MICHAEL ANDERSON

Senior Regulatory Affairs Specialist

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SUMMARY

Highly accomplished Medical Devices Regulatory Specialist with over a decade of extensive experience in navigating complex regulatory landscapes. Expertise in facilitating the approval processes for innovative medical devices, ensuring compliance with both domestic and international regulations. Proficient in collaborating with cross-functional teams to streamline product development and regulatory submissions. Demonstrated ability to interpret and implement regulatory guidelines, significantly reducing time-to-market for new products.

WORK EXPERIENCE

Senior Regulatory Affairs Specialist Global MedTech Solutions *Jan 2023 - Present*

- Developed and submitted 510(k) applications for various medical devices.
- Conducted thorough gap analyses to identify compliance issues.
- Managed cross-functional teams to ensure alignment on regulatory strategies.
- Provided training on regulatory requirements to internal stakeholders.
- Collaborated with R&D to integrate regulatory considerations in product design.
- Maintained up-to-date knowledge of FDA and ISO regulations.

Regulatory Affairs Associate Innovative Health Technologies *Jan 2020 - Dec 2022*

- Assisted in the preparation of regulatory submissions for CE marking.
- Reviewed labeling and promotional materials for compliance.
- Participated in internal audits to ensure adherence to regulatory standards.
- Created and maintained regulatory documentation and records.
- Engaged with regulatory bodies during pre-submission meetings.
- Supported post-market surveillance activities and reporting.

EDUCATION

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

ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory strategy, Compliance management, Risk assessment, Documentation, Project management, Cross-functional collaboration
- **Awards/Activities:** Successfully led a team that achieved FDA approval for a novel orthopedic device.
- **Awards/Activities:** Reduced regulatory submission timelines by 30% through process optimization.
- **Awards/Activities:** Received the 'Excellence in Regulatory Affairs' award for outstanding performance.
- **Languages:** English, Spanish, French