

CLINICAL DATA MANAGER

Essential Responsibilities: *Maintain the Clinical Data Management System (Database) which includes: Upgrade clinical database to a current SW version; accommodate revisions of the clinical protocol Update CRFs/data fields to accommodate revisions in the clinical protocol Maintain traceability of all changes*

- Perform data entry as necessary
- Audit data entry
- Maintain/Create necessary Data Management Documentation, including but not limited to DOPs, DMPs, Work Instructions, Software Validation
- Assist in the development of and implement the data management plan for clinical trials
- Develop and produce routine reports for internal and external circulation
- Prepare data reports, tables and graphs for regulatory submissions, IRB submissions, presentations and publications
- ***Maintain traceability of data sets used for various reports.***
- Perform consistency checks and data cleaning functions
- Review data on a regular basis for trends and relationships
- Liaise with clinical and Scientific research teams on data presentation
- Interact closely with cross-functional groups including Information Technology, Regulatory Affairs, Research and Corporate

EDUCATION/CERTIFICATION: BS degree required, preferably in Engineering, Physical or Biological sciences.

EXPERIENCE REQUIRED:

- 1-2 years of experience in data management for product approval trials, preferably with Class III devices, or equivalent combination of education and experience.
- ***Familiarity with eCRFs and eDC systems a must***
- This experience must include a sound working ability with Microsoft Excel, Access databases or similar.

REQUIRED KNOWLEDGE:

- Detailed working knowledge of US / OUS medical device clinical trial regulations, such as FDA QSR, FDA IDE/PMA regulations, and the European Active Implantable Medical Device Directive.
- Understanding of FDA and other regulatory compliance and GCPs in relation to electronic systems
- Understanding of FDA and other regulatory compliance and GCPs in relation to clinical processes