



MICHAEL ANDERSON

COMPLIANCE MANAGER

CONTACT

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-  San Francisco, CA

SKILLS

- GCP
- FDA regulations
- Risk management
- Training development
- Site monitoring
- Documentation management

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN BIOLOGY,
UNIVERSITY OF SCIENCE

ACHIEVEMENTS

- Led a compliance initiative that resulted in a 25% improvement in site audit scores over one year.
- Received the 'Compliance Excellence Award' for outstanding contributions to regulatory affairs.
- Developed a training program that increased staff compliance awareness, demonstrated by improved audit results.

PROFILE

Results-oriented Clinical Research Compliance Specialist with over 10 years of experience in regulatory affairs within the biotechnology industry. My extensive background includes developing compliance frameworks that enhance research integrity and protect participant safety. I possess a strong ability to navigate complex regulatory landscapes and have successfully managed compliance for multiple high-stakes clinical trials.

EXPERIENCE

COMPLIANCE MANAGER

BioTech Research Group

2016 - Present

- Oversaw compliance for multi-site clinical trials, ensuring adherence to GCP and FDA regulations.
- Developed and implemented a comprehensive risk management plan that reduced non-compliance incidents by 40%.
- Conducted regular training sessions for research staff on compliance issues and regulatory updates.
- Collaborated with legal teams to address compliance-related inquiries and resolve issues promptly.
- Utilized electronic data capture systems to monitor compliance metrics efficiently.
- Established a robust documentation process that improved audit readiness and compliance outcomes.

CLINICAL RESEARCH ASSOCIATE

Innovative Trials LLC

2014 - 2016

- Managed site compliance for clinical trials, ensuring adherence to protocol and regulatory standards.
- Reviewed and approved informed consent forms, ensuring participant understanding and ethical compliance.
- Conducted site visits to assess compliance with trial protocols and provided feedback for improvement.
- Worked closely with investigators to ensure timely reporting of adverse events while maintaining compliance.
- Prepared detailed reports on compliance findings and presented them to senior management.
- Maintained a comprehensive knowledge base of industry regulations and best practices.