Senior 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 **Senior Quality Assurance Officer** to join our expanding team and provide senior support to our busy ongoing GMP QA activities.

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 role of Senior QA Officer will report directly to the Quality Manager and will support the Quality Department with all activities related to maintenance of the Quality Management System. The role will also lead the team of QA Officers in the day to day activities required to support both of our sites.

Specific Responsibilities:

The responsibilities of the Senior QA Officer will vary but will include;

- Leading the review and management of RoslinCT document types including but not limited to SOPs, batch records and production material specifications to ensure compliance with company policies, practices and relevant standards and guidelines.
- Support the Quality Manager in the determination of training requirements for the QA team. Act as a trainer and lead training for the QA Officers in specific SOPs as required.
- Write, implement, review and maintain SOPs, policies and other documentation for QA activities.
- Lead the Quality Assurance Officers in the administration, review and approval key quality management system documents (QMS) including Incident Reports, Change Controls, CAPA and Risk Assessments.
- Lead and perform data review audits (Batch Production Records, Validation Documents and Development Documentation, Quality Control Data as required).

- Support the Qualified Person and Quality Manager in the definition and maintenance of the annual internal and external audit programs for RCT.
- Performing and review internal and external audits to determine compliance with GMP and identify areas for improvement.
- Reviewing and approving suppliers / service providers including supporting with audits of critical suppliers where required.
- Supporting the Quality Manager with hosting customer audits and regulatory inspections.
- Act as principal project lead for new and existing RCT projects providing advice and guidance to the RCT team with support from the Quality Manager.
- Maintain and deliver training in quality related topics to RCT personnel including annual GMP training.
- Lead the Quality Assurance team in preparation of weekly and monthly reports to be submitted to senior management and RCT departments to ensure visibility of QMS requirements and performance including the compilation of quality metrics to facilitate monitoring and management of the RCT Quality System.
- To perform tasks as reasonably expected by the Quality Manager.
- Act as deputy for the quality assurance manager as required including in appropriate meetings/ forums and presentation of quality reports/issues.
- Supporting the Quality Manager in the management of other Quality Assurance Officers within the Quality Team including day to day activities, training in procedures associated with the role and preparation of the role to deputise/assume responsibilities of the Senior Quality Assurance Officer role as required.

Qualifications Required:

The post holder will hold an Honours degree in a Life Sciences or related field, or an equivalent professional qualification.

Skills/Experience Required:

The ideal candidate will also have:

- Experience in a relevant GMP manufacturing industry (e.g. biologics, pharmaceuticals).
- Demonstrable leadership qualities, communication, interpersonal and motivational skills
- Demonstrable ability to take decisions, to analyse information in a logical manner and to prepare coherent investigative and/or technical reports
- A clear understanding of GMP, regulatory and accreditation systems and quality management
- Demonstrate competence in reporting and presenting internally / externally (MHRA visits, customer visits, training, auditing)
- Competent in computer packages including Microsoft Office and an electronic quality management package

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. *Please ensure that you can realistically commute to our site before applying.*

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