



MICHAEL ANDERSON

SENIOR REGULATORY AFFAIRS SPECIALIST

CONTACT

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-  San Francisco, CA

SKILLS

- Regulatory compliance
- Product lifecycle management
- Agency interaction
- Documentation management
- Team collaboration
- Industry analysis

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOTECHNOLOGY, UNIVERSITY OF FLORIDA

ACHIEVEMENTS

- Instrumental in securing FDA approval for a breakthrough diagnostic product ahead of schedule.
- Recognized for excellence in regulatory strategy development at the annual company awards.
- Contributed to a publication on regulatory best practices in biomedical research.

PROFILE

Accomplished Regulatory Affairs Specialist with extensive expertise in the biotechnology sector, specializing in regulatory compliance and product lifecycle management. Recognized for a meticulous approach to regulatory submissions, ensuring alignment with both domestic and international regulations. Demonstrates a strong ability to interpret complex regulatory guidelines and implement effective compliance strategies. Proven history of successful collaboration with scientific teams to facilitate the development of innovative therapies.

EXPERIENCE

SENIOR REGULATORY AFFAIRS SPECIALIST

Genomic Health Corp.

2016 - Present

- Led regulatory strategy development for novel diagnostic products, ensuring timely market access.
- Managed interactions with regulatory agencies, including pre-submission meetings and advisory committee presentations.
- Created and maintained regulatory submissions and documentation for product approvals.
- Evaluated changes in regulations and their implications for ongoing projects.
- Provided guidance on regulatory requirements to product development teams.
- Facilitated training for staff on regulatory compliance and submission processes.

REGULATORY AFFAIRS ASSOCIATE

BioPharma Ltd.

2014 - 2016

- Assisted in the preparation of regulatory submissions for clinical trial applications.
- Reviewed product labeling to ensure compliance with regulatory standards.
- Maintained regulatory documentation and tracking systems for submissions.
- Supported the regulatory team during inspections and audits.
- Collaborated with clinical research teams to ensure compliance with regulatory policies.
- Monitored industry trends and regulatory updates to inform strategic planning.