Quality Assurance Manager Process Validation 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 a position as QA Process Validation Manager. As a member of the QA department, you will be responsible under the guidance of the Qualification / Validation Group Lead to design, plan and oversee process validation activities/ studies intended to demonstrate the suitability and robustness of biotechnological manufacturing processes. You will work closely with other Quality experts as well as cross functionally with Development, Manufacturing Science & Technology (MSAT) and Manufacturing. In addition, you will act as key member in cross-functional technical project teams and support the site as subject matter expert during inspections by authorities or customer audits.

Key responsibilities:

- Issue process validation/ study protocols and reports (incl. hold time studies and leachable & extractable studies)
- Ensure that internal/ external GMP standards and regulatory requirements related to process validations are adhered to in projects
- Participate in or moderate cross-functional Risk Assessments to define the scope of validation/ study activities
- Assess validation data for conformance to protocol acceptance criteria and support the investigation and evaluation of deviations from the plans as well as the definition of associated corrective measures
- Issue, review or approve Standard Operating Procedures (SOPs) and project related documents
- Be involved as Subject Matter Expert in the execution of Discrepancy Records and Change Requests
- Represent the Quality Unit in cross-functional teams
- Assist the department in developing programs and SOPs to meet current industry standards, internal and external regulatory requirements
- Act as author of parts of Annual Product Quality Reviews
- Participate and support regulatory inspections and customer audits
- Supports cGMP training programs and train/ mentor junior Lonza employees to better accomplish and perform in their duties as quality professionals

Key requirements:

- Bachelor, Master degree or PhD in Chemistry, Biotechnology, Life Sciences or related field
- Significant experience in the GMP regulated pharmaceutical industry; preferable in a role within the Quality Unit
- Strong background in cGMP
- Broad knowledge in biotechnological manufacturing processes, validation approaches and risk management
- Sound experience in representing Quality and Compliance in projects
- 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 communications skills
- Excellent organizational skills
- Strong team orientation and solution- oriented way of working
- Fluency in English, 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.