Validation Officer

Based at the Edinburgh BioQuarter, RoslinCT is a leading Contract Manufacturing and Development organisation within the cellular therapies/ATMPs field, performing cutting edge investigational medicinal product manufacture for clinical trials across Europe and the US.

The Company is now embarking on an exciting period of planned growth, and we are recruiting for some key operational roles to help support and lead that growth into the future, including this one.

We are searching for a **Validation Officer** to join our expanding team and assist in the planning, review and execution of validation activities and the preparation of validation protocols and reports.

Candidates for this role must also be able to demonstrate a strong commitment to our Core Values, and so should be:

- Passionate about Customer Satisfaction
- Able to support a 'one team' approach
- A great communicator
- Committed to personal growth and development
- Accountable for their work

Main Function:

This new role of **Validation Officer** will report directly to the Validation Specialist and will assist in the planning, review and execution of RoslinCT validation activities including facility, equipment, assay and process validation, qualification and re-verification.

Specific Responsibilities:

Your responsibilities as the Validation Officer will vary, but will include;

- Routine maintenance of key performance indicators and data to enable management reporting on validation status and performance of validation activities.
- Preparation, review and execution of validation protocols and reports ensuring validation activities are aligned with regulatory requirements.
- To follow GAMP principles as appropriate, ensuring validation methods are consistent with the approach and that quality is built into each stage of the process.
- Management and co-ordination of routine qualification and calibration of equipment.
- Development and implementation of process improvements relating to validation activities.
- Supporting development and maintenance of the Validation Master Plan.
- Assisting with ensuring validation and re-qualification schedules are co-ordinated and communicated.

- Assisting with procurement and management of out-sourced validation and qualification service providers.
- Provision of comprehensive administrative support for all validation documentation and the associated reference drawings and specifications.
- Ensuring validation and qualification records, including on the electronic Quality Management System (Q-Pulse) are maintained up to date at all times.
- Assisting where required with quality related documentation including but not limited to validation documents, change controls, incidents/deviations and risk assessments in accordance with GMP and standard operating procedures.
- Ensuring that confidentiality of all information relating to clients and patients is maintained at all times.
- Demonstration of excellent customer service skills for both internal and external customers.
- Maintaining familiarity and act in compliance with all Health and Safety policies and procedures.
- Contributing to the set up and execution the validation schedule for a new facility.

Qualifications Required:

The post holder will hold a degree in a Life Sciences or related subject, or equivalent training and experience.

Skills/Experience Required:

The ideal candidate will also have:

- Flexibility and adaptability to react to rapid changes in project priorities.
- Experience in effectively communicating with customers and service providers
- A working knowledge of UK laws and regulations for cell therapy products and tissue donation would be advantageous.
- Excellent computer skills with experience in Microsoft Word and Excel
- Experience with validation of cleanroom facilities, manufacturing and QC testing equipment would be advantageous.
- Hands-on experience of validation activities such as temperature mapping is an advantage.
- Demonstrable knowledge and experience of GAMP principles and cGMP.
- Demonstrable experience of working within a validation program in a GMP environment.
- Experience in a sterile manufacturing facility strongly preferred.

Benefits:

- Group Personal Pension Plan: 3% Employee contribution with an Employer contribution of initially 5% for the first year of joining the scheme then a 1% increase per year until a maximum of 8% is reached.
- Group Life Cover, 3X Salary
- Health4All Cash Plan where you are able to claim cash back towards dental check-ups and treatment, new glasses, contact lenses and therapy treatments such as physiotherapy and chiropody and more.
- Employee Assistance Programme
- 31 days annual leave with an extra day from 3 years' service and a further day from 5 years' service.
- 4 public holidays

Location: Edinburgh BioQuarter. *Please check our location and ensure you can realistically commute to site as we have limited parking available.*

Closing Date: 18th September 2020.

To apply, please send your CV, a covering letter with your salary expectation and confirmation you have the right to work in the UK to jobs@roslinct.com