JOB DESCRIPTION

POSITION TITLE: **Clinical Data Manager**

REPORTS TO: **Sr. Director of Clinical Affairs**

DEPARTMENT: **Clinical**

PURPOSE OF JOB: The Clinical Data Manager (CDM) will provide clinical data management expertise associated with data cleaning and quality review processes for assigned projects. CDM ensures clinical trial data collected meet the highest standards of data integrity.

MAJOR DUTIES AND RESPONSIBILITIES:

- Lead CRF design, review and validation of clinical database;
- Be responsible for creation of data management plans and other data management documentation as needed;
- Monitor progress and conduct of their respective projects, including all data cleaning and QC activities to ensure all remain on target to project timelines.
- Lead, coordinate, facilitate and manage all data management activities from initiation of protocol through database lock, partnering as appropriate with Clinical Affairs;
- Proactively organize and manages ongoing data review throughout study conduct, including being responsible for the correction of errors and discrepancies management for the life of a project;
- Proactively identify and address issues that may impact the quality of the data, deliverables or timelines;
- Know and follow all laws and policies that apply to the job, and maintain the highest levels of professionalism, ethics and compliance at all times;
- Diligently participate in compliance program-related activities as denoted by the Sr. Director of Clinical Affairs
- Perform other duties as required.

EXPERINCE REQUIREMENTS:

- A Bachelor's degree (or equivalent) in the biological sciences, Computer Science or related discipline, with at least 3 years of clinical data management experience in Medical Device or Pharmaceuticals
- Experience of successful active participation in cross-functional teams
- Therapeutic area knowledge in the ENT space is a plus
- Proficiency in Microsoft Office applications
- Experience with Electronic Data Capture (EDC), medrio preferred

OTHER QUALIFICATIONS:

- Excellent verbal and written communication skills and ability to interact effectively in a team environment

- Highly organized, self-directed and demonstrates a consistent attention to detail
- Must demonstrate accountability for delivery of results and have good problem-solving and decision-making skills
- Must be able to manage their own work, with ability to prioritize, plan and organize work assignments while working under strict timelines
- Must have the ability to work collaboratively as part of a team in a fast-paced dynamic environment and cross functional interactions
- Knowledge of GCP and regulatory requirements regarding clinical data management documentation and software.
- Authorization to work in the US for any employer