Position Title: Head of Biometrics

Department: Clinical Affairs and Medical Affairs

Reports To (title): SVP Clinical Development and Medical Affairs

Location: Boston, MA or King of Prussia, PA (preferred)

Date: 9/22/17

☒ Exempt ☐ Non-Exempt

Summary of Position:

The Head of Biometrics, will act as the leader for all Biostatistics and Statistical Programming in support of all clinical development and medical affairs programs. The role will play a critical role in design of new clinical programs and trials as well as playing a key role with regulatory submissions and interaction with global health authorities.

Position Responsibilities:

- Provide strategic and operational statistical expertise for early through late stage clinical development programs and post marketing programs.
- Participate in vendor evaluation/selection and manage vendors.
- Instruct and lead Biometrics function of vendors.
- Write/review statistical analysis plans as well as statistical section of reports/protocols.
- Instruct and provide statistical guidance to statistical programmers.
- Participate as an active member of the protocol development core team providing input in design, outcome measures, endpoint assessment, and sample size/power calculations.
- Plan and manage Biometrics related submission activities.
- Represent the company at FDA/ EMA meetings, including Advisory Committee meetings.
- If needed, lead the Rapid Response Team (RRT) to provide analysis for regulatory queries and during Advisory Committee meetings.

Candidate Requirements:

- Works in a changing and busy environment. Exercises judgment in interpreting, modifying, and adapting procedures, practices, methods, etc. in accordance with existing policies and standards for application to specific problems or tasks. Works independently - self-directed, high energy and strong work ethic. High degree of creativity, latitude and attention to detail required.
- Demonstrated strong leadership, project management, teamwork, and interpersonal skills.
- Excellent presentation skills.
- Experience and proven ability leading and managing major process and technology initiatives with utilization and impact across multiple functional groups.
- Broad knowledge and superior understanding of advanced statistical concepts and techniques.
- Outstanding ability and skills to effectively represent Biostatistics and Data Management in interaction with senior management or cross-functional committees.
- Thorough knowledge of pharmaceutical clinical development and life cycle management; ability to innovatively apply technical principles, theories and concepts to clinical drug development leading to regulatory approvals.

- Thorough working knowledge of regulatory guidelines on drug development, regulatory submissions, and statistical practice.
- Understanding of the drug discovery and development process, regionally and globally.
- Strong administrative skills.
- SAS, S-Plus/R, Sample size calculation software (e.g., EaSt and Nquery).
- May report to a VP or above. Requires the ability to influence others to achieve results. Manage subordinate supervisors.
- Also acceptable - Ph.D. in statistics or related discipline with 12+ years of experience in the biotechnology, pharmaceutical or health related industry, including significant interaction with both FDA and EMEA, history of successful project and people management (6+ years), and expertise in multiple therapeutic areas.

Additional Information:

- Technology needs: Microsoft Office
- Travel requirements (%):