Process and Validation Engineer

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 a Process Engineering group to support continuous improvement of the GMP manufacturing process and development of pipeline products.

The Role
Reporting directly to the Head of Engineering, the Process Engineer position will be a key member of a team responsible for delivering a new manufacturing facility and scaled, automated manufacturing process for a stem cell therapy in clinical trials. The role will involve working with process development partners to develop a robust manufacturing process, design and hands on execution of experiments to support process development and evaluating cell culture process equipment suitable for GMP manufacturing. To support the new facility build, the individual will be responsible for reviewing equipment specifications and P&IDs and providing input into facility design, utility usage and facility process flows.

As the project progresses, the role will involve assisting with writing, reviewing and execution of technical transfer and validation protocols, process troubleshooting and writing SOPs to establish the in-house manufacturing process. Once established, the

role will support manufacturing through continuous improvement projects to increase productivity and reduce cost of goods.

Responsibilities
The Process Engineer will be an integral part of a team with responsibilities including:

- Supporting the design and development of new equipment/processes for clinical trials including hands-on design, execution and documentation of experiments
- Review of equipment specifications for process and where necessary participation in FATs, SATs, IQ and OQ
- Writing, executing and documenting technical transfer and validation protocols
- Supporting the Manufacturing function by troubleshooting during tech transfer, validation and production
- The position may require up to 20% travel
- The candidate will need the ability to perform functions in a cleanroom environment while fully gowned for up to 6 hours per day (with breaks).
- The candidate must be willing to work off-hours and weekends as needed to accommodate critical production and validation schedules during start-up of new processing facilities.

The person
Degree or equivalent in Engineering, Science or related technological field

- Strong process aptitude with an enthusiastic hands-on approach
- Good communication, interpersonal and organizational skills. Ability to multitask, be detail oriented and open to change
- 1-3 years of industry related experience preferred
- High Proficiency in MS Office: Word, Excel, PowerPoint, Project.
- Experience with documentation and practices in a regulated environment preferred (e.g. GMP, GLP)
- Process development experience
- Good communication skills; able to interact with and influence individuals across a variety of functions (without a direct reporting relationship).
- Hands-on approach to problem solving and be a highly motivated, team oriented individual
- We are seeking an independent self-starter who will take ownership of projects from concept through implementation.