ReNeuron
pioneering stem cell therapeutics

Role Profile

Job Title	Clinical Compliance Project Manager	**Reports to:**	Clinical Operations Manager
Date	February 2015	**Location**	Guildford/Thames Valley

Role Purpose

Clinical Project Manager (CPM) is responsible for the overall coordination and management of clinical trials from start up through close out activities. Additionally, this position will lead the GCP standards and ensuring they are built into the QMS at ReNeuron. Working within the Clinical Operations Team and supporting the Head of Quality to generate the GCP strategy going forward for ReNeuron.

Responsibilities

- Operational project management of assigned clinical trials
- Ensure that CRAs/CTAs are trained on the study protocol and all other study related processes
- Review site visit reports and conduct site initiation, monitoring and close out co-evaluation visits
- Development and maintenance of SOPs in conjunction with QA
- Work with CQA management and clinical study team to develop and implement detailed audit plans and schedules
- Review, draft and update clinical Protocol/amendments, IBs, PIS-ICFs and other study documents.
- Prepare Regulatory and Ethics submissions.
- Primary liaison and management/oversight of external service providers e.g. CROs, data management, PV etc.
- Prepare, negotiate and manage financial study budgets
- Set-up and maintain study trackers using excel and other software and reporting tools
- Ensure Trial Master File maintenance
- Prepare and respond to corrective action and preventative maintenance plans
- Prepare and present at Investigator Meetings and other external conferences
- Adhere to professional standards, SOPs, GCP and applicable local regulations
- Participate in the development and delivery of internal training programs.
- Support and participate in, the preparation, coordination, and management of regulatory agency inspections of ReNeuron clinical operations

. Perform other tasks that are commensurate with this position.

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Skills

- Excellent interpersonal skills and ability to establish and maintain strong working relationships with colleagues, vendors and investigational site staff
- Exceptional planning, analytical and organizational skills
- High levels of personal initiative and an effective at multi-tasker
- Ability to be both a highly effective team member and conscientious independent worker
- Outstanding leadership skills, including motivation and delegation
- Strong financial acumen with experience managing clinical budgets
- Proven ability to meet recruitment targets with challenging timelines
- Strong computer skills and ability to use MS Office products and other software and reporting tools
- Ability to proactively identify problems and develop innovative solutions

Additional information (e.g. Part-time, remote working etc.)

Minimum Requirements:

- Bachelor's Degree or equivalent required (scientific or healthcare discipline preferred). Advanced degree preferred
- Experienced in managing Phase II/III clinical studies (6+ years clinical trial development of which at least 3 must be in a project management role)
- Experience in various therapeutic areas, cardiovascular and stroke would be beneficial
- Competent in the use of MS Office including Word, PowerPoint and Excel
- Full clean driving licence
- Current UK valid permit to work in the UK
- Willingness to travel both nationally and internationally
- Predominantly office based in Guildford/Thames Valley with some flexibility for remote working