

Senior Quality Manager Compliance 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 <u>Ibex™ Solutions</u>, our recently launched unique biological manufacturing and development concept in <u>Visp, Switzerland</u>, we have multiple openings. Become part of this exciting opportunity and join our team by applying for the position as Senior Quality Manager Compliance Ibex™. The Senior Quality Manager Compliance Ibex™ reports to the Quality Systems Team Leader Ibex™ and works in close collaboration with Operations to ensure compliance of manufacturing and support functions in executing the overall quality strategy for Ibex™.

Key responsibilities:

- Support the preparation and coordination of customer audits and health authority inspections (e.g. Swissmedic, FDA, etc.).
- Support the development and implementation of the overall quality strategy for Ibex™
- · Write or revise SOPs in your area of expertise and act as owner of such documents
- Drive and coordinate activities related to raw material and supplier qualifications
- Ensure that the impact of new or revised global guidance documents on the local quality system is assessed and that appropriate measures are defined and implemented where necessary
- Create and maintain the annual training plan and act as trainer of Quality Systems processes
- Participate in the execution of Quality Risk Analyses related to raw materials (e.g. excipients)
- · Act as Subject Matter Expert for Quality/ GMP compliance issues at the site
- Collect and evaluate on a regular basis KPI data suitable to assess the effectiveness of the Quality Systems

Key requirements:

- Bachelor, Master degree or PhD in Biology, Chemistry, Biotechnology, Life Science or related field
- Working experience in the GMP regulated pharmaceutical/ API industry in a Quality Assurance/ Quality Systems role
- Experienced with inspections and in the interaction with health authorities (e.g. Swissmedic, FDA etc.)
- · Strong background in cGMP regulations
- · Solution-oriented and strongly team-minded
- · Ability to oversee project execution to identify non-compliance from quality standards
- Structured, focused and well-organized working attitude; open-minded for new ideas and suggestions
- · Agile, highly motivated and dynamic drive
- Fluency in English, German would be an asset