Quality Investigator

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 **Quality Investigator** to join our expanding team and support our Cell Therapy Manufacturing Operations.

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 **Quality Investigator,** created to support growth across the business**,** will report directly to the Head of Manufacturing Operations and will be responsible for performing detailed and thorough investigations of non-compliances by closure date including product impact assessment, systematic root cause analysis and identification of effectual corrective and preventative actions.

Specific Responsibilities:

- Conduct and summarise technical deviation / incident investigations, translating complex operational events into an understandable and cohesive summary reports.
- Analyse each event and assess impact in the context of the sterile medicines cGMP regulations.
- Gather data from across the organisation, lead and perform systematic Root Cause Analysis (RCA) to determine most likely cause.
- Identify realistic but effectual corrective and preventative actions.
- Perform 'in the field' investigations, collecting data and interviewing involved personnel.
- Ensure timely completion and closure of deviations and investigations.
- Plan, execute and lead RCA events with attendance from relevant departments.

- Work closely and collaboratively with Operational departments to identify appropriate actions and facilitate deviation closure.
- Attend the daily Operations meeting to provide appropriate feedback in respect status and progression.
- Present technical status updates of RCA and findings to RoslinCT management, customers, customer auditors and regulatory inspectors.
- Train and coach relevant Operational personnel to develop their technical writing and investigation skills.
- Work with Lead Scientists, Supervisors and Trainers to conduct sharing sessions with operators on investigation outcomes, impacts and CAPAs.
- Evaluate trends and work pro-actively and collaboratively on targeted initiatives to reduce deviations.
- Input into other Quality Management work such as Change Controls, Risk Assessments, FMEA, document updates and CAPA implementation.

Qualifications Required:

The post holder will hold;

- Life Science degree or equivalent qualification/experience
- Green Belt certification with experience of implementation of Lean Six Sigma tools is desirable

Skills/Experience Required:

The ideal candidate will also have:

- 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.
- Working knowledge PICS and ISO regulations.
- Experience with technical writing.
- Background of technical RCA and FMEA techniques.

Behavioural skills:

- 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.
- Creates a positive environment through self-awareness and social skills.
- Takes 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:

- 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 ensure you can realistically commute to our site as we have limited parking available.

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