Becton Dickinson & Company

Baltimore, MD

Becton Dickinson is seeking a Senior Statistician who specializes in process control statistics to conceive and develop data interpretation methods used directly in several new molecular diagnostic products. These products will enable new and unique technologies in the clinical lab, presenting interesting design, process control, and quality testing challenges. This role will be the lead statistician on multiple R&D project teams. This role will be expected to establish innovative mathematical solutions to make possible precise and robust products. Senior Statistician will guide scientists in experimental design and capability analysis, translating results into measurable specifications. The role requires continued support of product and process development throughout the full project life-cycle, working closely with cross-functional teams across the organization. This role offers an excellent opportunity to impact many aspects of the medical diagnostic business, while providing a substantial contribution to BD’s already strong culture and commitment to quality product design and manufacture.

Responsibilities

- Works directly as a member and statistical lead of multiple R&D project teams to develop harmonized algorithms, metrics and methods for interpreting quantitative data on automated molecular diagnostic platforms.
- Provides a lead role for product development teams to translate clinical and customer requirements into quantitative and measurable specifications.
- Develops process control statistics and specifications to enable robust manufacture and quality control of quantitative molecular diagnostic products.
- Collaborates closely with other functions to translate into operating and test procedures for product manufacturing and release.
- Provides statistical expertise in experimental design and capability analysis as part of product development team.
- Consults with project teams to plan and analyze studies; uses statistical knowledge to support and guide business decisions and to help facilitate strategic decision making for management and project teams.
- As a member of the R&D bioinformatics and statistics team, identifies and works to implement process improvement initiatives.
- Develops tools to enable internal use of statistical and algorithm methods.
- Programs, documents, and validates software code to execute data handling tasks, perform data analysis, develop statistical approaches to handle non-standard statistical problems, and produce data visualization results.
- Provides statistics deliverables for projects to meet schedules and goals. Develops/revises work plans independently except for unusual situations, which might require consultation.
- Reviews and/or prepares formal written reports/documents for distribution within and outside the department.
- Keeps abreast of new statistical developments and regulatory guidance; survey related fields for techniques that could be adapted to BD’s needs.
- Represent BD with external organizations, regulatory authorities, and key opinion leaders. May make presentations or contribute to publications for industry-related conference and journals.
• Provides internal consulting services, including specifications and user needs analysis for complex project requirements.
  Establishes and maintains sound working relationships with other functional groups.

QUALIFICATIONS

• A minimum of a master’s degree plus 3 years of statistical process control experience OR a PhD plus 1 year of statistical process control experience is required.
• Individuals with a degree in Statistics, Biostatistics, or closely related field preferred.
• Prior experience working within a manufacturing process control environment highly desired.
• Prior experience working within a regulated device or healthcare industry is preferred.
• Experience providing statistical consulting for non-statisticians.
• Demonstrated competence in the application of statistical techniques used in product development, process control, manufacturing operations, quality, regulatory, and continuous improvement is required.
• Ability to program, document, and validate statistical software code in at least one statistical programming language is required. Individuals with R or SAS experience are preferred.
• Ability to interpret project level requirements and develop programming specifications, as appropriate, for complex studies is required.
• Working knowledge of applicable regulations and the ability to apply without supervision is preferred.
• Ability to identify process improvement opportunities within the function or across related functions, and work or collaborate to implement them is required.
• Ability to credibly represent a BD Business or function to external stakeholders, such as business partners, regulatory authorities, and key opinion leaders is required.

https://www.statsjobs.com/jobs/senior-statistician-becton-dickinson-company/