



Michael ANDERSON

REGULATORY AFFAIRS CONSULTANT

Dynamic Regulatory Affairs Specialist with a robust background in pharmaceutical product development and regulatory compliance. Proven track record in managing the regulatory submission process and ensuring adherence to FDA guidelines. Adept at conducting comprehensive reviews of regulatory documents, identifying potential issues, and implementing corrective actions. Strong analytical skills facilitate the evaluation of regulatory trends and their implications for product development.

CONTACT

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- 📍 San Francisco, CA

SKILLS

- Regulatory compliance
- Document review
- Analytical skills
- Training and development
- Risk assessment
- Project coordination

LANGUAGES

- English
- Spanish
- French

EDUCATION

**BACHELOR OF SCIENCE IN BIOLOGY,
UNIVERSITY OF NORTH CAROLINA**

ACHIEVEMENTS

- Reduced submission errors by 50% through improved review processes.
- Recognized as a top consultant for delivering exceptional client results.
- Played a key role in the successful approval of a critical product line.

WORK EXPERIENCE

REGULATORY AFFAIRS CONSULTANT

Regulatory Solutions Group

2020 - 2025

- Provided regulatory consulting services to pharmaceutical companies on compliance issues.
- Reviewed and assessed regulatory submissions for completeness and accuracy.
- Developed comprehensive regulatory strategies for product approvals.
- Conducted training workshops on FDA regulations and submission processes.
- Collaborated with cross-functional teams to streamline regulatory practices.
- Maintained current knowledge of regulatory changes and industry best practices.

REGULATORY AFFAIRS SPECIALIST

PharmaCare Ltd.

2015 - 2020

- Managed the preparation of regulatory submissions for new drug applications.
- Conducted audits of regulatory files to ensure compliance with internal standards.
- Engaged with regulatory agencies to clarify submission requirements.
- Provided regulatory support for clinical trial applications.
- Tracked and reported on regulatory changes impacting the organization.
- Participated in risk assessments to identify compliance gaps.