

MICHAEL ANDERSON

Global Regulatory Affairs Manager

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Results-driven Clinical Regulatory Affairs Manager with a specialization in global regulatory compliance for life sciences. Demonstrated expertise in managing submission processes for a wide range of therapeutic areas, including vaccines and diagnostics. Highly skilled in developing regulatory strategies that align with business objectives while ensuring adherence to international regulations. Proven track record of leading cross-functional teams to achieve successful product approvals in highly regulated environments.

WORK EXPERIENCE

Global Regulatory Affairs Manager | LifeScience Global Solutions

Jan 2022 – Present

- Managed global regulatory submissions for vaccines, ensuring compliance with WHO and FDA regulations.
- Developed and implemented global regulatory strategies for product launches.
- Collaborated with international teams to ensure alignment on regulatory requirements.
- Conducted training on global regulatory compliance for internal stakeholders.
- Reviewed and approved regulatory documents for accuracy and compliance.
- Maintained up-to-date knowledge of global regulatory changes and trends.

Regulatory Affairs Manager | Diagnostics Solutions Inc.

Jul 2019 – Dec 2021

- Supported regulatory submissions for diagnostic devices, ensuring compliance with FDA and CE marking.
- Assisted in the development of regulatory documents and quality management systems.
- Conducted regulatory risk assessments to identify potential compliance issues.
- Collaborated with clinical teams to ensure adherence to regulatory standards.
- Provided regulatory guidance for clinical trial applications.
- Participated in audits and inspections to ensure compliance with regulatory requirements.

SKILLS

Global Regulatory Compliance

Vaccines

Diagnostics

Quality Management

Regulatory Strategy

Cross-Functional Collaboration

EDUCATION

Master of Science in Life Sciences

2015 – 2019

Harvard University

ACHIEVEMENTS

- Successfully led a project that resulted in the approval of a novel vaccine within 12 months.
- Awarded for excellence in regulatory submissions and compliance.
- Improved submission timelines by 30% through process enhancements.

LANGUAGES

English

Spanish

French