

Senior Quality Systems Manager Ibex™

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.

For Libex Solutions, our recently launched unique biological manufacturing and development concept in Visp, Switzerland, we have multiple openings. Become part of this exciting opportunity and join our team by applying for the position as Senior Quality Systems Manager. As Quality Systems Manager, you will be part of the QA department and be responsible for establishing and maintaining the Quality Management Systems as well for planning, realizing and monitoring all associated activities. Thereby, you will ensure that the entire Quality Management System activities meet the requirements of internal instructions, regulatory expectations and industry standards. In this role, you will cooperate closely with other Quality experts and work cross-functionally with subject matter experts of other departments, such as Development, MSAT, Manufacturing, Quality Control and Engineering. In addition, you will represent QA in interdisciplinary, technical project teams and support training of internal staff on QMS (Quality Management Systems) principle.

Key responsibilities:

- · Report to Head of Quality Management Systems
- Support the development, maintenance and implementation of the Quality Management Systems to
 ensure that that the relevant global Quality standards, as well as the requirements of the current cGMP
 regulations and customer expectations are fulfilled
- Assist in definition of Quality Strategy and definition of subsequent initiatives such as lean Quality System structure including digitalization
- · Drive digitalization with respect to the Quality Management System
- Establish, review and approve SOPs (Standard Operating Procedures) relevant to Quality Systems
- · Collection and trending of Core Processes KPIs data to assess the performance of the Quality Systems
- Provide the Quality Council with regular overviews of the implementation status of Corrective And Preventive Actions (CAPAs) resulting from audits/ inspections, major/ critical deviations or the implementation of new global requirements
- · Responsible for management and review of Quality Agreement
- · Maintain the Site Master File
- Represent the QMS Quality Unit in cross-functional teams
- Support Head of QA and Head of QMS in management of Health Authorities und customer audits and supplier audits

Key requirements:

- · Bachelor, Master degree or PhD in biotechnology, chemistry, life science or related field
- Substantial experience in the GMP regulated pharmaceutical industry; preferably in a role within the Quality Unit
- · Significant experience with Quality management System processes
- Strong background in cGMPs with a strong flavor for IT/ Digitalization
- · Sound experience in representing Quality and Compliance in projects
- · Ability to train and coach staff on QS topics
- Knowledge in biotechnological manufacturing processes is an advantage
- Good communication skills and experience in interaction with all kind of interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.)
- Excellent verbal, written and interpersonal communication and skills; high attention to detail and great organizational skills
- · Strong team work skills and solution-orientation
- · Languages: English fluent, German would be an advantage

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.