#2860 Corporate Statistician

Responsible for developing, directing and implementing company-wide statistical policies and programs. They will work directly with scientists, process engineers and quality representatives in the design experiments for technology transfer, process validation, optimization, dosage release, stability, annual product reviews and other scientific documentation.

ESSENTIAL DUTIES / RESPONSIBILITIES:

- Candidate will assist in determining manufacturing design spaces
- Analyzes the data obtained from these activities and data generated by process analytic technologies to support development of specifications and regulatory filings.
- Engages in scientific and technical discussions with team members.
- Prepares reports and has the ability to clearly communicate the results to stakeholders
- Develops visualization techniques that can be used by scientists to interpret experimental and analytic data.
- Trains scientists and engineers in data analysis and visualization.
- Applies regulatory guidelines to work and keeps abreast of technical and regulatory developments.
- Assists in developing responses to FDA and foreign health authorities

REQUIRED EDUCATION:

- Bachelor's Degree – B.S in Statistics, Bio statistics, or a related field

QUALIFICATIONS/EXPERIENCE:

- Desired minimum of BS + 2 years' experience, MS + 1 year experience with a pharmaceutical background
- Experience in the pharmaceutical industry is preferred.
- Demonstrated ability to prioritize, organize, and work effectively with minimal supervision.
- Experience in Statistician or Biostatistician role, knowledge of GMPs, and knowledge of statistical methodology are preferred.
- Demonstrated ability to prioritize, organize, and work effectively with minimal supervision.

SPECIFIC SKILLS:

- Knowledge of DoE and general linear models is essential.
- Proficient with Mini-tab, JMP, SAS or other statistical software and have familiarity with MS Excel and Visio.
- Experience in the application of statistics to the development and optimization of drug product in support of small molecule regulatory filings is preferred.
- Familiar with the types of data generated in drug product development (e.g. dissolution, content uniformity, assay)
- Excellent computational, written and verbal communication skills, strong organizational abilities
- Strong observational skills and attention to detail are required.
- Strong follow-up skills and ability to provide timely closure of assigned tasks.
- Strong computer skills are required, with proficiency in the following applications desired: MS Word, MS Excel, and Minitab. Familiarity with SAP & MasterControl is a plus.
- Strong technical writing and problem-solving skills. Experience in reviewing scientific documents/reports to assure compliance.
- Strong communication skills (both oral and written) for internal contacts are required.

- Strong interpersonal skills with ability to work in a team setting and cooperate with various departments and personalities.