MICHAEL ANDERSON

Regulatory Affairs Specialist

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SUMMARY

Results-driven Biomedical Regulatory Scientist with over 8 years of experience in ensuring compliance with FDA regulations and international standards. Proven track record in managing regulatory submissions for medical devices and pharmaceuticals, with a focus on pre-market and post-market activities. Adept at conducting risk assessments, preparing documentation for product approvals, and collaborating with cross-functional teams.

WORK EXPERIENCE

Regulatory Affairs Specialist HealthTech Innovations *Jan 2023 - Present*

- Led regulatory submissions for Class II medical devices, resulting in 100% approval rate from FDA.
- Developed and maintained regulatory documentation in compliance with ISO 13485 standards.
- Conducted training sessions on regulatory requirements for cross-functional teams, enhancing compliance understanding.
- Managed post-market surveillance activities, ensuring timely reporting of adverse events.
- Collaborated with R&D teams to integrate regulatory considerations into product design processes.
- Participated in audits by regulatory bodies, achieving positive outcomes without non-conformities.

Quality Assurance Analyst MedSafe Solutions *Jan 2020 - Dec 2022*

- Performed quality audits on manufacturing processes, leading to a 30% reduction in non-conformance reports.
- Assisted in the development of SOPs to enhance compliance with regulatory standards.
- Evaluated product labeling to ensure accuracy and compliance with industry regulations.
- Coordinated internal training programs on quality management systems and regulatory updates.
- Utilized statistical analysis tools to assess quality trends and implement corrective actions.
- Participated in the preparation of regulatory submissions, contributing to expedited approval timelines.

EDUCATION

Master of Science in Regulatory Affairs, University of California, 2012 *Sep 2019 - Oct 2020*

ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory submissions, FDA compliance, ISO standards, Risk assessment, Quality assurance, Documentation management
- **Awards/Activities:** Successfully led a project that achieved 50% faster regulatory approval through process optimization.
- **Awards/Activities:** Received the 'Excellence in Compliance' award for outstanding contributions to regulatory affairs.
- **Awards/Activities:** Developed a comprehensive training manual that improved compliance knowledge across the organization.
- **Languages:** English, Spanish, French