Quality Investigator

RoslinCT is looking for a driven individual to join us as a **Quality Investigator**.

We are a world-leading contract manufacturing and development organisation, specialising in the field of cellular therapies, advanced therapeutic medicinal products and regenerative medicine.

We perform cutting edge therapy discovery and manufacture with a focus on stem cell therapies for clinical trials across Europe and the US. We have embarked on an exciting period of growth and are now recruiting across all our teams to support our expansion. This position of **Quality Investigator** forms a key part of that growth.

The Role:

Reporting to the Head of Manufacturing Operations, you will join the rapidly expanding Manufacturing team and to perform detailed and thorough investigations of non-compliances across our rapidly growing sterile cellular therapy manufacturing operations including, but not limited to, product impact assessment, systematic root cause analysis and identification of effectual CAPAs. The ideal candidate will hold an excellent working knowledge of cGMP regulations particularly in respect of aseptic processing.

Responsibilities:

As this is a fast-paced role your responsibilities as the Quality Investigator will be varied, but will include;

- Conducting and summarising technical deviation/incident investigations with relation to cellular therapy manufacturing, translating complex operational events into an understandable and cohesive summary reports.
- Analysing each event and assessing impact in the context of the sterile medicines cGMP regulations.
- Gathering data from across the organisation, leading and performing systematic Root Cause Analysis (RCA) to determine most likely cause. You will also plan, execute and lead RCA events with attendance from relevant departments.
- Identification of realistic but effectual corrective and preventative actions.
- Performing 'in the field' investigations, collecting data and interviewing involved personnel.
- Ensuring timely completion and closure of deviations and investigations.
- Working closely and collaboratively with Operational departments to identify appropriate actions and facilitate deviation closure. Attending the daily Operations meeting to provide appropriate feedback in respect status and progression.
- Presenting technical status updates of RCA and findings to RoslinCT management, customers, customer auditors and regulatory inspectors.
- Training of relevant junior Operational personnel to develop their technical writing and investigation skills.

- Working closely with Lead Scientists, Supervisors and Trainers to conduct sharing sessions with operators on investigation outcomes, impacts and CAPAs.
- Evaluation of trends and working pro-actively and collaboratively on targeted initiatives to reduce deviations.
- Providing input into other Quality Management work such as Change Controls, Risk Assessments, FMEA, document updates and CAPA implementation.

Values:

A key part of working at RoslinCT is being able to embody our company values, which are integral to the work we do here. As such, you should be able to demonstrate:

- Passion for customer satisfaction
- Ability to support a 'one team' approach
- Great communication
- Commitment to personal growth and development
- Accountability for your work

Qualifications:

The ideal candidate will hold a Life Science degree or equivalent relevant qualification/experience. A Green Belt certification with experience of implementation of Lean Six Sigma tools is desirable, but not essential.

Skills and Experience:

The ideal candidate will demonstrate:

- Experience of cell culture methods and techniques.
- Experience of working in an aseptic sterile manufacturing environment or supporting function.
- Excellent working knowledge of cGMP regulations particularly in respect of aseptic processing, contamination control, documentation and record management, and technical writing.
- Working knowledge PICS and ISO regulations and background of technical RCA and FMEA techniques.

Behaviours:

The ideal candidate should also be able to demonstrate:

- Exceptional organisational and planning skills with the ability to plan ahead whilst delivering to deadline.
- Excellent communication and interpersonal skills and a proven track record in maintaining effective relationships and working with a wide range of people.
- Excellent oral and written communication skills; able to explain technical or complex concepts in a clear format.
- Proven logic and decision making abilities, critical thinking skills.
- Excellent administration and record keeping skills.

- Ability to learn and share knowledge with the management team and the wider team where appropriate.
- Excellent attention to detail.
- A determination to succeed, with a 'can do attitude'
- A determination to continually develop and improve standards.
- Ability to create a positive environment through self-awareness and social skills.
- Ability to take responsibility for setting high standards and looks at the bigger picture to recognise the impact of actions.
- Emotional resilience and an ability to work under pressure with good humour.

Benefits:

In addition to a competitive salary and the opportunity to join an exciting, rapidly expanding company delivering life-changing therapies, we can offer:

- 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: 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 days public holidays leave.

Location:

We are based at Edinburgh BioQuarter, which acts as a hub for Scottish Life Science with close links to the University and the Royal Infirmary.

To apply, please send your CV, cover letter and salary expectations to jobs@roslinct.com**. Please note we are currently unable to provide sponsorship for visas to work in the UK and can therefore unfortunately only consider applications from those with full eligibility to work in the UK.**