Validation Specialist

RoslinCT is looking for an enthusiastic and motivated Validation Specialist to join their expanding team based at the Edinburgh BioQuarter. RoslinCT is a leading cell therapy / ATMP Contract Development and Manufacturing Organisation (CDMO) performing cutting edge investigational medicinal product manufacture for clinical trials across Europe and the US.

Main Function:

The main function of the Validation Specialist is take responsibility for the regulatory compliance of the facility and equipment validation activities and the preparation and execution of validation protocols and reports. In addition, they will specifically support GMP project management activities in the validation of a new cell therapy facility.

Specific Responsibilities

- Plan, manage and execute (as appropriate) RoslinCT validation activities to include facility and equipment validation, qualification and re-verification.
- Provide regular reports to RoslinCT management on the status of validation tasks.
- Preparation and execution of validation protocols and reports.
- Management and performance of routine qualification, calibration and maintenance of equipment.
- Supervision of a small team undertaking planned and preventative maintenance and validation activities for facilities and equipment.
- Complete and review 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.
- Ensure that confidentiality of all information relating to clients and patients is maintained at all times.
- Communicate procedures and results with clients.
- Demonstrate excellent customer service skills for both internal and external customers.
- Plan and undertake the Validation of new equipment and to advise and assist others in this.
- Compliance with all Health and Safety policies and procedures.
- Providing out of hours cover for critical equipment alarms as required on a rotational basis.
- Contribute to the set up and execution the validation schedule for the new facility.
- Ensuring data integrity of software systems

Qualifications Required:

The post holder should possess a Life Sciences Degree, or a related subject, or equivalent training and experience.

Skills/Experience Required:

The ideal candidate will also have:

- Experience with cleanroom facilities, manufacturing and QC testing equipment would be advantageous.
- Demonstrable experience of managing a validation program in a GMP environment.
- Experience in a sterile manufacturing facility strongly preferred.
- Experience supervising other staff.
- 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.

The successful candidates for this role will have the following behavioural competencies:

- A determination to succeed with a "can do attitude".
- The ability to work effectively within a small team.
- Excellent attention to detail with a desire to continually develop and improve our processes.
- Ability to learn and share knowledge where appropriate.
- Flexible and enthusiastic with the ability to adapt to changing priorities.
- Excellent communication and interpersonal skills.
- Exceptional organisational and time management skills.
- Emotional resilience and an ability to work under pressure with good humour.

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

Salary: Dependent on experience and qualifications

Location: Edinburgh and Lothian