MA

Phone: (555) 234-5678

Email: michael.anderson@email.com

Address: San Francisco, CA

Website: www.michaelanderson.com

EXPERTISE SKILLS

- Medical devices
- Quality assurance
- Regulatory submissions
- Compliance audits
- Team collaboration
- Documentation management

LANGUAGES

- English
- Spanish
- French

CERTIFICATION

- Bachelor of Science in Biomedical Engineering, University of California, Berkeley

REFERENCES

John Smith
Senior Manager, Tech Corp
john.smith@email.com

Sarah Johnson
Director, Innovation Labs
sarah.j@email.com

Michael Brown
VP Engineering, Solutions Inc
mbrown@email.com

MICHAEL ANDERSON

REGULATORY AFFAIRS ANALYST

Versatile Regulatory Affairs Analyst proficient in the medical device sector, with a strong foundation in quality assurance and regulatory compliance. Demonstrated ability to navigate the regulatory landscape to ensure timely product approvals and market access. Highly skilled in preparing and reviewing regulatory submissions, including 510(k)s and PMAs, with a focus on maintaining compliance with ISO standards.

PROFESSIONAL EXPERIENCE

MedTech Innovations

Mar 2018 - Present

Regulatory Affairs Analyst

- Managed the preparation and submission of 510(k) applications for new medical devices.
- Conducted audits of regulatory documentation to ensure compliance with ISO 13485.
- Collaborated with engineering teams to address regulatory concerns during product development.
- Reviewed labeling and promotional materials for regulatory compliance.
- Participated in regulatory strategy meetings to align with business goals.
- Maintained up-to-date knowledge of regulatory trends and guidelines.

Device Solutions Corp.

Dec 2015 - Jan 2018

Quality Assurance Specialist

- Assisted in maintaining the quality management system in compliance with FDA regulations.
- Conducted training on quality assurance and regulatory compliance for staff.
- Reviewed and approved change controls to ensure regulatory compliance.
- Participated in internal audits and inspections.
- Maintained documentation for regulatory submissions and audits.
- Supported product development teams with regulatory guidance.

ACHIEVEMENTS

- Successfully reduced submission preparation time by 25% through process improvements.
- Received recognition for excellence in compliance during a corporate audit.
- Contributed to a team that achieved ISO certification for quality management systems.