



MICHAEL ANDERSON

REGULATORY AFFAIRS ASSOCIATE

CONTACT

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-  San Francisco, CA

SKILLS

- Regulatory submissions
- IND/NDA preparation
- Clinical trials
- Project management
- Compliance documentation
- Communication skills

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOLOGY,
UNIVERSITY OF FLORIDA, 2016

ACHIEVEMENTS

- Contributed to the successful approval of a new drug leading to market entry within 12 months.
- Recognized for outstanding teamwork during a critical regulatory audit, leading to zero findings.
- Implemented a tracking system for regulatory submissions that improved efficiency by 25%.

PROFILE

Dedicated Biomedical Regulatory Scientist with 5 years of experience in the pharmaceutical industry, specializing in drug development and regulatory submissions. Skilled in preparing IND and NDA submissions, ensuring compliance with FDA guidelines. Experienced in collaborating with clinical teams to facilitate smooth regulatory processes and expedite product approvals. Strong project management abilities, with a focus on maintaining timelines and budget constraints.

EXPERIENCE

REGULATORY AFFAIRS ASSOCIATE

PharmaLife Inc.

2016 - Present

- Assisted in the preparation and submission of IND applications, leading to successful trial initiation.
- Coordinated with clinical teams to ensure timely submission of clinical study reports.
- Reviewed and updated regulatory documentation to reflect current FDA guidelines.
- Participated in regulatory meetings with FDA representatives to discuss trial progress.
- Maintained electronic regulatory files, ensuring easy access for audits.
- Conducted literature reviews to support regulatory submissions and responses to inquiries.

CLINICAL RESEARCH COORDINATOR

Clinical Trials Group

2014 - 2016

- Managed day-to-day operations of clinical trials, ensuring adherence to regulatory standards.
- Developed and maintained trial documentation and regulatory binders for audits.
- Assisted in the preparation of regulatory submissions for clinical trials.
- Trained new staff on regulatory processes and compliance requirements.
- Monitored trial progress, ensuring compliance with study protocols and regulatory timelines.
- Submitted reports on trial outcomes to regulatory bodies, ensuring transparency and accountability.