Quality Control Manager (w/m)

Lisbon, Portugal

Company description

Labatec Pharma is a Swiss pharmaceuticals company backed by more than 50 years' experience in proposing high-quality products to its home market. Our strategy is to continuously extend our drugs portfolio, focus on injectable generics for the hospital market, as well as grow multi-market.

Purpose and scope

Labatec is developing a new site in Portugal and is looking for someone capable of supervising all the activities to deliver a Quality Control Lab for physicochemical analysis according to the business needs. After a successful implementation of the lab, the responsibility will be driven to the coordination of all the activities related to the Quality Control Lab.

Key responsibilities and accountabilities

- Coordinate the different construction stages for a physicochemical control Lab
- Subject matter expert in QC for the Portugal site regarding Health Authorities inspections
- Supervise the Quality Control functions/activities, including Quality Control inspection schedules and the collection of Quality Records
- Support the Quality Assurance department with creation of internal procedures and with all the Quality matters (i.e, Quality Risk Management, investigations, OOS, non-conformities, training, audits)
- Assess the implementation of the Quality Plan and Quality Control Plans on the site
- Support the validation activities related to the Quality Control systems, i.e., equipment, utilities, cleaning validation, computerized systems
- Develop Quality Control KPIs
- Coordinate the Quality Control Department and ensure compliance with applicable regulations, as well as Labatec policies and procedures
- Drive and develop long-range planning for the QC Laboratory with respect to personnel, facilities and equipment
- Coordinate analytical methods validation and/or analytical methods transfer
- Interact with all the departments to assure equipment, processes and guarantee that results meet project needs and deadlines
- Drive continuous innovation and state-of-the-art technology in the QC Laboratory by identifying and implementing new technologies that improve efficiency and/or GMP Compliance
- Plan and organize calibration, maintenance and validation of instruments, as required
- Prioritize daily work schedule to ensure effective analysis of product and adherence to Operational schedule and stability program timelines
- Determine the Quality Status of starting materials, bulk product and packaging materials
- Issue Certificate of Analysis for materials and Finished Product

- Be in charge of the stability studies: planning, creation of protocols and reports
- Be in charge of Environmental monitoring for microbiology and T/H conditions
- Perform a detailed review of all analytical data generated in QC on raw materials, and finished products as required to meet the production schedule
- Lead QC team from recruiting, assessing and developing each team member according to the values of the company

Education / Languages

- Bachelor's degree in Chemistry, Microbiology, or Pharmacy with at least five years of supervisory experience (i.e., personnel and budget experience) in a government regulated industry or cGMP laboratory (including supervising professional level scientists)
- Knowledge in chemical and analytical disciplines, understanding of microbiology, pharmaceutical technology, stability testing, physical inspection techniques and statistical methodology
- Knowledge of good control Laboratory practices
- Fluent in English, French (plus)

Professional skills and experiences

- We are looking for candidates who have highly developed communication skills to interact effectively with leadership teams and across functions with all levels of employees, customers, and suppliers
- Knowledge of Lean manufacturing and continuous improvement initiatives
- Basic knowledge of process and production steps and 'general' plant lay-outs / restrictions
- Be capable to work in an international environment with many different cultures
- Must be able to travel occasionally (10-15%) for site visits and supplier audits
- Knowledge of LIMS and SAGE X3 ERP
- Excellent interpersonal skills and strong verbal and written communication
- Good problem-solving and decision-making skills
- Knowledge of good control Laboratory practices
- Experience leading a Technical team is essential
- Promotion of Teamwork and Values within the Laboratory

Recruitment process

Labatec is valuing each candidate.
Our recruitment process includes a pre-recorded online video interview (via the platform Easyrecrue) to which you will be invited in case you decide to apply to this job opening.

Please send your application to: Careers/PT/QCM