BioLyo Technologies BV
Job opportunity: Project Leader

About BioLyo

BioLyo Technologies is a dynamic biotech company based in Ghent, Belgium, dedicated to the development of live bacterial micro-organisms to be used as vaccines or live biotherapeutic products (LBPs). The company provides services to third parties to help speed up the development of their Live Biologicals 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 bacterial 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. 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 **Project Leader**. This role will be key in guiding BioLyo projects to deliver successful production processes and quality control of drug products to clients for pre-clinical and clinical evaluation.

Job Description:

- Give input to client and supplier contracts and to risk assessments at project onboarding
- Provide Work Breakdown Structure of a project plan, allocating time and budget
- Coordination between internal departments: Development, Quality Control and Quality Assurance
- Point of contact for clients and contracted CDMOs
- Organize Kick-off meeting, make project charter
- Host internal team meetings, client meetings and meetings with the contracted CDMO
- Follow-up tasks, report on project progress, manage scope changes and resource assignments
- Manage activities outsourced to service providers
- Review development protocols and summary reports for alignment with the quotations/contracts
- Support in process risk assessments according to the principles of quality risk management
- Support review of CMC sections of regulatory submissions
- Ensure timely signing and sending of development and QC protocols and reports
- Organize wrap up meetings to capture lessons learned
- Initiate shipment of products and follow up arrival with the client
- Initiate and verify invoicing to the client

Education and Competences:

- PhD or Master's Degree in pharmaceutical science, biotechnology, bioengineering, biomedical sciences or a related field, or equivalent by experience
- Minimum of 5 years of experience in a GMP environment in pharma or biotech, of which a minimum of 2 years of demonstrated Project Leader experience
- Experience in overseeing outsourced manufacturing activities is preferred
- Working knowledge of Fermentation and Lyophilization of live organisms or biologics is a strong plus
- Knowledge of cGMP and both EU and USA guidelines for pharmaceutical development, scale up and technology transfer
- Certificate of project management training and communication courses are welcomed
- Ability to lead and motivate a team, to guide complex discussions and reach consensus
- A heart for communication and relationship building
- Fluent in English, written and spoken.
- Excellent planning and organizational skills, focus on priorities

- Pragmatic mindset of continuous improvement to get things done

What we offer:

- Working location in the vibrant Tech Lane Ghent Science Park in Zwijnaarde, easily accessible by public transport
- Flexible working hours according to a sliding schedule
- Ability to work full-time, but this is not a requirement
- A competitive salary package with meal vouchers, a mobile phone subscription, maximum bicycle allowance, a pension plan and hospitalization insurance
- A young team of colleagues and regular team building activities

Please send your application, including your CV and a motivation letter to info@biolyotech.com before 15 September 2025.