



Quality Assurance 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 talented **Quality Assurance Officer** to join our expanding team!

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:

The QA Officer will provide support for the Quality department within our company. We operate a Quality Management System which ensures compliance with the necessary legislation including Human Tissue and Human Medicines regulations, GMP, ATMP Directives and ISO 9001.

Specific Responsibilities:

Your duties and responsibilities as a QA Officer will vary, but will include:

- Reviewing and approving Incident Reports, Change Controls and Risk Assessments
- Performing data review audits (Batch Production Records, Validation Documents and Development Documentation as required)
- Supporting the operation with Validation activities
- Reviewing Standard Operating Procedures (SOPs) to ensure compliance with GMP and other relevant regulatory requirements
- Performing internal audits to determine compliance with GMP and identify areas for improvement.
- Issuing and reviewing Corrective and Preventative Actions (CA/PAs).
- Reviewing and approving suppliers / service providers including audit of critical suppliers where required.
- Supporting the QA Manager with hosting customer audits.

- Providing advice and guidance to the RoslinCT team with support from the QA Manager.
- Supporting the administration of the company's Q-Pulse documents management system.
- Demonstrate excellent customer service skills for both internal and external customers.
- Compliance with all Health and Safety policies and procedures.

Qualifications Required:

The post holder will have:

- A degree or equivalent qualification within the life sciences

Skills/Experience Required:

The post holder will also have:

- Experience within a GMP Quality Department
- Experience in using Q-Pulse Document Management system or similar system
- Experience of quality support for IT systems and software, including validation
- A good working knowledge of GMP clean rooms operating at a Grade A/B level.
- A good scientific knowledge of cell therapies or cell biology is desirable.
- Excellent administration skills.
- Excellent data recording and record keeping skills with a good eye for detail
- Organisational and planning skills with the ability to plan ahead whilst delivering results to deadline

Behavioural Competencies:

This is an exciting role and the successful candidate will be able to demonstrate the following behavioural competencies:

- Emotional resilience and an ability to work under pressure with a "can do attitude".
- Ability to process a high volume of planned and un-planned work effectively
- The ability to multitask and manage time effectively to ensure all work streams are managed
- A determination to continually develop and improve our processes.
- Effective communicator with the ability to build strong working relationships
- The ability to provide constructive feedback for issues affecting Quality
- Keen to learn and share knowledge with the whole team
- A team player with the ability to work unsupervised
- Conscientious and takes personal responsibility for own actions and behaviours
- Understands the needs of the customers and responds accordingly to deliver excellent customer service

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.