Lonza

Associate Director, Quality project lead SGIE

Job Description Summary

Today Lonza is a global leader in life sciences. We are more than 15,000 employees in more than 100 locations around the world. While we work in science, there's no magic formula to how we do it. Our greatest scientific solution is talented people working together, devising ideas that help businesses to help people. In exchange, we let our people own their careers. Their ideas, big and small, genuinely improve the world. And that's the kind of work we want to be part of.

In order to support the strategic growth investment of the company in Europe, we are looking for an experienced quality leader responsible for the quality oversight of our CAPEX projects portfolio.

The position is based in Visp Switzerland, the site is easily commutable from the Bernese Oberland (40 minutes by train from Thun). Visp, also known as the sun center of Switzerland, is located in the Swiss Alps close to Zermatt, Saas Fee, Verbier and Cran-Montana – a beautiful area to go skiing in the winter or enjoying great views during hiking and biking tours in the summer.

Key responsibilities:

- Provide accurate and timely input related Quality and Regulatory topics related to Lonza's Strategic Growth Investments for the phases "Ideation", "Feasibility", "Concept Design" and "Basic Design", including the CAR preparation and approval process.
- Keep an oversight on Large CAPEX projects during the execution stage (Detail Design, Procurement, Construction, Commissioning, Qualification & Validation and Start Up steps) and support as the sites as required.
- Responsible for the Quality and Regulatory aspects during CAPEX project execution.
- Ensure that strategic growths projects are in compliance with current Quality and Regulatory guidelines.
- Proactive identification and rectification of Project weaknesses and detect potential gaps in early project stages as well as initiate corrective and preventive actions (continuous improvement) in collaboration with SGIE.
- Implement a quality strategy for CAPEX project which are aligned with Quality and Regulatory guidelines and entrepreneurial approaches.
- Supporting the sites in the collaboration with authorities and customers which are linked to strategic growth projects.

Key requirements:

- Relevant experience in a regulated pharmaceutical industry including engineering, manufacturing, quality assurance, quality control, R&D and/or drug regulatory affairs.
- Experience of chemical and biological GMP API manufacturing with demonstrated ability to interpret and implement related quality and regulatory requirements.
- Proven management experience in an EMA / FDA regulated environment, and have an excellent working knowledge of current ICH, PIC/S, EU and US regulatory requirements and their implementation.
- Experience in QA aspects of facility design to build a compliant but cost effective plant (area classification, CQV requirements etc.)
- Experience of planning and execution of large projects (resource planning, the timing of regulatory meetings with the inspection authorities, audit needs etc.)
- Knowledge of modern CQV approaches to minimize the time from construction completion to routine production while maintaining compliance
- Experience in managing Swissmedic, USFDA, EMA, MHRA Audits etc.

People come to Lonza for the challenge and creativity of solving complex problems and developing new ideas in life sciences. In return, we offer the satisfaction that comes with improving lives all around the world. The satisfaction that comes with making a meaningful difference.