Quality Assurance Manager Qualification, Ibex™ Solutions

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 Ibex™ 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 Quality Assurance Manager Qualification. In this role, you own all quality related responsibilities for the daily qualification activities of new facilities, equipment, utilities and systems (incl. CSV) related to the cGMP manufacture of pharmaceutical products.

Key responsibilities:

- Representative of QA Qualification in the project organization for new facilities or other projects in regards to qualification of facilities, utilities, equipment and systems
- Coordinate the different QA interests during the project phase e.g. process, cleaning or other relevant QA objectives
- Identify new QA relevant topics e.g. as part of a strategic project of new technologies and work actively on their development into new or already established QA strategies or standards
- Act as decision-maker if new or changed QA strategies or standards are identified e.g. during the Engineering-Phase of a project
- Support the transfer from the project into production phase and support the takeover of QA Operation
- Compile review and release Qualification Documents (e.g. Qualification Plan & Report)
- Representative of QA Qualification during FAT's and attend Supplier Qualification Audits as SME (willingness to travel required)
- Perform assessments and approvals of technical changes requests during the different phases of a project and their relevance to the qualification of facilities, equipment, utilities and systems
- Support and approve quality risk analysis (e.g. FMEA)
- Ensure deviations are appropriately investigated and recorded in Deviation Reports
- Responsible to drive CAPA and Effectiveness Checks items to completion and timely closing
- Write or revise SOPs in your area of SME and acts as Owner of such documents
- Represent qualification topics during customer audits and regulatory inspections

Key requirements:

- Bachelor's or Master's degree in Engineering, Chemistry, Biotechnology, or related field
- Significant experience in the pharmaceutical industry, ideally in a QA role
- Good understanding of the applicable cGMP regulations
- General knowledge of engineering and manufacturing processes
- Auditing experience is an asset
- Ability to oversee project execution to identify non-compliance from quality standards
- Excellent organizational skills
- Strong problem-solving skills and attention to quality
- Ability to prioritize and manage work to critical project timelines in a fast-paced environment
- Fluency in English, German language knowledge would be an advantage

Every day, Lonza's products and services have a positive impact on millions of people. For us, this is not only a great privilege, but also a great responsibility. How we achieve our business results is just as important as the achievements themselves. At Lonza, we respect and protect our people and our environment. Any success we achieve is no success at all if not achieved ethically.

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.