MA

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SKILLS

- Regulatory Compliance
- Quality Management
- Clinical Trials
- Risk Assessment
- Training Facilitation
- Audit Management

EDUCATION

BACHELOR OF SCIENCE IN BIOMEDICAL ENGINEERING, TECH UNIVERSITY

LANGUAGE

- English
- Spanish
- German

ACHIEVEMENTS

- Achieved the Quality Excellence Award for outstanding contributions to clinical trial quality improvements.
- Implemented a new quality management system that increased operational efficiency by 30%.
- Contributed to successful regulatory submissions with zero findings during audits.

Michael Anderson

CLINICAL QUALITY SPECIALIST

Highly skilled Clinical Research Quality Specialist with a decade of experience in the medical device industry, dedicated to ensuring compliance and quality in clinical trials. My expertise encompasses the full lifecycle of clinical research, from protocol development to audit preparation. I have a strong background in regulatory requirements and quality management systems, allowing me to effectively assess and improve clinical trial processes.

EXPERIENCE

CLINICAL QUALITY SPECIALIST

MedDevice Corp.

2016 - Present

- Managed quality assurance processes for multiple clinical trials, ensuring adherence to ISO and FDA regulations.
- Conducted risk assessments for clinical trial protocols, identifying potential compliance issues and recommending solutions.
- Facilitated training sessions for clinical staff on quality standards and regulatory requirements, increasing compliance knowledge by 50%.
- Performed site audits to evaluate compliance, resulting in a 40% reduction in non-compliance findings.
- Collaborated with clinical teams to develop and implement corrective actions for identified quality issues.
- Maintained quality documentation for regulatory submissions and audits, ensuring accuracy and completeness.

QUALITY ASSURANCE COORDINATOR

SafeMed Technologies

2014 - 2016

- Supported clinical trial operations by ensuring compliance with internal quality standards and external regulations.
- Conducted internal audits and prepared reports for management review, enhancing transparency in quality processes.
- Assisted in the development of quality management systems, improving trial efficiency by 25%.
- Engaged with stakeholders to address quality issues and implement solutions effectively.
- Trained new hires on compliance protocols and quality standards, promoting a culture of excellence.
- Monitored trial progress and compliance metrics, reporting findings to senior management.