MA

Michael ANDERSON

SENIOR COMPLIANCE SPECIALIST

Experienced Clinical Research Compliance Specialist with a solid background in medical device research and regulatory compliance. With over 7 years in the field, I have honed my skills in ensuring that research practices align with both ethical standards and regulatory requirements. My experience includes leading compliance audits, training research teams, and collaborating with regulatory agencies to facilitate seamless approvals.

CONTACT

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San Francisco, CA

SKILLS

- ISO compliance
- FDA regulations
- Audit management
- Training development
- Documentation
- Risk assessment

LANGUAGES

- English
- Spanish
- French

EDUCATION

MASTER'S IN REGULATORY AFFAIRS, UNIVERSITY OF REGULATORY SCIENCES

ACHIEVEMENTS

- Achieved a 100% compliance rate during external audits over the past two years.
- Successfully implemented a compliance training program that improved team performance by 30%.
- Recognized for outstanding contributions to compliance in medical device trials at the annual industry conference.

WORK EXPERIENCE

SENIOR COMPLIANCE SPECIALIST

MedDevice Solutions

2020 - 2025

- Led compliance audits for clinical trials involving medical devices, ensuring adherence to ISO and FDA standards.
- Developed and maintained compliance documentation, including SOPs and training materials.
- Trained research staff on compliance protocols, resulting in improved audit readiness.
- Collaborated with regulatory bodies to address compliance issues and ensure timely approvals.
- Utilized compliance management software to track audit findings and corrective actions.
- Monitored clinical trials for compliance with ethical standards and regulatory requirements.

CLINICAL RESEARCH COORDINATOR

Research Innovations Group

2015 - 2020

- Managed compliance for clinical trials, ensuring adherence to protocol and regulatory requirements.
- Conducted regular site visits to assess compliance and provide feedback for improvement.
- Reviewed informed consent documents to ensure clarity and compliance with regulations.
- Prepared compliance reports for management and regulatory agencies.
- Assisted in the development of trial protocols, focusing on compliance aspects.
- Maintained up-to-date knowledge of medical device regulations and best practices.