ReNeuron
pioneering stem cell therapeutics

Manufacturing Manager

Background
ReNeuron is a well-known SME, life sciences company, with unique and pioneering technologies already delivering therapeutic product candidates that are in the clinic. Its primary objective is the development of novel stem cell therapies targeting areas of significant unmet or poorly met medical need. Full information on the company and the nature of its business can be found at www.reneuron.com.

All of the company's current operations – R & D, Manufacturing Development, Clinical, Regulatory, Admin etc. are based in one site on the Surrey Research Park in Guildford, Surrey. Manufacturing of clinical material is currently outsourced to CMOs. It is the intention of the company to move its base to South Wales within the next 12 months to a new, custom-built facility that will house both the R & D Group and a new state of the art manufacturing facility. This facility will produce material for the planned Phase III trial through to market authorization and commercial supply.
The current headcount at ReNeuron is c. 30, but this is anticipated to rise to c. 50 during 2015 as the new manufacturing facility comes on line.

The Need
In line with establishing its own manufacturing facility, ReNeuron will need to develop an in-house Manufacturing function to carry out GMP production of Phase III clinical trial material. Currently, Phase I and II clinical product is manufactured by CMOs and a scaled-up, automated Phase III process is in development to be ready for technical transfer into the new Welsh ATMP facility in early 2015.

The Role
This is an exciting role with the key responsibility of establishing a new GMP Manufacturing Function in the new Welsh facility to produce clinical trial ATMPs. We are looking for a hands-on Manufacturing Manager with experience in building GMP manufacturing functions and working in cleanrooms to produce cell therapies for clinical trials. Initially, the role will require involvement in late stage process development to ensure that the Phase III automated process is operationally robust and GMP compliant. This will be followed by participating in technical transfer and execution of process validations and ensuring that qualified, trained resources are available for these activities. The role will also involve participating in the detailed design of the new manufacturing facility to ensure maximum operational efficiency. Strong interpersonal skills, cross-functional outlook and understanding of the needs of internal and external stakeholders are required. Proven leadership, managerial experience, the ability to work under pressure and to aggressive timelines is also necessary.

This is a unique opportunity to be part of the development and implementation of an ATMP process for Phase III clinical manufacture and design of a new facility.

Responsibilities

The job holder will be responsible for all facets of establishing a new GMP Manufacturing Function in a new facility including the recruitment and training of the team, creation of all necessary GMP documents and establishing the smooth operation of the production process, initially for the manufacture of clinical material before moving to full scale production for commercially licensed material.

- Contribute to late-stage production process development from the perspective of operational robustness and GMP compliance
- Contribute to the development and execution of the technical transfer protocol and process qualification and validation
- Attend FATs, SATs, IQ/OQ as appropriate during validation on the plant and equipment
- Prepare and manage the manufacturing budget.
- Plan the production start-up in the new facility and recruit and train new team members in a timely fashion.
- Participate actively in the preparation for the Manufacturer's Licence- be the named person responsible for production on the license.
- Establish and manage the production schedule to meet clinical needs and ensure that output is manufactured in accordance to cGMP and Regulatory expectations
- Manage all Manufacturing personnel and ensure that the department, premises and equipment are maintained and operated to the required standards and in a safe manner. Ensure full compliance to HS&E across the manufacturing facility.
- Participate in, and lead elements of inspections by Regulatory Authorities including MHRA and FDA. Ensure close-out of any deficiencies identified during those inspections that relate to the role-holder's scope of operations.
- Champion continuous improvement in the manufacturing facility to enable production to be completed in the most effective manner.
- Complete and review risk assessments to ensure no disruption of product to the clinic.
- Champion strong relationships with cross functional departments including Quality and Regulatory groups
- Actively maintain and update knowledge and expertise of current developments, standards and operating practices within the ATMP and pharmaceutical industries
- Support the design or development of new equipment/processes for existing and future requirements

The person

- Degree or equivalent in biological science, engineering or related area
- At least 3 years of hands-on aseptic manufacturing experience (preferably in cell therapies) and managing a GMP manufacturing function
- Current working knowledge of GMP requirements for ATMPs
- Experience with manufacturing ATMPs for clinical trials and establishing a manufacturing function
- Good communication skills; able to interact with and influence individuals across a variety of functions (without a direct reporting relationship).
- Ability to take a pragmatic approach to defining problems, resolving conflict, and developing practical solutions.

- Good understanding of the Quality Management System and proactive approach to resolving deviations and CAPAs
- Good understanding of lean manufacturing principles.