



MICHAEL ANDERSON

Clinical Regulatory Affairs Specialist

Proactive Regulatory Affairs Officer with a comprehensive background in clinical research and regulatory compliance within the biotechnology industry. Known for a meticulous approach to managing clinical trial submissions and ensuring adherence to regulatory standards. Extensive experience in collaborating with clinical teams to support product development and ensure compliance with regulatory requirements.

WORK EXPERIENCE

Clinical Regulatory Affairs Specialist

2020-2023

Biotech Innovations

- Managed regulatory submissions for clinical trials, ensuring compliance with all regulatory requirements.
- Collaborated with clinical research teams to develop regulatory strategies.
- Conducted regulatory reviews of clinical trial protocols and informed consent documents.
- Participated in regulatory meetings with health authorities.
- Developed and maintained regulatory documentation for clinical studies.
- Trained staff on regulatory compliance and clinical trial processes.

Regulatory Affairs Coordinator

2019-2020

Clinical Solutions Inc.

- Assisted in the preparation of regulatory submissions for new drug applications.
- Monitored regulatory changes impacting clinical trial operations.
- Coordinated with internal teams to ensure compliance with regulatory standards.
- Reviewed and approved clinical trial materials for regulatory compliance.
- Supported audits and inspections related to clinical trials.
- Developed internal compliance reports for management review.

ACHIEVEMENTS

- Successfully managed regulatory submissions for over 10 clinical trials.
- Recognized for developing a comprehensive training program for clinical compliance.
- Improved submission quality, leading to a 20% reduction in review timelines.

CONTACT

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EDUCATION

Master of Science in Clinical Research

University of Southern California
2016-2020

SKILLS

- Clinical Research
- Regulatory Compliance
- Submission Management
- Stakeholder Communication
- Risk Assessment
- Training Development

LANGUAGES

- English
- Spanish
- French