MICHAEL ANDERSON

Senior Regulatory Affairs Specialist

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SUMMARY

Visionary Regulatory Manager with over a decade of experience navigating complex regulatory landscapes across multiple sectors. Expertise encompasses strategic compliance, risk assessment, and operational excellence. Demonstrated ability to lead cross-functional teams in the development and implementation of regulatory strategies that ensure adherence to global standards. Proficient in interpreting legislation and translating it into actionable policies, fostering a culture of compliance within organizations.

WORK EXPERIENCE

Senior Regulatory Affairs Specialist Global Pharmaceuticals Inc. *Jan 2023 - Present*

- Led the regulatory strategy for new drug applications in multiple regions.
- Managed submissions to regulatory authorities, ensuring compliance with local and international guidelines.
- Conducted risk assessments to identify potential compliance issues and developed mitigation strategies.
- Collaborated with R&D teams to align product development with regulatory expectations.
- Facilitated training sessions for staff on regulatory requirements and best practices.
- Monitored changes in legislation and updated internal policies accordingly.

Regulatory Affairs Consultant Regulatory Solutions Group *Jan 2020 - Dec 2022*

- Provided expert guidance on regulatory submissions for medical devices.
- Developed comprehensive compliance programs tailored to client needs.
- Assisted clients in preparing for regulatory audits and inspections.
- Reviewed and approved labeling and promotional materials for compliance.
- Established metrics to evaluate the effectiveness of compliance programs.
- Supported clients in navigating post-market surveillance requirements.

EDUCATION

Master of Science in Regulatory Affairs, University of California, Berkeley *Sep 2019 - Oct 2020*

ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory Compliance, Risk Management, Strategic Planning, Stakeholder Engagement, Audit Management, Policy Development
- **Awards/Activities:** Successfully led a team in obtaining FDA approval for a novel therapeutic product, reducing time to market by 30%.
- **Awards/Activities:** Recognized as Employee of the Year for exceptional contributions to regulatory processes.
- **Awards/Activities:** Implemented a new compliance tracking system that improved audit readiness by 50%.
- **Languages:** English, Spanish, French