EXTERNAL JOB POSTING

Job Title Sr. Manager Clinical Operations Req# 1104-20

Location: Valencia, CA

POSITION SUMMARY:
Responsible for developing and conducting clinical trials/studies and ensuring that all programs are in compliance with FDA and other regulatory body regulations. Directs and manages the Clinical Affairs team, as well as external contractors, monitors and consultants. For each study, the Sr. Manager, Clinical Affairs is accountable for creating the clinical trial plan, then overseeing that the trial is conducted in compliance with GCP, FDA, ICH guidelines, and HIPAA requirements, national and local regulations, and Bioness' policies and procedures. In addition, the Sr. Manager, Clinical Operations will assist with regulatory submissions such as IDE/PMA, 510(k) and annual progress reports, as related to clinical trials from concept to study conclusion and reporting.

SPECIFIC DUTIES AND RESPONSIBILITIES:

- Drives the development, optimization, alignment, and implementation of clinical trial processes across the Clinical Operations group.
- Oversees clinical management for pre-market trials and post-approval studies, and registry studies, including protocol development and training, CRO management, data capturing, biostatistical analysis, site monitoring, and timely reporting.
- Partners with respective functions for development, optimization, and alignment of shared clinical trial processes.
- Identifies and leads Process Improvement opportunities.
- Provides Clinical Operations SME support to the Regulatory and Marketing teams.
- Assists in the development of standard operating procedures (SOPs).
- Directs the development of policies, procedures, and quality standards in Clinical Operations group.
- Maintains awareness of changes within the industry and regulatory environment (i.e. ICH E6 (R3)) to ensure Clinical Development processes are updated as necessary.
- Assists in developing department budget and is accountable for the profit/loss and the overall financial performance of the Clinical department.
- Develops and implements Investigator Brochures, Clinical Protocols and associated amendments.
- Assists with 510(k) and IDE/PMA submissions the FDA.
- Sets up cadaver labs for investigator and staff training.
- Identifies, and oversees timely reporting of Serious Adverse Events.
- Provides regular updates of study results to upper management.
- Participates in writing Clinical Study Report.
- Forecasts of Investigative Product quantities in collaboration with mfg. department.
- Manages shipping and tracking of study related materials and devices.
- Manages study files for audit readiness (training records, central files, system validation, etc.) and assists in internal/external audits.

- Able to react to change productively.
- Able to travel up to 30%.

EDUCATIONAL REQUIREMENTS:
Bachelor's degree in a life science program required; RN or BSN degree or equivalent. Advanced degree preferred.

EXPERIENCE REQUIREMENTS:
- A minimum of 7+ years of clinical research experience in the Medical Device Industry to include multicenter IDE clinical trials, surveillance and clinical team management.
- Knowledge of International and FDA regulations and GCP guidelines.
- Advanced computer skills with experience in electronic data capturing (EDC)

KNOWLEDGE, SKILLS & ABILITIES:
- Strong leadership and management skills to provide planning, coordination and direction to staff and ability to propose innovative solutions to challenges.
- Excellent interpersonal and communication skills.
- Outcome driven; can thrive in an environment of rapid change while effectively managing pressure in a professional manner.
- Analytical with strong organizational skills and the ability to manage large volumes of information.
- High level of accuracy and attention to detail.
- Ability to understand and implement the requirements of providing patient care within a highly regulated and constantly changing environment.
- Positive attitude and ability to interact with all levels of staff.

CONTACT: Submit **resume to careers@bioness.com**

EOE/Minorities/Females/Vet/Disability