatory submissions for clinical trials, ensuring alignment with FDA and EMA standards.
- Coordinated cross-departmental efforts to streamline regulatory processes.
- Developed training materials for staff on regulatory compliance and best practices.
- Conducted internal audits to assess compliance with regulatory requirements.
- Managed relationships with regulatory agencies to facilitate communication and resolve issues.
- Reviewed and approved all regulatory documentation prior to submission.

REGULATORY AFFAIRS ASSOCIATE

Innovative Biologics Corp.

2014 - 2016

- Assisted in the preparation of IND submissions and BLA applications.
- Conducted research on regulatory guidelines and industry best practices.
- Prepared reports for management on regulatory compliance status.
- Supported the development of product labeling and patient information materials.
- Participated in regulatory inspections and audits, ensuring readiness.
- Collaborated with scientific teams to ensure compliance during product development.