spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Biostatistician

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:

The Biostatistian provides statistical expertise to the clinical development program for assigned projects to ensure that scientifically valid conclusions are drawn concerning claims with respect to efficacy and safety of the compound which is under development. The Biostatistician supports all statistical activities in all phases of project related clinical development programme, and to play an active role in multi-disciplinary project and study teams.

Essential Duties and Responsibilities:

- Contribute to the development and maintenance of methods and procedures based on Regulatory Guidelines and Company requirements
- Participate in Clinical Study Team meetings for assigned studies
- Responsible within the Clinical Study Team for the quality, accuracy and timely completion of assigned tasks
- Responsible for making statistic model selection, experimental design, design and analysis of clinical trials
- Analyse and interpret data from individual trials
- Perform meta-analyses by pooling data from several studies
- Develop project analysis plan, including computer-generated table specifications, statistical analysis plan, and research report format
- Co-operate in further development of internal guidelines and SOPs
- Prepare project summaries for weekly/monthly status meetings
- Update knowledge in statistical concepts, methods, and techniques
- Maintain state of the art statistical applications in clinical research
- Responsible for data processing for accurate relocation, formatting, generating and transmitting required data

- Prepare statistical contribution to Integrated Study Report

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:

- Experience with SAS/STAT, the SAS Macro language, SAS/GRAPH and the SAS Output Delivery System (ODS) required
- Strong DATA step programming skills
- PROC REPORT familiarity and the handling of coding dictionaries preferred
- Experience with design and analysis of clinical trials
- Ability to read, write, and interpret the English language.
- Strong communication skills, both written and verbal
- Maintains strong attention to detail in high-pressure situations
- Solid understanding of business practices with fundamental understanding of project management methodology
- Requires excellent computer skills

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:

- Experience in Biostatistical Analysis & SAS for clinical trials in the medical device, pharmaceutical or biotechnology industry. 3 to 5 years of statistical analysis experience in a clinical trials environment
- Bachelors in Biostatistics or experience in a related subject with a high statistical content.
- Master's Degree in Biostatistics or Statistics with at least 3 years' experience in clinical research in a biopharmaceutical or academic setting is required. Candidate must have sound knowledge of the application of advanced statistical methods in clinical research gained through experience and education.

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 _____