

MICHAEL ANDERSON

Quality Assurance Manager

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Innovative Clinical Research Quality Specialist with over 9 years of experience in the biopharmaceutical industry, specializing in quality assurance and regulatory compliance. I have a proven history of developing and implementing quality management systems that enhance clinical trial integrity and patient safety. My analytical mindset allows me to identify compliance gaps and propose effective solutions, resulting in improved trial outcomes.

WORK EXPERIENCE

Quality Assurance Manager | BioTech Innovations

Jan 2022 – Present

- Managed quality assurance initiatives for clinical trials, achieving a 50% reduction in compliance issues over three years.
- Designed and implemented training programs for clinical staff on quality standards, enhancing compliance rates by 35%.
- Conducted site audits to assess compliance with GCP, leading to improved trial execution and data integrity.
- Collaborated with cross-functional teams to develop risk management strategies, reducing potential trial disruptions.
- Reviewed and approved clinical trial documentation, ensuring accuracy and compliance with regulatory requirements.
- Presented quality metrics and findings to senior leadership, driving informed decision-making in trial management.

Clinical Quality Assurance Specialist | PharmaCare Solutions

Jul 2019 – Dec 2021

- Supported clinical trial operations by ensuring adherence to quality standards and regulatory requirements.
- Conducted internal audits and prepared documentation for regulatory inspections, achieving zero findings during audits.
- Assisted in the development of quality assurance policies and SOPs, enhancing trial efficiency by 20%.
- Engaged with clinical teams to address quality concerns and implement effective solutions.
- Trained staff on compliance protocols and quality standards, fostering a culture of continuous improvement.
- Monitored compliance metrics and reported findings to management, facilitating informed decision-making.

SKILLS

Quality Assurance

Regulatory Compliance

Clinical Trials

Risk Management

Training Development

Audit Facilitation

EDUCATION

Master of Science in Pharmaceutical Sciences

2015 – 2019

University of Pharmacy

ACHIEVEMENTS

- Recipient of the Quality Excellence Award for exceptional contributions to clinical trial quality improvements.
- Implemented a new quality management system that increased operational efficiency by 25%.
- Contributed to successful regulatory submissions with zero findings during inspections.

LANGUAGES

English

Spanish

French