MICHAEL ANDERSON

REGULATORY AFFAIRS MANAGER

CONTACT

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San Francisco, CA

SKILLS

- Regulatory strategy
- Submission management
- Team leadership
- Compliance assurance
- Documentation quality
- Stakeholder engagement

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOLOGY, UNIVERSITY OF FLORIDA

ACHIEVEMENTS

- Successfully led a team that submitted a groundbreaking drug application that received priority review status.
- Increased submission efficiency by 40% through process optimization initiatives.
- Awarded 'Regulatory Excellence' for outstanding leadership in submission efforts.

PROFILE

Distinguished Regulatory Submissions Specialist with extensive experience in the biotechnology sector, specializing in the strategic development and execution of regulatory submissions. Expertise in navigating complex regulatory environments, ensuring compliance with international standards. Strong analytical skills facilitate the assessment of regulatory requirements and the development of innovative submission strategies. Proficient in fostering productive relationships with regulatory agencies and internal stakeholders, ensuring alignment on project objectives.

EXPERIENCE

REGULATORY AFFAIRS MANAGER

GenBio Corporation

2016 - Present

- Directed the regulatory submission strategy for multiple product lines.
- Oversaw the preparation of regulatory documents for global submissions.
- Engaged with regulatory agencies to facilitate timely feedback.
- Managed a team of regulatory professionals, providing mentorship and guidance.
- Ensured compliance with both FDA and EMA regulations.
- Reviewed and approved all regulatory submissions prior to filing.

REGULATORY AFFAIRS ASSOCIATE

NextGen Biotech

2014 - 2016

- Coordinated submissions for investigational new drugs (INDs) and new drug applications (NDAs).
- Assisted in the development of regulatory strategies for clinical trials.
- Ensured timely responses to regulatory inquiries and requests for information.
- Conducted training sessions on submission processes for cross-functional teams.
- Maintained regulatory files and submission databases.
- Participated in external audits and inspections.