Quality Assurance Manager Process Validation (CAPEX) (f/m/d) (80-100%)

Job Description Summary

Today, Lonza is a global leader in life sciences operating across three continents. 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 Visp, we are looking for an experienced quality leader (f/m/d) responsible for the QA Process Validation aspects of our CAPEX projects portfolio. As a member of the QA department, you will be responsible under the guidance of the QA lification / 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:

- Representing the Quality Unit in cross-functional teams and Participating in or moderation of cross-functional Risk Assessments to define the scope of validation/ study activities
- Being involved as Subject Matter Expert in the execution of Discrepancy Records and Change Requests
- Issuing process validation / study protocols and reports (incl. hold time studies and leachable & extractable studies) and ensuring that internal / external GMP standards and regulatory requirements related to process validations are adhered to in projects
- Assessing validation data for conformance to protocol acceptance criteria and supporting the investigation and evaluation of deviations from the plans as well as the definition of associated corrective measures
- Assisting the department in developing programs and SOPs to meet current industry standards, internal and external regulatory requirements
- Participating and support regulatory inspections and customer audits

Key requirements:

- Bachelor in Chemistry, Biotechnology, Life Sciences or related field
- Experience in project management, preferable in Quality and Compliance
- Significant experience in the GMP regulated pharmaceutical industry, preferable in a role within the Quality Unit would be an advantage
- Knowledge in biotechnological manufacturing processes, validation approaches and risk management would be an advantage
- Experience in interaction with different stakeholders within an organization and with regulatory agencies (Swissmedic, FDA etc.) would be an advantage
- Fluency in English, German 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.