LABATEC
– Valuing People. Science. Life –

Quality Assurance Officer (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 with expertise in QA area to join the Quality team. Also, this person should be capable to support Labatec Farmacêutica S. A. in all the business needs.

Key responsibilities and accountabilities

- Check, observe, follow up, communicate, training, supervise and maintain the highest pharmaceutical quality standards according to the cGMP/GDP guidelines, regulatory requirements and other applicable, towards the overall activities that can be, but not limited to, routine tasks, documentation, manufacturing processes, training, investigation, communication, reporting and continuous improvements following the internal Quality Management system;
- Support the Head of Quality and Qualified Person on all the activities related to the Quality Management System and batch certification;
- Initiate, prepare, write, review and follow up to approval quality documentation reports, standard procedures and other quality documents;
- Together with each Subject Matter Expert, ensure the conduction of adequate training for all GMP and GDP related activities by defining, planning and supporting training activities;
- Work in close collaboration with production, packaging, quality control, supply-chain, regulatory affairs and other technical teams;
- Prepare, write, review and follow up to approval the Product Quality Review Reports;
- Participation in management reviews of process performance, product quality and of the quality management system and advocating continual improvement, including revision of data for Environmental monitoring for microbiology and T/H conditions of rooms and pieces of equipment;

- Together with each User Area, ensure conduct of adequate qualification status of supplier and/ or Service providers for all GMP and GDP related activities, including the management of supplier audits;
- Together with each CAPA owner, define and monitor the CAPA process;
- Record, investigate and properly document complaints, deviations and other quality issues;

Education / Languages

- Master's degree in Chemistry, Pharmacy or related scientific-fields with at least 3 years of experience of Quality Systems in a Pharmaceutic Industry Environment;
- Relevant experience in GMP/GDP environment;
- Good level of proficiency in Microsoft Word/Excel;
- English fluent in speaking and writing, French (would be of benefit);
- Auditors experience will be a plus;
- Lean / 6-sigma knowledge will be a plus;

Professional skills and experiences

- Be capable to work in an international environment with many different cultures
- Excellent interpersonal skills and strong verbal and written communication
- Good problem-solving and decision-making skills
- Strong organizational skills / ability to prioritize work
- Strong attention to detail
- Have a critical thinking and ability to detect issues and escalate them
- Be capable to work in accordance with Labatec's values: Excellence, Integrity, Collaboration, Accountability and Creativity.

Please send your application to: https://labatec.bamboohr.com/jobs/view.php?id=14