



# MICHAEL ANDERSON

## Senior Regulatory Affairs Specialist

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### SUMMARY

Distinguished Pharmaceutical Regulatory Affairs Specialist with over a decade of experience in navigating complex regulatory frameworks across the pharmaceutical industry. Expertise encompasses the preparation and submission of regulatory documents, compliance with FDA and EMA guidelines, and strategic planning for product launches. Proficient in conducting regulatory assessments to ensure product alignment with evolving regulations.

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### WORK EXPERIENCE

#### Senior Regulatory Affairs Specialist Global Pharma Solutions

Jan 2023 - Present

- Led the preparation of IND and NDA submissions, ensuring adherence to regulatory standards.
- Collaborated with clinical teams to align study protocols with regulatory requirements.
- Developed and maintained regulatory submission timelines to optimize project delivery.
- Conducted regulatory intelligence to inform strategic decision-making processes.
- Facilitated meetings with regulatory agencies to address inquiries and obtain guidance.
- Trained junior staff on regulatory processes and submission best practices.

#### Regulatory Affairs Associate Pharma Innovations Inc.

Jan 2020 - Dec 2022

- Assisted in the preparation of regulatory submissions, including 510(k) applications.
  - Monitored regulatory developments and communicated impacts to internal teams.
  - Coordinated document reviews and approvals to ensure compliance.
  - Maintained regulatory databases and tracked submission status.
  - Participated in cross-functional teams to support product development initiatives.
  - Supported post-marketing surveillance activities to ensure ongoing compliance.
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### EDUCATION

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

Sep 2019 - Oct 2020

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### ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory submissions, Compliance management, Strategic planning, Cross-functional collaboration, Regulatory intelligence, Project management
- **Awards/Activities:** Successfully reduced submission timelines by 25% through process improvements.
- **Awards/Activities:** Received 'Excellence in Regulatory Affairs' award in 2021 for outstanding performance.
- **Awards/Activities:** Contributed to a product launch that achieved \$10M in first-year sales.
- **Languages:** English, Spanish, French