ReNeuron
pioneering stem cell therapeutics

Role Profile

Job Title: GMP QA Manager	**Reports to: Head of Quality**
Date: April 2015	**Location: Guildford/Pencoed**

Role Summary

To take responsibility for QA within GMP and will manage the QMS at ReNeuron.

The incumbent will have oversight of the GMP status of the Pencoed facility, all major operational programmes, both internal and external and will be expected to proactively monitor these programmes for compliance, working closely with CMOs, providing quality oversight and managing the technical agreements.

Responsibilities

- The GMP QA Manager will have responsibility for GMP procedures and systems to ensure that they meet the Company's changing needs and coordinating training to ensure compliance. This will extend to auditing suppliers, ensuring that specifications are agreed for supply of materials etc, that these are consistent with regulatory requirements and that procedures operate to monitor compliance.

- Conduct contractor selection, for cause and routine monitoring audits of GMP service providers. Building effective working relationships and overseeing the closure of CAPA plans.

- Oversee the QA input into operational activities. Assessment of changes and deviations so as to maintain regulatory compliance and identify continuous improvement initiatives through CAPA plans.

- Work with the Head of Quality to establish and continually evolve the Quality culture to meet the Company's rapidly expanding

research programmes and development programmes that offer major regulatory challenges.

- Oversees the Medical Devices handling and control including inspection and release.

- Be responsible for the GMP status of the Wales Facility, ensuring the organization is kept current with respect to changing regulatory and industry GMP expectations, working with the other departments to ensure the facility operates to GMP.

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

None