United Kingdom Jobs Expertini®

Quality Assurance Manager

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Company: Northreach

Location: London Area

Category: other-general

Northreach is a dynamic recruitment agency that connects businesses with top talent in the Advanced therapy, fintech, and digital sectors. Our mission is to provide a seamless and personalised recruitment experience for clients and candidates, and to create a positive work environment that encourages equality, innovation, and professional growth. Job Summary: As the Senior Manager, Site Quality Assurance, you will play a pivotal role in overseeing and enhancing quality assurance operations at our manufacturing site. Reporting to the Site Leadership Team (SLT), you will lead a team of QA professionals, ensuring compliance with regulatory standards and fostering a culture of continuous improvement. Key Responsibilities: Manage all site-related QA operations in accordance with Quality Agreements and GMP guidelines. Serve as the QA representative on the Site Leadership Team.Lead adherence to local or corporate Quality Management Systems (QMS).Collaborate in developing the Quell PQS, including implementing an eQMS where applicable. Define and develop new quality processes, policies, and data management systems. Establish and monitor quality standards and metrics to ensure compliance and effectiveness. Utilize quality metrics to mitigate risks, enhance compliance, and improve business processes. Identify and communicate significant quality-related matters or risks affecting product quality and regulatory compliance. Oversee complex QA activities related to manufacturing, testing, and clinical trials, ensuring compliance with regulatory requirements. Manage elements of the PQS pertaining to cellular therapies manufacture, including document control, risk management, training, and audits. Develop, review, and approve Quality and GxP-related documentation. Lead risk assessments and investigations as required. Approve equipment,

materials, and services for site use. Conduct external audits as necessary. Provide strategic input into decisions impacting the Quality Assurance department. Deliver QA-related training and basic GMP training as needed. Act as a subject matter expert on Quality-related processes.Lead or represent QA in related projects, identifying metrics, issues, and mitigation strategies. Foster a quality culture of continuous improvement within the team and across the Site Leadership Team. Ensure inspection readiness and support regulatory agency inspections. Recruit, lead, motivate, and develop a team of QA professionals. Support qualityrelated activities across sites as required. Minimum Qualifications and Experience: Minimum 10 years' experience in GMP manufacturing, with a focus on QA/Quality roles. Experience in QA support for ATMP manufacture preferred. Demonstrated leadership of small QA teams. Proficient in providing scientifically sound, risk-based quality advice. Extensive experience in writing and reviewing GxP documents. Strong knowledge of GMP principles, sterile production, and regulatory requirements for cell therapy products. Experience in generating and utilizing quality metrics. Educational Requirements: University degree in a biological science, chemistry, or equivalent field.IRCA Associate Auditor certification desired.

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