Role Profile

Job Title: GMP QA Manager	**Reports to: Head of Quality**
Date: Sept 2016	**Location: 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 .
The QA Manager will have a key role in the preparation of regulatory dossiers providing advice on the presentation and analysis of data and audit of final reports.

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.

- Ensure that appropriate quality audit is applied to CMC submissions, data, procedures and reports (both internal and external) such that they are suitable for inclusion into regulatory submissions and in turn to critical sections of regulatory submissions.

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

- Work in conjunction with the company's Designated Individual to maintain the company's Human Tissue Licence for the processing, import/export and storage of cells/tissue for scheduled purposes, regularly auditing internal activities and acting as the delegated person for the disposition of acquired tissues and cells.

- Be responsible for the GMP status of the Wales Facility, working with the other departments to ensure the facility operates to GMP.

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