MICHAEL
ANDERSON

Regulatory Affairs Specialist

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Experienced Clinical Data Researcher with a comprehensive background in regulatory affairs and compliance spanning over 9 years. My expertise lies in ensuring that all clinical data practices adhere to stringent regulatory standards. I have a strong track record of conducting audits, preparing compliance reports, and collaborating with regulatory agencies. My ability to analyze clinical data and identify compliance gaps has been instrumental in achieving successful audits and maintaining data integrity.

WORK EXPERIENCE

Regulatory Affairs Specialist | PharmaReg Solutions Jan 2022 – Present

- Conducted internal audits of clinical data processes, achieving a 100% pass rate during external reviews.
- Prepared comprehensive compliance reports for regulatory submissions, ensuring accuracy and completeness.
- Coordinated with clinical teams to identify and address compliance gaps, enhancing data integrity.
- Developed and delivered training programs for staff on regulatory best practices, improving compliance awareness.
- Reviewed study protocols to ensure alignment with regulatory standards, facilitating smoother approvals.
- Participated in regulatory agency meetings, providing insights on data practices and compliance.

Clinical Data Researcher | Clinical Compliance Group Jul 2019 – Dec 2021

- Analyzed clinical trial data for compliance with regulatory requirements, ensuring data integrity.
- Conducted regular data audits, identifying and rectifying discrepancies in data records.
- Collaborated with clinical teams to develop compliance strategies, enhancing overall data quality.
- Assisted in the preparation of regulatory submissions that facilitated timely approvals.
- Provided guidance to project teams on regulatory changes impacting clinical research.
- Maintained up-to-date knowledge of regulatory requirements, ensuring compliance across projects.

SKILLS

Regulatory Compliance | Data Integrity | Clinical Audits | Training Development | Data Analysis | Quality Assurance

EDUCATION

Master of Science in Regulatory Affairs 2015 – 2019
University of Compliance

ACHIEVEMENTS

- Achieved 'Compliance Champion' award at PharmaReg Solutions for outstanding contributions.
- Successfully led a project that improved audit readiness, reducing preparation time by 40%.
- Presented findings at a national conference on regulatory compliance in clinical research.

LANGUAGES

English | Spanish | French