Title: **Medical Safety Specialist**   Department: **Pharmacovigilance**

Position Summary:

This position will provide crucial support to Principal Investigators, contribute to safety documents, and play a key role in regulatory and clinical activities with other study team members. Dive into responsibilities that include literature review, medical assessment, and collaboration with safety leads.

Responsibilities:

- Co-author safety documents and assist in providing safety input to regulatory and clinical documents.
- Monitor the safety profile of products through activities like literature review and medical assessment.
- Support safety leads in reviewing Health Authority assessment reports and writing safety deliverables.
- Engage in activities related to Clinical Overview, Risk Management Plan, and Development Safety Update Report.
- Contribute to responses to internal and external safety queries.
- Support in Root Cause Analysis and Corrective and Preventive Actions.
- Collaborate in writing working instructions, procedures, and presentations for various safety teams.

Minimum Qualifications & Experience:

- **MD in Clinical Pharmacology** from a recognized University with at least **two years** of **post-qualification work** experience after completing an internship, preferably in **Critical Care, Oncology, or Emergency Medicine**.
- Experience in safety document or medical writing.
- Good understanding of clinical trial methodology, ICH GCP, GVP guidelines, and medical terminology.
- Strong attention to detail and a focus on quality.
- Excellent communication skills for effective operation in an international environment.
- Good understanding of Human physiology, pharmacology, clinical study objectives, and the drug development process.

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Title: **Principal Biostatistician**   Department: **Clinical Data Management**

Position Summary:

This position will be responsible for independently leading the development and execution of statistical aspects for low to moderate-complexity studies, participating in PRC (Protocol Review Committee) reviews of study protocols and SAPs, Providing data interpretation for study documents like CSR, and participating in statistical organization continuous improvement initiatives.

Responsibilities:

- Provides support across all assigned statistical tasks during the project lifecycle, from protocol to CSR.
- Prepares Statistical Analysis Plans (SAPs), including developing well-presented mock-up displays for tables, listings, and figures. Collaborate with the sponsor, if required.
- May be responsible for the statistical aspects of the protocol, generation of randomization schedule, publications, and input to the clinical study report.
- Coordinates the activities of other biostatistics and statistical programming personnel on assigned projects to ensure the timely completion of high-quality work. Provides independent review of project work produced by other biostatisticians in the department.
- Creates or reviews programming specifications to analyse datasets, tables, listings, and figures. (CDISC, SDTM)
- Reviews SAS annotated case report forms (CRFs), database design, and other study documentation to ensure protocol criteria are met and all data is captured to support a high-quality database and the planned analysis.
- Conducted and participated in verification and quality control of project deliverables, ensuring that output meets expectations and is consistent with the analysis described in SAP and specifications.
- Implements company objectives and creates alternative solutions to address business and operational challenges.
- Serves as biostatistics representative on project teams, interfacing as necessary with other departmental project team representatives. This would include preparing for internal meetings, contributing ideas, and demonstrating respect for the opinions of others.

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- Manages scheduling and time constraints across multiple projects, sets goals based on priorities from management, adapts to timeline or priority changes by reorganizing daily workload, and proactively communicates to biostatistics management any difficulties meeting these timelines.

- Monitors progress on study activities against agreed-upon milestones and ensures the study timelines for project deliverables are met. Identifies out-of-scope tasks and escalates to management.

- Provides statistical programming support as needed.

- May participate in Data Safety Monitoring Board and/or Data Monitoring Committee activities, including charter development and serving as an independent non-voting biostatistician.

- May lead projects involving integrated analyses, attend regulatory agency meetings or respond to questions, as needed, to support the statistical analysis results of clinical trials on behalf of the sponsor.

- Follows applicable SOPs, WIs, and relevant regulatory guidelines (e.g. ICH).

- Maintains well-organized, complete, and up-to-date project documentation and verification/quality control documents and programs, ensuring inspection readiness.

- Displays willingness to work with others and assists with projects and initiatives as necessary to meet the needs of the business.

- Supports business development activities by contributing to proposals and budgets and attending sponsor bid defence meetings.

- Coaches and mentors other Biostatistics staff.

- Performs other work-related duties as assigned.

Minimum Qualifications & Experience:

- Master's degree in Statistics or equivalent & ≥ 5 years of industry-related experience OR Ph.D. in Statistics or equivalent & ≥ 3 years of industry-related experience

- Demonstrated knowledge of statistical/clinical trials methodology related to clinical development.

- Relevant prior data analysis planning, execution, and delivery experience

- Ability to work successfully within cross-functional teams, leading to successful global regulatory filings and approvals

- Excellent verbal and written communication skills.

- Ability to be flexible and adapt quickly to the organization's changing needs.

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- Ability to organize multiple work assignments and establish priorities.
- Strong interpersonal skills evidenced in interactions with individuals at all levels of the organization and demonstrated ability to develop relationships and leverage the formal and informal organizational structure to assist in goal achievement.
- Sample size calculation and adaptive design is preferred.

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