Quality Assurance Manager (GMP)

Salary: Competitive, based on experience.

Vacancy:

An exciting opportunity has arisen within the management team of RoslinCT for a Quality Assurance Manager to manage the QA function for the company and to lead the team in the evolving field of Cell and Gene Therapies. RoslinCT is a leading Cell and Gene Therapy CDMO based in Edinburgh and currently expanding to meet the growing manufacturing demand within the field. Reporting to the Chief Operating Officer, we are looking for an individual who shares our passion for Quality and delivering an excellent service to our clients.

Candidates for this role must also be able to demonstrate a strong commitment to our Core Values, and so should be:

- Able to demonstrate exceptional leadership skills
- 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:

As the RoslinCT Quality Assurance Manager the primary function is to lead the QA team on further developing the Quality Management System and managing the Quality Assurance requirements of the company, thereby ensuring compliance with the necessary legislation.

The principal objective is to ensure that the cell and gene therapies and stem cell banks manufactured by RoslinCT fully comply with the requirements of Good Manufacturing Practice (GMP) and meet the various applicable regulatory standards.

Specific Responsibilities:

- Lead and develop an effective and motivated team of Quality Assurance professionals on core QA activities. Ensure that the team are managed effectively and that their work is prioritised effectively so that agreed targets are met consistently.

- Maintain and continually improve RoslinCT's Quality Management Systems (QMS) and ensure full compliance with the UK, EU and US regulations and legislation for ATMPs and Stem Cell manufacture. In particular, the post holder will ensure compliance with the applicable HTA regulations, and the requirements of the MHRA and FDA.

  Through an 'on the ground' approach, develop and maintain a full understanding of the operational quality standards within the business and, with the team, promote best

practice on a daily basis. Responsible for championing compliance standards and aseptic processing training initiatives on site.

- Review and approve the procedures relating to all RoslinCT activities to ensure their compliance with the relevant standard/guidelines.

- Liaise with our clients on the quality aspects of each manufacturing project.

- Participate in RoslinCT management processes by membership of key management teams to ensure strategic and developmental decision can be made on the basis of informed advice on issues of quality and regulatory matters.

- Provide advice to support the Cell Therapy Development and Technology Transfer activities.

- Provide regular reports to RoslinCT's management team and quality governance function detailing the performance of the QMS and where appropriate advising on opportunities for improvement.

- Drive quality improvement projects and always drive sustainable continual quality improvement using a positive pro-active team approach.

- Ensure that effective training systems are in place throughout RoslinCT and that effective training in all aspects of Quality Management and GMP is delivered.

- Ensure data integrity is mainatained across all aspects of the GMP operation.

- Ensure systems are in place and are followed for the reporting and investigation of quality related incidents, defective products or adverse events. These systems will identify the root cause of such incidents and generate strategies for preventative actions.

- Ensure systems are in place for the control of critical documents (e.g. SOPs, policies) and records (e.g. batch production records) to ensure they are reviewed regularly to reflect current processes and they are available at the point of use.

- Ensure risk Management procedures are in place and risk assessments are performed across all aspects of the GMP activities.

- Ensure effective validation systems and procedures are in place and that equipment and processes used in the manufacture, storage and distribution of products are subject to effective validation and that documentation used in validations are approved.

- Ensure that QA are effectively represented on all large RoslinCT technical and building projects. Liaise with project managers to ensure that key QA approvals are delivered on time within the qualification and validation process.

- Ensure that effective change control procedures are in place for changes to the manufacturing process, GMP activities and other areas of the company as applicable.

- Lead on a program for auditing of all internal RoslinCT operations and external suppliers of raw materials and services used in the processes of RoslinCT. Lead on the response to third party (customer) audits of RoslinCT (Including regulatory Inspections).

- Lead in the recruitment of Quality staff, as required, and ensure that the department is adequately provided with trained, motivated staff who are able to perform effectively.

- Ensure effective communication with and provide regular quality reports to Qualified Persons to highlight any areas of deficiencies or concerns.

- Professionally represent RoslinCT at conferences and business meetings.

Skills/Experience Required:

The successful candidate will have:

- An honours degree in a relevant life science or equivalent qualification.
- Experience in the successful management of a GMP Quality Assurance department, ideally within manufacturing of biologicals for clinical trials.
- Ideally have a good working knowledge of sterile manufacturing, particularly with cell-based processing.
- A good scientific knowledge of cell therapies is desirable, but an understanding of biological systems is essential.
- Excellent report writing skills with the ability to simplify and clearly present complex information.
- Excellent administration and office management skills.
- Excellent data recording and record keeping skills.
- Experience in using Q-Pulse Electronic Quality Management system would be highly desirable.

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

- Excellent leadership with the management skills and confidence to inspire others to achieve.
- Delivering excellent customer service.
- Solid organisational and planning skills with the ability to plan whilst delivering results to deadline.
- Emotional resilience and an ability to work under pressure with a "can do attitude".
- A determination to continually develop and improve our processes.
- Keen to learn and share knowledge with the whole team.
- Good networking skills both internally and externally.
- Effective communicator with the understanding of the dynamics around relationships and a proven track record in effective relationships management.

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 and Lothian. ***Please check our location and ensure that you can realistically commute to site, as we have limited parking facilities.***

Closing Date: 29 July 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