



Role Profile- Draft

Job Title	GCP QA Manager	Reports to:	Head of Quality
Date	April 2014	Location	Guildford/Pencoed

Role Purpose

Lead the GCP standards and ensuring they are built into the QMS at ReNeuron. Working with the Head of Quality to ensure all GCP requirements are demonstrably met. Working with the Clinical Team and Head of Quality to generate the GCP strategy going forward for ReNeuron.

Responsibilities

- Work pro-actively with the Clinical study team to ensure appropriate standards are being met
- Act as expert and champion for GCP and work with the quality team to ensure continuous improvement to the systems and quality culture.
- Work with CQA management and clinical study team to develop and implement detailed audit plans and schedules in support of Clinical QA objectives.
- Execute against CQA audit plans via coordination and conduct of internal and external GCP- related audits e.g.
 - Investigator Site Audits
 - Vendor audits (CROs, Labs)
 - Trial Master File Audits
 - System / Process Audits
 - Data Audits
- Attend and lead selected audits.
- Issue audit reports in a timely manner and ensure that root cause and categorisation of findings is in line with ReNeuron procedures and regulatory expectations. Follow up with auditees to ensure responses are provided in a timely manner allowing for audit closure. Issue audit certificates
- Provide compliance advice to project teams
- Review SOPs to assess their adherence to applicable regulatory and corporate standards. Identify need for additional or less SOPs and

implement revisions.

- 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.

Additional information (eg Part-time, remote working etc)

Skills/experience

Significant recent experience in GCP for Phase II trials and later

Experience of GCP inspections

Experience of auditing (leading audits?)

Experience of working in small companies or a CRO preferred?

Person

Good communicator

Able to cope with change

Flexible re location – Guildford to Wales

Team worker

Diligent – attention to detail but able to prioritise and see the wood from the trees.