BioLyo Technologies BV
Job opportunity: QA Lead Outsourced Manufacturing

About BioLyo

BioLyo Technologies is a dynamic biotech company based in Ghent, Belgium, dedicated to the development of live micro-organisms to be used as vaccines or biotherapeutics. The company provides services to third parties to help speed up the development of their Live Bacterial Products (LBPs) by offering GMP compatible and scalable process development, analytical development, process characterization and GMP QC services. Areas of expertise include medium optimization, fermentation & harvest strategies, pre-and post-lyophilization formulation and lyophilization of LBPs. Quality by Design principles and Design of Experiments software are applied to perform process characterization to work towards commercial manufacturing, a service few CDMO's offer. As a growing company, BioLyo has implemented a QMS, has a cGMP license for Quality Control testing of Investigational Medicinal Products (IMPs), and offers QC testing services for batch release and stability studies. BioLyo also provides experienced consultancy for companies, including those with their own in-house development capabilities.

BioLyo is looking to strengthen its team with a **Quality Assurance Lead Outsourced Manufacturing**, to provide quality oversight and manage production of IMPs at the Contract Developling and Manufacturing Organisation (CDMO).

Job Description:

- Audit CDMO facilities and their respective Quality Management Systems (QMS) to ensure readiness for cGMP production, process performance qualification, and health authority inspections
- Establish and maintain CDMOs as qualified vendors for Drug Substance, Drug Product and Cell Bank production
- Closely interact with the quality, production, warehouse and site representatives and build a relationship of trust
- Quality oversight of manufacturing activities and the QMS of the CDMO
- Person in Plant (PIP) at CDMO (Europe) on a regular basis during manufacturing and critical activities
- Ensure that the activities of the CDMO are performed in compliance with cGMP, relevant procedures, Product Specification Files and Quality Agreements
- Assist in Batch record review
- Oversee deviations, change controls, CAPA and OOX related to CDMO activities
- QA review and approval of root cause investigations and risk assessments
- Timely identification and communication of risks and gaps that could affect cGMP compliance; implementation of risk mitigation measures to close any gaps
- Establish timelines in collaboration with the stakeholders, monitor execution and flag deviations from the scope
- Work in close collaboration with the BioLyo QA team
- Drive regular meetings with the Quality Units of the CDMO and sponsor and with respective management
- Contribute experience, skills and knowledge of quality and regulatory requirements for Phase 3 and commercial production
- QA review of Process Performance Qualification (PPQ) protocols and oversee execution of PPQ lot production at the CDMO as part of process validation
- Set up of an inspection readiness program to prepare for marketing applications and health authority inspections, including US BLA and US FDA Pre-Approval Inspection (PAI)

Education and Competences:

- Master degree in Sciences, Pharmacy or Engineering, or equivalent by experience.
- Minimum of 10 years of experience in QA in a sponsor company to oversee outsourced manufacturing activities of biologics
- Being involved in starting up a GMP manufacturing facility for biological (investigational) medicinal products
- Extensive knowledge of commissioning and qualification of a production plant

- Implementation of pharmaceutical QMS, both from a sponsor and manufacturer perspective
- Thorough knowledge of both EU and USA cGMP, regulations and guidelines for IMPs and MPs
- Demonstrated experience with Process Performance Qualification (PPQ) and successful Biologic License Applications (BLA) from a QA perspective
- Participated in on-site Health Authority inspection; US FDA inspection is a plus
- Ability to lead, develop and motivate a team
- Excellent planning and organizational skills, focus on priorities
- Pragmatic mindset of continuous improvement
- Fluent in English, written and spoken. Knowledge of Spanish or Portuguese is a plus.

Please send your application, including your CV and a motivation letter before 06 April 2024 to sarah.pattyn@biolyotech.com