spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Medical Writer

SPAULDING CLINICAL aims to be the clinical research organization by which all others are measured. Pioneering in our approach to redefining how the industry perceives and achieves success; passionate in our pursuit of ingenious solutions that mitigate risk; loving in our care for our volunteers, customers and employees; and heroic in our ambitions to ensure the health and safety of people around the globe - Spaulding Clinical is taking ***research beyond results*** to create a marketplace of safer drugs.

Original Date: 14 Jun 2011

Revision Date:

Position Reports To: Director of Information Technology & Data Management

Position Supervises: None

Job Summary:

It is the Medical Writer's role to oversee all report writing activities for the projects he/she is supporting. The Medical Writer must ensure consistency across documents and improve overall document quality. It is the Medical Writer's responsibility to provide the appropriate background information, guidance, and training to any writer producing documents to support their tasks. The Medical Writer will prepare and/or review all final documents (i.e., protocols/analysis plans/reports/Investigator Brochures/submission pieces).

Essential Duties and Responsibilities:

- Oversee document preparation activities.
- Build and maintain knowledge base to improve the overall medical content of documents.
- Write and/or review reports and regulatory submission documents.
- Write and/or review protocols, amendments, review statistical analysis plans. Ensure appropriate incorporation into reports.
- Drive the clinical study report writing process by conducting or ensuring the following activities have been accomplished:
  - Identify report contributors and their responsibilities.
  - Develop and maintain timelines.
  - Ensure that all possible report activities are completed prior to database lock.
  - Review primary statistical output and participate in results review meetings.
  - Lead discussions on report finalization.
- Prepare reports, manage review cycles, and incorporate comments as appropriate.
- Manage compilation of report appendices.
- Prepare, review and edit publications.

- Ensure Quality Control review of protocols, protocol amendments, Clinical Trial Reports, Investigator Brochures and regulatory submission documents.
- Work effectively with other staff in Clinical Operations (e.g., Biostatistics, Data Management, Clinical Monitoring) in team situations.
- Other duties as assigned.

The Statements made in the job description are intended to describe the general nature and level of work being performed by people assigned to this job. These statements are not intended to be an exhaustive list of all responsibilities, duties and skills required of people assigned to this job.

Skills/Qualifications:

- Thorough understanding of CFR and ICH guidelines.
- Demonstrated strong writing skills as evidenced by good quality writing in publications in peer-reviewed journals.
- Analyzed and interpreted complex data from a broad range of scientific disciplines.
- Knowledge of statistics and their application to the interpretation and presentation of clinical data.
- Demonstrated ability to manage timelines and quality of work using strong organizational, communication, facilitation and interpersonal skills in a cross-functional team.
- Understanding of documentation requirements related to submission of manuscripts to scientific and medical journals.
- Ability to mentor and train others.
- Superior computer skills, including high-level word processing and graphic presentations. Experience with Microsoft Office including PowerPoint required.
- Ability to read, write, and interpret the English language.
- Maintains strong attention to detail in high-pressure situations

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Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Ability to sit, stand, walk, reach with hands and arms, and use hands along with fingers, to handle or feel.
- Ability to lift and/or move up to 25 pounds.
- Specific vision abilities required by this job include clarity of vision both near and far.
- Ability to identify and distinguish colors.

Hazards:

- Potential for exposure to toxic or caustic chemicals
- Potential for exposure to blood borne pathogens

Education and Experience:

- Master's degree in science or writing discipline
- Three to five years medical writing experience.

Spaulding Clinical Research management has the discretion to hire personnel with a combination of experience and education which may vary from the above listed skills and qualifications.

This is to acknowledge that I have read and understand the above job description. This copy supersedes any others previously distributed. I further understand that Spaulding Clinical may change, add or delete any essential duties and responsibilities described at its discretion with or without prior notice.

Employee Name (Printed) Date

Employee Signature