



MICHAEL ANDERSON

CLINICAL RESEARCH AUDITOR

PROFILE

Dynamic Medical Research Auditor with over 5 years of experience in auditing clinical research for major pharmaceutical companies. I specialize in ensuring compliance with FDA regulations and internal processes, effectively identifying areas for improvement. My analytical abilities allow me to assess complex datasets to detect discrepancies and recommend actionable solutions. I possess strong communication skills, enabling me to liaise effectively with various stakeholders, including clinical teams and regulatory bodies.

EXPERIENCE

CLINICAL RESEARCH AUDITOR

Global Pharma Inc.

2016 - Present

- Performed audits across multiple clinical trial sites to assess adherence to regulatory standards.
- Developed and maintained comprehensive audit checklists that improved the auditing process by 15%.
- Collaborated with clinical project managers to address audit findings and implement corrective actions.
- Monitored compliance with study protocols, resulting in a 20% decrease in protocol deviations.
- Utilized statistical software to analyze audit data and generate insights for stakeholders.
- Facilitated training workshops on best practices in clinical auditing for research staff.

RESEARCH ASSOCIATE

Innovative Health Solutions

2014 - 2016

- Assisted in the design and implementation of clinical studies, ensuring adherence to regulatory guidelines.
- Reviewed and monitored data collection processes for accuracy and compliance.
- Contributed to the preparation of regulatory submissions, enhancing submission timelines by 30%.
- Conducted site visits to engage with research teams and ensure protocol compliance.
- Utilized electronic medical records systems to track patient data and outcomes.
- Collaborated with multidisciplinary teams to improve study workflows and efficiency.

CONTACT

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SKILLS

- Regulatory Compliance
- Data Monitoring
- Audit Management
- Communication Skills
- Statistical Analysis
- Training Development

LANGUAGES

- English
- Spanish
- French

EDUCATION

BACHELOR OF SCIENCE IN LIFE SCIENCES, UNIVERSITY OF MASSACHUSETTS, 2015

ACHIEVEMENTS

- Achieved a 100% success rate in passing all external audits conducted on clinical trials.
- Recognized as 'Employee of the Month' for exceptional performance in audit activities.
- Implemented a new tracking system that improved audit documentation efficiency by 35%.