Facility 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 ensure the compliant working of the GMP cleanroom suites and maintain R&D labs and general office areas.

The Role
The new facility at Pencoed will comprise of both R&D facilities and a manufacturing plant for the production of ATMP products to cGMP, meeting MHRA and FDA standards. This role requires an experienced, hands-on Facilities Manager who will act as the building owner for the Pencoed Facility on behalf of the site director and who will be accountable for the smooth running and safe operation of all aspects of the building and equipment.
This is an evolving role where initially the facilities manager will be responsible for the maintenance of the current Guildford facility to ensure business continuity and will work closely with the Programme Manager to facilitate the relocation of R&D equipment to the new facility in Wales. Concurrently, the role will involve input into the detailed design phase of the new facility to ensure that the building systems (including HVAC and water), equipment, building management system and environmental monitoring systems are specified for ease of use and maintenance. The role will also require establishment of all facilities management systems to meet relevant regulations including, work order system, preventative and predictive maintenance and calibration programmes to support a GMP facility for the production of cell therapies for clinical trials. Following relocation to the new facility, the facilities manager will be responsible for ensuring that all utilities, cleanrooms and equipment

are monitored, maintained and available for production and be responsible for the running and maintenance of the general facility.
This is a unique opportunity to be involved in the design of a new ATMP R&D and GMP manufacturing facility, establishment of facility management systems and day-to-day smooth operations of facility and equipment..

Responsibilities

Initially

- Maintenance of existing site and facilitation of relocating R&D lab equipment.
- Act as project point of contact for issues relating to design and maintenance of the new facilities input into in the design of the BMS, EMS and facility design to meet relevant regulations
- Attendance of FATs, IQ, OQs as appropriate

For the new facility

Total facilities service provision including repairs, maintenance ,physical security, cleaning, H&S and utilities for both R&D and GMP Manufacturing facility .establishment and running of: maintenance documentation systems required by GMP; preventative maintenance and calibration programme and work order system for equipment and utilities and building

- Writing facility related SOPs
- Set-up and management of external contracts and contractors including cleaning, pest control, alarm and security systems
- Identify and maintain stocks of critical spare parts
- Provide support for validation of equipment and system IQ, OQ, and PQs.
- Ensure availability of equipment and cleanrooms for validation and production. Complete emergency repairs when necessary to offset downtime and production delays.
- Participate in investigation of facility or equipment related change controls, deviations, CAPAs, non-conformances.
- Propose facility annual expense and capital budgets.
- Maintaining facility drawings and P&IDs
- Prepare for, attend and support inspections by regulatory authorities including MHRA and FDA.

The person

- Degree preferably in chemical or mechanical engineering or related discipline
- Considerable experience of facilities management in the bio-pharmaceutical Industry
- Needs the working skills and experience of a technician with experience of starting up and establishing facility systems for a new facility in a regulated industry
- Experience in specifying and running building management and environmental monitoring systems and working with computerized maintenance management systems. Experience with Siemen's BMS preferred.
- Experience in electrical, plumbing, HVAC, carpentry, refrigeration, controls and basic laboratory and pharmaceutical production equipment (autoclaves, ovens, incubators etc.)

- Experienced in basic calibration practices.
- Current working knowledge of facility maintenance GMP, GAMP and regulatory requirements for ATMPs and good maintenance practices
- 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
- Ability to work in controlled environments requiring special gowning
- Ability to use Autocad and read and write P&IDs is preferable