MICHAEL ANDERSON

Senior Regulatory Affairs Specialist

- San Francisco, CA
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Distinguished Regulatory Affairs Consultant with an extensive background in navigating complex regulatory landscapes across the pharmaceutical and biotechnology sectors. Expertise encompasses strategic regulatory planning, compliance assessments, and the facilitation of product approvals in global markets. Demonstrated ability to enhance organizational efficiency through the implementation of best practices in regulatory submissions and interactions with health authorities.

WORK EXPERIENCE

Senior Regulatory Affairs Specialist | Global Pharma Solutions Jan 2022 – Present

- Led regulatory submissions for new drug applications, achieving a 95% approval rate within target timelines.
- Coordinated with cross-functional teams to align regulatory strategies with corporate objectives.
- Developed and implemented training programs for staff on regulatory compliance processes.
- Conducted gap analyses to identify potential compliance issues and formulated action plans.
- Managed relationships with regulatory authorities, ensuring clear communication during product review processes.
- Authored detailed regulatory documents, including INDs and NDAs, adhering to stringent quality standards.

Regulatory Affairs Associate | MedTech Innovations Jul 2019 – Dec 2021

- Assisted in the preparation of regulatory submissions for medical devices, contributing to a 30% reduction in time to market.
- Performed regulatory intelligence research to stay abreast of changes in legislation affecting product compliance.
- Collaborated with R&D teams to ensure compliance from the inception of product development.
- Monitored post-market surveillance data to ensure ongoing compliance and address any emerging issues.
- Participated in audits and inspections, leading to zero findings during regulatory inspections.
- Maintained regulatory documentation and submission files in accordance with company standards.

SKILLS

Regulatory strategy | Compliance management | Risk assessment | Submission preparation | Cross-functional collaboration | Regulatory intelligence

EDUCATION

Master of Science in Regulatory Affairs San Francisco

University of California

ACHIEVEMENTS

- Successfully navigated the approval of over 30 pharmaceutical products across diverse therapeutic areas.
- Developed a regulatory compliance framework that reduced non-compliance incidents by 40%.
- Recognized with the "Excellence in Regulatory Affairs" award for outstanding contributions to product approvals.

LANGUAGES

English | Spanish | French