



MICHAEL ANDERSON

Senior Regulatory Affairs Manager

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SUMMARY

Distinguished Regulatory Affairs Executive with over 15 years of experience in the pharmaceutical sector, specializing in global regulatory strategies and compliance. Demonstrated expertise in navigating complex regulatory landscapes and securing timely approvals for innovative therapies. Proven track record in leading cross-functional teams to enhance regulatory submissions and optimize product development timelines.

WORK EXPERIENCE

Senior Regulatory Affairs Manager Global Pharma Solutions

Jan 2023 - Present

- Led regulatory submission strategies for over 20 products across multiple regions.
- Collaborated with R&D teams to ensure compliance with FDA and EMA guidelines.
- Managed regulatory audits and inspections, achieving zero non-compliances.
- Developed training programs for regulatory staff on updated regulations.
- Streamlined submission processes, reducing approval times by 30%.
- Acted as the primary liaison with regulatory agencies to facilitate communication.

Regulatory Affairs Specialist BioHealth Innovations

Jan 2020 - Dec 2022

- Executed regulatory submissions for investigational new drugs (INDs) and new drug applications (NDAs).
 - Conducted gap analyses to identify compliance risks and implement corrective actions.
 - Participated in cross-functional teams for product development and regulatory strategies.
 - Maintained up-to-date knowledge of global regulatory changes and trends.
 - Provided regulatory guidance during clinical trial phases to ensure compliance.
 - Prepared and submitted annual reports and updates to regulatory authorities.
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EDUCATION

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

Sep 2019 - Oct 2020

ADDITIONAL INFORMATION

- **Technical Skills:** regulatory strategy, compliance management, cross-functional leadership, submission processes, audit management, stakeholder engagement
- **Awards/Activities:** Successfully led a team that achieved a 95% approval rate for regulatory submissions.
- **Awards/Activities:** Recognized with the 'Excellence in Regulatory Affairs' award for outstanding performance.
- **Awards/Activities:** Implemented a new regulatory tracking system, increasing efficiency by 25%.
- **Languages:** English, Spanish, French