BioLyo Technologies BV

Job opportunity: Process and Product Development Manager

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. After process development, processes are transferred to GMP CDMOs in our network or to a client specified CDMO. 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 consultancy for companies, including those with their own in-house development capabilities.

BioLyo is looking for a **Process and Product Development Manager**, to guide the development team of four scientists.

Job Description:

- Day-to-day assignment of staff and other resources to project tasks
- Give input to quotations and risk assessments at project onboarding, defining process unit operations, process parameters and attributes
- Translate an approved business proposal to a project plan
- Implementation of Quality by Design principles in the development of a biotechnological product and its production process
- Apply Design of Experiments strategy using Sartorius Modde software and statistical analysis
- Guard timelines in collaboration with project stakeholders, monitor execution and flag deviations from the scope
- Review development protocols and reports, related to Research Cell Bank (RCB) production, medium and formulation development, fermentation and lyophilization
- Contribute to process risk assessments and risk mitigation measures
- Support data analysis, accountable for data review, storage and archiving
- Prepare scale up and technology transfer plan for IMP production processes to an external GMP facility
- Contribute to CMC sections of regulatory submissions
- Responsible for daily operations of the team
- Accountable for equipment qualification, maintenance and calibration
- Expand the Quality Management System that supports the development activities
- Accountable for training and evaluation of the team members
- Chair regular meetings with the team and participate in management meetings
- Work in collaboration with the Quality Control and Quality Assurance teams and closely interact with the Chief Operating Officer and Project Manager
- Contribute experience, skills and knowledge of Pharmaceutical Development for (pre-) clinical production

Education and Competences:

- PhD or Master degree in Sciences, Pharmacy or Engineering, or equivalent by experience
- Minimum of 5 years of experience in Process Development for Biologics production, of which a minimum of 2 years of demonstrated experience in a team leader or manager position, preferably at a CDMO
- Working knowledge of Fermentation and Lyophilization of live organisms or biologics is a strong plus
- Implementation of DoE in pharmaceutical process development
- Knowledge of cGMP and both EU and USA guidelines for pharmaceutical development, scale up and technology transfer
- Know-how of statistical data analysis software 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.

Please send your application, including your CV and a motivation letter before 30 April 2024 to sarah.pattyn@biolyotech.com