Global Clinical Operations Manager

The Clinical Operations Manager will provide operational leadership for the execution of clinical trials and will be responsible for the day to day management of global clinical operations. This role will ensure the management of appropriately skilled internal and external resources so that trials are delivered according to agreed company objectives. The Clinical Operations Manager will provide strategic input and leadership for the execution of trials, provide trial schedules and budgets for management review and ensure successful delivery of clinical study milestones. The role will oversee vendor activities with appropriate process for vendor selection, schedules of work, day to day vendor management, risk mitigations and contingency planning. Responsibilities will also include liaison with regulatory and CMC functions as they impact on planning and delivery of the clinical trial program. The Clinical Operations Manager will be a key member of the clinical team working closely with the management team, with a reporting relationship to the Head of Clinical Operations or Chief Medical Officer.
Responsibilities:

- Ensure successful execution and completion of clinical trials according to agreed deadlines and within budget. Accountable for ensuring all needed aspects of clinical operations are identified (drug, resources, contracts, budgets, etc) and planned in timely manner.
- Generate contingency plans where necessary, proactively identify potential issues/risks and mitigate as agreed by the Head of Clinical Operations.
- Manage and monitor performance of all team members and vendors or consultants in order to deliver projects/clinical studies according to plan.
- Provide overall efficient day-to-day management of the projects/clinical trials.
- Ensure that the work within the clinical programs is in accordance with ethical, regulatory and safety guidelines.
- Evaluate and select external partners needed for clinical trials.
- Review and co-develop documents required for clinical development: CTAs / IND, clinical study reports, protocols, investigators brochures, IMPDs, application forms, informed consent forms, abstracts, publications.
- Coordinate internal and external clinical development activities (including regulatory and CMC activities) of all team members involved in the design and conduct of assigned clinical trials.
- Meet regularly with the clinical team and management team to ensure alignment in goals and contingency activities.
- Provide progress reports to the management teams.

Perception Neuroscience Holdings, Inc.
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Qualifications:

- A minimum of 6 years of clinical operations experience within the Biotech / Pharmaceutical industry or CRO.
- A minimum of 3 years of vendor management experience.
- Thorough understanding of the processes associated with executing a clinical development program including: clinical trial design, implementation, management and reporting.
- Advanced project management, resource management, administrative and technical capabilities.
- Excellent verbal and written communication and negotiation skills.
- Experience with early and late phase clinical trials.
- Knowledge of the drug development process in the bio / pharmaceutical industry with an understanding of relevant regulatory requirements.
- Experience developing trial plans including, site monitoring strategies, risk mitigation strategies, trial budgets, site selection, and clinical supplies management.
- Substantial experience managing contractors and interacting effectively in the establishment, oversight and maintenance of vendor relationships.
- Knowledge of GCP and ICH required, global clinical management experience preferred
- Working conditions (ability to travel, etc.):
    - This position requires approximately 20% travel.

Education:

- Master's degree in Life Sciences or Pharmacy. Advanced degree preferred.

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