Clinical Trial Manager (US based)

The Clinical Trial Manager will be accountable for the implementation, management and reporting of assigned clinical trials. In this role, the Clinical Trial Manager will lead the execution of the clinical studies in conformance with Good Clinical Practices (GCP) and in accordance with the International Conference of Harmonization (ICH) Guidelines. Moreover, the Clinical Trial Manager will be held accountable for all aspects of assigned study execution including (where applicable): input to study plan design, execution, study start-up, CRO and vendor management and performance, study budget and timelines. The Clinical Trial Manager will be a key member of the clinical team working closely with the Clinical Operations Manager, with a reporting relationship to the Head of Clinical Operations.

Responsibilities:

- Manage all operational activities of assigned clinical trials (Phase 1 - 3) ensuring consistency with company strategy, commitments and goals.
- Execute and finalize projects / clinical trials according to strict deadlines and within budget.
- Coordinate the efforts of 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 assigned projects/clinical trials.
- Interface and collaborate with site personnel, IRBs / ECs, Competent Authorities, and vendors.
- Guarantee 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, clinical study reports, protocols, investigators brochures, IMPDs, application forms, informed consent forms, abstracts, publications.
- Support of the Clinical Operations Manager as needed.
- Proactively identify and provide solutions to project risks.
- Provide internal communication of important clinical data and events.
- Coordinate and participate in project team meetings, including the preparation of meeting agendas minutes and follow up on action items.

Qualifications:

- A minimum of 5 years of project and clinical trial management (early and late phase) experience within the Biotech / Pharmaceutical industry or CRO.
- A minimum of 2 years of vendor management experience.
- Thorough understanding of the processes associated with executing clinical trials.
- Advanced project management, resource management, administrative and technical capabilities.
- Excellent verbal and written communication skills.
- 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.

Perception Neuroscience Holdings, Inc.
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Location:

- This position can be home based in USA but will involve approx. 20% travel and considerable liaison telecoms with Australia within their working time zones.

Education:

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

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