MICHAEL ANDERSON

Senior Regulatory Affairs Specialist

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SUMMARY

Distinguished Clinical Regulatory Affairs Manager with over a decade of expertise in navigating complex regulatory landscapes within the pharmaceutical sector. Proven track record of successfully leading cross-functional teams to ensure compliance with FDA regulations and international standards. Adept at developing and implementing regulatory strategies that facilitate product approvals and market access.

WORK EXPERIENCE

Senior Regulatory Affairs Specialist PharmaTech Solutions *Jan 2023 - Present*

- Led the preparation and submission of IND applications, ensuring compliance with regulatory standards.
- Collaborated with clinical teams to develop regulatory strategies for multiple pipeline products.
- Conducted gap analyses to identify regulatory risks and proposed mitigation strategies.
- Reviewed and approved labeling and promotional materials for compliance with FDA regulations.
- Managed interactions with regulatory agencies, resulting in expedited review timelines.
- Trained junior staff on regulatory submission processes and compliance requirements.

Regulatory Affairs Associate HealthCorp Innovations *Jan 2020 - Dec 2022*

- Assisted in the preparation of 510(k) submissions and PMA applications.
- Maintained regulatory documentation and ensured timely updates in compliance systems.
- Participated in product development meetings to provide regulatory insights and guidance.
- Analyzed competitor submissions to enhance regulatory strategies.
- Facilitated training sessions on regulatory compliance for internal stakeholders.
- Collaborated with quality assurance to ensure adherence to regulatory requirements.

EDUCATION

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

ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory Compliance, FDA Regulations, Clinical Trials, Risk Assessment, Project Management, Stakeholder Engagement
- **Awards/Activities:** Successfully led a team that achieved a 30% reduction in submission timelines.
- **Awards/Activities:** Received the 'Excellence in Regulatory Affairs' award for outstanding performance.
- **Awards/Activities:** Implemented a new documentation system that improved compliance tracking efficiency by 40%.
- **Languages:** English, Spanish, French