Clinical Trials Manager

Edison, NJ

Overview:

Hepion Pharmaceuticals is excited to be expanding our clinical team. We are currently searching for a highly experienced Clinical Trials Manager. Ideally, we are looking for somebody with deep hepatology experience, but will consider all highly motivated and qualified candidates who want to roll up their sleeves and help our team with our clinical trials.

Primary Responsibilities:

- Overall coordination and management of clinical trials from startup to closeout
- Coordinate country cross functional teams and act as the main point of contact for study team members
- Work with team to select and manage CROs and other consultants and vendors to ensure adherence to domestic and international regulations and standards (GCP and ICH)
- Work with Management to negotiate contracts and budgets with investigational sites and other vendors
- Oversee study timelines and clinical trial budgets with finance group
- Ensure timely and accurate documentation and communication of study progress and issue escalation as needed
- Investigator Meeting participation and preparation
- Prepare and present materials for Site Initiation Visits
- May perform site closure activities, including post-close out
- May act as point of contact for Sites
- Participate in study team meetings and update project management on a weekly basis of study timelines and activities
- Contribute to the design, preparation, and finalization of clinical protocols, study manuals, study reports and other key operational/regulatory documents
- Ensure compliance with study protocols, federal and local regulations and standard operating procedures (SOPs) and GCPs
- Coordinate, develop and write the Corrective Actions / Preventive Actions (CAPA) and ensures implementation for audit level findings. Drives CAPA review, implementation and completion

- Interface with other departments within the organization to exchange technical data and negotiate courses of action on behalf of Clinical Operations
- Working knowledge of CTMS, eTMF and EDC systems
- Lead problem solving and resolution efforts including management of risk, contingencies, issue resolution and escalation to the appropriate stakeholder(s)
- Ability to mentor, train and/or educate junior, or new employees
- Participate in the review and update of existing procedures and develop new procedures as needed
- Perform other related duties as required to support Clinical Operations

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Qualifications:

- *Bachelors degree in scientific or medical discipline and 10-15 years work experience in the clinical trial industry monitoring and managing clinical trials; or equivalent combination of education and experience*
- *Familiarity with the life-cycle of a clinical trial: from protocol development and feasibility through study close-out and reporting*
- *Must have experience managing multiple vendors/contractors*
- *Ability to manage time, multi-task and prioritize in order to complete deliverables on schedule*
- *Ability to get along well with different personalities and to work well in teams*
- *Excellent written and oral communication skills, as well as conflict management, time management and organizational skills*
- *Hepatology experience is highly preferred*

Additional Information:

Hepion offers a competitive salary, great benefits package, and the opportunity to join an amazing team!