BioLyo Technologies BV
Job opportunity: Senior 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, and pre-and post-lyophilization formulation of live biological products. 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. In addition, BioLyo manages the cGMP manufacturing of IMPs at contracted CDMOs to support pre-clinical and clinical phases I to III for its clients.

Due to expanding activities, BioLyo needs to strengthen its team with a **Senior QA Lead Outsourced manufacturing**. This role will be a key subject matter expert in Quality, contributing to Quality strategies in addition to tactical activities.

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.
- Quality oversight of manufacturing activities and the QMS of the CDMO. Ensure that the activities of the CDMO are performed in compliance with cGMP, relevant procedures, Product Specification Files and Quality Agreements.
- Define and execute PAI readiness strategies in collaboration with CDMO, and with BioLyo.
- Person in Plant (PIP) at CDMO on a regular basis during manufacturing and critical activities.
- Review and approval of Tech Transfer documentation, Master Batch Records, specifications, etc.
- Quality reviewer/approver for QMS records including deviations, change controls, CAPA and OOX related to CDMO activities.
- Review of executed batch records, root cause investigations and risk assessments.
- Timely identification and communication of risks and gaps that could affect cGMP compliance at CDMO and at BioLyo; implementation of risk mitigation measures to close any gaps.
- Work in close collaboration with the Director CMC external manufacturing.
- Work in close collaboration with the QA Manager/QP, QC Manager, Project leader and Process and Product Development Manager at BioLyo.
- Support the QA Manager/QP to continuously improve the QMS of BioLyo.
- Demonstrates leadership relative to sharing of QA knowledge and experience across the organization.
- Give input to management review meetings.
- Support the execution of the internal audit program.
- Drive implementation and validation of an eQMS
- Ensure data integrity and computerized system validation.
- Give input to risk assessments (process and quality related)

Education and Competences:

- A minimum of a Master's Degree in pharmaceutical science, bioengineering, biomedical sciences or a related field, or equivalent experience.
- Preferred 10 to 15 years of QA experience in a GMP environment in pharma or biotech, preferably in late stage clinical development.

- Minimum of 5 years of experience in QA in overseeing outsourced manufacturing activities, preferentially for biologicals.
- Demonstrated experience with cGMP (EudraLex Vol 4)/ working knowledge of EP/USP, ICH/WHO guidelines, and 21 CFR and guidance documents
- Demonstrated experience with Process Performance Qualification (PPQ) and successful Biologic License Applications (BLA) from a QA perspective.
- Participated in on-site Health Authority inspection, including US FDA inspections.
- Good written and verbal communication, planning and organization skills.
- Fluent in English written and spoken. Knowledge of Dutch, Spanish or Portuguese is a plus.
- Ability to work in a motivated team in a dynamic and fast-paced environment.
- Ability to lead, develop and motivate a team.
- Accurate, precise, detail-oriented, critical, pragmatic and problem solving.

Please send your application, including your CV and a motivation letter to info@biolyotech.com before 31 March 2025.