MICHAEL ANDERSON

Regulatory Affairs Coordinator

- San Francisco, CA
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Dynamic Medical Devices Regulatory Specialist with a solid foundation in regulatory compliance and quality assurance in the healthcare sector. Experienced in managing regulatory submissions and ensuring adherence to both domestic and international regulations. Skilled in conducting risk assessments and audits to enhance product safety and efficacy. Proven ability to collaborate effectively with cross-functional teams to achieve strategic objectives.

WORK EXPERIENCE

Regulatory Affairs Coordinator | Future Health Technologies Jan 2022 – Present

- Coordinated regulatory submissions for new medical devices in compliance with FDA standards.
- Assisted in the development of internal regulatory policies and procedures.
- Conducted training sessions on regulatory requirements for staff.
- Reviewed technical documents for compliance with regulatory standards.
- Engaged with regulatory authorities during the submission process.
- Maintained regulatory documentation and databases.

Regulatory Affairs Intern | HealthTech Innovations Jul 2019 – Dec 2021

- Supported regulatory submissions for Class I and II medical devices.
- Assisted in the review of labeling and promotional materials.
- Participated in post-market surveillance activities.
- Conducted market research to support regulatory strategies.
- Maintained compliance documentation and records.
- Collaborated with teams to ensure regulatory adherence.

SKILLS

Regulatory compliance | Quality assurance | Risk assessment | Documentation | Team collaboration | Training

EDUCATION

Bachelor of Science in Biomedical Engineering 2015 – 2019

University of Michigan

ACHIEVEMENTS

- Successfully coordinated multiple regulatory submissions leading to timely approvals.
- Improved regulatory processes, increasing efficiency by 15%.
- Recognized for outstanding contributions to compliance training initiatives.

LANGUAGES

English | Spanish | French