SANDY MILLER

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CLINICAL TRIAL MANAGEMENT

REGULATION COMPLIANCE ♦ DATA ANALYSIS ♦ QUALITY ASSURANCE AUDITS

Highly accomplished Project Leader, with previous Clinical Management experience and extensive knowledge of Drug and Device GCPs, ICH Guidelines, and FDA Regulations. Possess significant experience with US and International Phase II & III trial management. Strengths lie in the protocol, report preparation, and vendor selection process. Expertise in providing source document validation, including CRF, Data Capture and QDE/QDM. Talent for managing cross functional teams throughout the clinical trial process.

CORE COMPETENCIES

- Clinical Trial Management
- Research Acumen
- Process Development
- Protocol Preparation
- Vendor Selection/Oversight
- Personnel Training
- Quality Assurance Audits
- Budget Administration
- Report Formulation

PROFESSIONAL EXPERIENCE

RESEARCH CORPORATION
New Dodge, New Jersey February 2002-Present

Project Leader – Clinical Research

Serve as a Project Leader on the international clinical trials. Manage a Contract CRA and other individuals on the project teams. Perform clinical trial management, protocol preparation, report preparation, vendor selection, oversight of vendors, and budget administration. Engage in clinical investigation or other research, production, and technical writing. Conduct informational searches, review technical literature, and make recommendations for supporting literature to utilize in product launches.

Key Achievements:

- Developed tracking system for collecting publications from Medical Journals, interfacing with Physicians, Marketing, and Medical Affairs.
- Serve as a Mentor to other clinical research in the mentoring and training program.
- Clinical representative for cross-functional New Product Development Team.
- Participate on the Ergonomic Committee, conducting ergonomic evaluations and recommending corrective actions for personnel.
- Integral part of the internal Task Force which gathered feedback from internal and external customers to rate departmental service and quality control.

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PROFESSIONAL EXPERIENCE CONTINUED

PHARMACEUTICAL COMPANY
New York, New York 1998- 2002

Lead Clinical Scientist/Manager - Clinical Research

Facilitated clinical trial management, investigative site selection, protocol preparation, and preparation of final study reports. Trained, mentored and supervised CRA's. Served as the Clinical Leader for weekly project teleconferences with cross-functional teams. Monitored overall study progress ensuring adherence to timelines. Negotiated study budgets with vendors and investigational study sites. Presented new information at Investigator and CRA meetings. Designed CRF's, developed source documentation, evaluated vendor selection and provided clinical oversight, reviewed Informed Consents/Assents, and managed budgets.

Key Achievements:

- Interfaced with Academic Clinical Research Organization, Site Management Organization, Core Laboratory, Investigative Sites, and Study Coordinators.
- Directed the Clinical Working Group and provided oversight of CRA's.
- Participated on the Clinical Research Initiative Committee.

MEDICAL COMPANY
Baltimore, Maryland 1989 – 1998

Clinical Research Associate

Monitored Phase II/III drug trials throughout U.S. and Canada and National trials. Monitored Investigator compliance and patient eligibility, conducted pharmacy inspections, and drug accountability. Provided source document validation, including CRF, Data Capture and QDE/QDM. Conducted Compliance and Quality Assurance Audits. Trained and supervised new Clinical Research Associates. Presented findings at Investigator meetings.

Key Achievements:

- Represented the company as a team delegate conducting National Center Compliance/Quality assurance Audits.

EDUCATION

Masters in Business Administration ♠ My University – 2003
Bachelor of Science in Nursing ♠ My University – 1994