



Michael ANDERSON

CLINICAL QUALITY ASSURANCE MANAGER

Innovative Biomedical Quality Specialist with over 9 years of experience in clinical trials and medical research. Specializes in ensuring compliance with Good Clinical Practice (GCP) and regulatory requirements throughout the trial process. Proven ability to develop and implement quality assurance strategies that enhance the integrity of clinical data. Strong problem-solving skills and attention to detail allow for effective risk management and mitigation.

CONTACT

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SKILLS

- Good Clinical Practice
- Compliance Auditing
- Risk Management
- Data Integrity
- Training Development
- Regulatory Standards

LANGUAGES

- English
- Spanish
- French

EDUCATION

**MASTER OF PUBLIC HEALTH, JOHNS
HOPKINS UNIVERSITY**

ACHIEVEMENTS

- Achieved 100% compliance during GCP inspections for three consecutive years.
- Developed a quality training program that reduced audit findings by 35%.
- Recognized for exemplary contributions to clinical trial quality assurance by industry professionals.

WORK EXPERIENCE

CLINICAL QUALITY ASSURANCE MANAGER

Clinical Trials Group

2020 - 2025

- Managed the quality assurance program for multiple clinical trials, ensuring adherence to GCP standards.
- Conducted audits of clinical sites and study documentation to ensure compliance with regulatory guidelines.
- Developed training materials for clinical staff on quality standards and practices.
- Collaborated with regulatory affairs to address findings from audits effectively.
- Implemented risk management strategies to enhance data integrity and patient safety.
- Reviewed and approved study protocols and informed consent documents for quality compliance.

QUALITY ASSURANCE AUDITOR

Research Solutions Inc.

2015 - 2020

- Performed audits of clinical trial sites to ensure compliance with regulatory and ethical standards.
- Assisted in the development of quality management plans for clinical studies.
- Evaluated data management processes and provided recommendations for improvements.
- Participated in investigator meetings to communicate quality expectations.
- Collaborated with sponsors to address quality issues identified during audits.
- Maintained documentation of audit findings and corrective actions taken.