Lonza

QA 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.

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 QA Manager Process Validation (CAPEX) (f/m/d). 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:

- Issuing process validation, studying protocols and reports (incl. hold time studies and leachable & extractable studies)
- Participation in / or moderation of cross-functional Risk Assessments to define the scope of validation / study activities
- 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
- Being involved as Subject Matter Expert in the execution of Discrepancy Records and Change Requests
- Representing the quality unit in cross-functional teams
- Assisting the department in developing programs and SOPs to meet current industry standards as well as internal and external regulatory requirements
- Participating and supporting regulatory inspections and customer audits

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
- Broad knowledge in biotechnological manufacturing processes, validation approaches and risk management
- Good communication skills and experience in interaction with all kind of interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.)
- Fluency in English, German would be an advantage

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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.