



# MICHAEL ANDERSON

## Senior Regulatory Affairs Associate

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### SUMMARY

Highly skilled Regulatory Submissions Specialist with a profound understanding of the regulatory landscape in the pharmaceutical industry. Expertise encompasses the preparation, submission, and management of regulatory documents to ensure compliance with global health authorities. A proven track record in leading cross-functional teams to navigate complex regulatory pathways, ensuring timely submissions and approvals.

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### WORK EXPERIENCE

#### Senior Regulatory Affairs Associate PharmaTech Solutions

Jan 2023 - Present

- Led the preparation of IND, NDA, and BLA submissions to the FDA.
- Developed and maintained regulatory submission timelines and project plans.
- Collaborated with clinical and manufacturing teams to gather essential documentation.
- Reviewed labeling and advertising materials for compliance with regulatory requirements.
- Conducted gap analysis on regulatory submissions to enhance approval success rates.
- Trained junior staff on regulatory submission processes and best practices.

#### Regulatory Affairs Specialist BioMed Innovations

Jan 2020 - Dec 2022

- Managed submissions for clinical trial applications across multiple regions.
  - Provided regulatory guidance during product development phases.
  - Facilitated communication with regulatory authorities for efficient resolution of inquiries.
  - Performed audits of regulatory documentation to ensure compliance.
  - Maintained up-to-date knowledge of regulatory changes and industry trends.
  - Participated in risk assessment activities to mitigate regulatory risks.
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### EDUCATION

#### Master of Science in Regulatory Affairs, University of California, San Francisco

Sep 2019 - Oct 2020

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### ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory submissions, Compliance management, Project planning, Cross-functional collaboration, Quality assurance, Risk assessment
- **Awards/Activities:** Achieved a 95% approval rate for regulatory submissions within the first submission cycle.
- **Awards/Activities:** Recognized with the 'Excellence in Regulatory Affairs' award in 2021.
- **Awards/Activities:** Implemented a new electronic submission tracking system that reduced processing time by 30%.
- **Languages:** English, Spanish, French