MICHAEL ANDERSON

Regulatory Affairs Specialist

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SUMMARY

Distinguished Regulatory Affairs Analyst with extensive expertise in navigating the complex landscape of regulatory compliance within the pharmaceutical industry. Proven track record of managing regulatory submissions and ensuring adherence to FDA guidelines, resulting in expedited product approvals. Adept at conducting thorough reviews of clinical trial protocols and submissions, leading to enhanced operational efficiencies.

WORK EXPERIENCE

Regulatory Affairs Specialist Pharma Innovations Inc. *Jan 2023 - Present*

- Managed the submission of IND applications and subsequent amendments to regulatory authorities.
- Conducted regulatory intelligence assessments to inform product development strategies.
- Collaborated with R&D teams to ensure compliance with regulatory standards during product lifecycle.
- Reviewed and approved labeling and promotional materials to ensure regulatory compliance.
- Facilitated training sessions for staff on regulatory requirements and best practices.
- Monitored changes in regulations and communicated impacts to relevant stakeholders.

Regulatory Affairs Associate Health Solutions LLC *Jan 2020 - Dec 2022*

- Assisted in the preparation and submission of 510(k) applications for medical devices.
- Conducted risk assessments to ensure compliance with ISO standards.
- Maintained compliance documentation and regulatory files for internal audits.
- Supported the development of regulatory strategies for new product launches.
- Participated in cross-departmental project teams to align regulatory goals with business objectives.
- Performed data analysis to track regulatory submission timelines and outcomes.

EDUCATION

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

ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory compliance, FDA submissions, Clinical trials, Risk assessment, Strategic planning, Cross-functional collaboration
- **Awards/Activities:** Led a team that achieved a 30% reduction in regulatory submission timelines.
- **Awards/Activities:** Received the 'Excellence in Compliance' award for outstanding contributions to regulatory projects.
- **Awards/Activities:** Successfully navigated a high-profile FDA audit with zero findings.
- **Languages:** English, Spanish, French