CLINICAL MANAGER

Employment Type: **Full-Time / Exempt**
Department: **Clinical/Regulatory / #410**
Effective: **March, 2020**

Position Summary:

Provides study management and assures successful conduct of clinical studies consistent with applicable regulations, guidelines and policies. Provides oversight of monitoring activities and operations functions. Develops a clinical strategy for products in development to achieve clearances and approvals in the US and internationally. Independently handles multiple clinical study assignments.

Required Education and Experience:

B.S. degree in a scientific discipline or equivalent experience with a minimum of 3-5 years demonstrated experience managing clinical activities in a medical device or in vitro diagnostic field. Thorough knowledge of GCP, ICH guidelines and other US and international clinical regulatory requirements. Demonstrated experience in managing clinical trials, including risk assessment and contingency planning. Monitoring experience required. Excellent communication, management and organizational skills, along with problem solving, conflict resolution, leadership and team building skills. Knowledge of data management platforms is desirable. Able to travel up to 25% of the time.

Essential Functions/Major Responsibilities:

- Responsible for compliance with the company's quality system requirements through training and adherence to policies, procedures and processes.
- Responsible for the day to day management of company-sponsored clinical trials.
- Participates on product development teams as clinical representative.
- Ensures appropriate resources and priorities are maintained for the assigned projects.
- Monitors or ensures adequate monitoring of study is conducted.
- Creates and implements departmental standard operating procedures and clinical trial documents.
- Communicates and presents study results and program issues to project team and other key internal stakeholders (development, marketing, operations, etc.).
- Manages clinical development budget within stated financial goals.
- Monitors compliance with all FDA and applicable international regulations concerning clinical activities.
- Oversees the internal and external audit programs for clinical studies.
- Evaluates clinical data/information and writes reports as required.
- Writes abstracts, papers, and manuscripts related to study results as required.