



MICHAEL ANDERSON

Senior Quality Assurance Specialist

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SUMMARY

Dedicated Clinical Research Quality Specialist with over 10 years of comprehensive experience in the pharmaceutical and biotechnology industries. Proven track record in ensuring compliance with regulatory requirements and enhancing the quality of clinical trials. My expertise lies in developing quality assurance systems that align with both local and international regulatory standards.

WORK EXPERIENCE

Senior Quality Assurance Specialist BioPharma Inc.

Jan 2023 - Present

- Conducted internal audits to ensure compliance with regulatory standards, resulting in a 30% decrease in findings over three years.
- Collaborated with clinical teams to develop quality management plans, enhancing trial integrity and data reliability.
- Trained staff on Good Clinical Practice (GCP) guidelines, improving adherence rates by 40% across clinical sites.
- Implemented corrective and preventive action (CAPA) plans following audits, leading to improved operational processes.
- Reviewed clinical trial protocols for compliance, reducing protocol deviations by 25%.
- Maintained thorough documentation of quality assurance activities, facilitating transparency during regulatory inspections.

Quality Control Analyst MediTech Solutions

Jan 2020 - Dec 2022

- Performed risk assessments on clinical trial data, identifying potential quality risks and implementing mitigation strategies.
 - Assisted in the preparation for FDA inspections, achieving zero findings during the last three audits.
 - Developed and maintained quality metrics dashboards, enabling real-time tracking of compliance and performance.
 - Coordinated external audits with regulatory bodies, ensuring all documentation met required standards.
 - Facilitated training sessions on data integrity and quality standards for new hires, fostering a culture of compliance.
 - Analyzed trend data to identify areas for improvement, leading to a 15% increase in overall quality scores.
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EDUCATION

Master of Science in Clinical Research, University of Health Sciences

Sep 2019 - Oct 2020

ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory Compliance, Quality Assurance, Clinical Trials, Data Analysis, CAPA Management, GCP Training
- **Awards/Activities:** Received the Excellence in Quality Award for outstanding contributions to clinical trial quality improvement.
- **Awards/Activities:** Successfully led a project that resulted in a 50% reduction in protocol deviations across multiple studies.
- **Awards/Activities:** Published research on quality assurance practices in a peer-reviewed journal, contributing to industry standards.
- **Languages:** English, Spanish, French