Compliance Officer (GMP)

Job Summary:

An exciting opportunity has arisen within RoslinCT for a Compliance Officer to join our team based at Edinburgh BioQuarter.

Main Function:

The position will be within the Manufacturing team with the primary role of the Compliance Officer being to ensure the effective completion of compliance related documentation within Manufacturing and provide a link with Quality Assurance to ensure compliance standards are maintained within Manufacturing. The RoslinCT Compliance Officer will report to the Manufacturing Manager and Quality Assurance

Specific Responsibilities

- Ensuring the Quality Management System KPIs are met through the review and subsequent coordination of document completion within the manufacturing team and monitoring progress against agreed timelines
- To write, progress and coordinate the completion of manufacturing incident reports and support with root cause analysis investigations ensuring completion within agreed timescales
- To draft, and review change controls and support change control activities including post implementation reviews
- To perform production batch record reviews ensuring good data integrity is maintained
- To write and review SOPs
- To review Validation documentation and witness key validation activities
- To collate information and assemble data for report compilation
- To monitor Manufacturing activities and ensure compliance against SOPs
- To deliver in house training on quality related issues as required
- Assist in the preparation process for Client and Regulatory audits
- Coordinate the preparation of response documents to internal audits
- Carry out departmental quality checks with guidance from QA
- Carry out quality improvement reviews and projects
- To perform additional activities as reasonably requested by the Manufacturing Manager

Qualifications Required:

The post holder should possess a Life Sciences Degree, or a related subject, or equivalent training and experience.

Skills/Experience Required:

The ideal candidate will also have:

- A sound working knowledge of GMP and the ability to lead others to maintain and uphold GMP standards across all manufacturing activities
- Experience of sterile GMP manufacturing within GMP clean rooms
- Experience with Quality Management Software e.g. Q-Pulse would be an advantage.
- Experience in the biologics/ cell therapy manufacture/ cell banking/ stem cell biology
- Excellent computer skills with experience in Microsoft Word and Excel

The successful candidates for this role will be able to demonstrate:

- Exceptional organisational and planning skills with the ability to plan ahead whilst delivering results to deadline
- Excellent communication and interpersonal skills and a proven track record in managing relationships
- Excellent administration and record keeping skills
- Emotional resilience and an ability to work under pressure.
- A determination to continually develop and improve standards

To apply, please send your CV and a covering letter with your salary expectation to jobs@roslinct.com

Salary: Attractive Salary & Benefits

Location: Edinburgh and Lothian