ReNeuron
pioneering stem cell therapeutics

Role Profile

Job Title	QA Documentation Associate (Relocation Programme)	**Reports to:**	**Head of QA**
Date	21 August 2014	**Location**	**Guildford and relocation to Pencoed**

Role Purpose

To provide a comprehensive documentation service to the Relocation Programme in respect of GMP controlled documentation including Standard Operating Procedures ("SOP's"), Qualification & Validation Protocols and Quality Control Documentation.
To provide a robust system for the review and approval of documentation related to the Programme and give regular status reports to the Programme Steering Board.

Responsibilities

- Control of GMP documentation within the Quality Management System including SOPs, Policies and Validation Master Plan.
- Proactive management of the system to ensure timely review and approval of documentation to be generated for the qualification and operation of the new R&D and GMP manufacturing facility.
- Receive documentation generated by the external specialist building contractor and incorporate it into the ReNeuron Quality system.
- Provide regular progress reports to the Programme team on the completion of planned documentation.
- Provide an interface between the Documentation Controller within the exernal specialist building contractor and the ReNeuron Programme team to ensure all documentation is co-ordinated and filed appropriately within the Quality System.
- Frequent communications between ReNeuron Programme team members and key members of the building contractor teams.
- Prepare documentation for presentation to, and inspection by MHRA. Attend and support facility inspections by MHRA.

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

- Initially based at Guildford, transferring to complete the project in Pencoed.
- Full-time role, could work remotely one day per week.
- Occasional travel to Wales for project meetings
- Rare need to stay in Wales overnight on business.

Person Specification:

- Detailed understanding of GMP Quality systems and GMP documentation usage.
- Able to complete & review documentation with high level of precision.
- Computer literate, including a good working knowledge of Word, Excel, Visio.
- Strict attention to detail, able to work unsupervised
- A confident communicator with excellent interpersonal skills
- Experience of working within a GMP manufacturing environment.
- Ability to work calmly during phases of aggressive timelines.