Senior Quality Assurance Specialist (f/m/d)

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.

Ibex® Solutions (www.ibex.lonza.com) is a modular build complex to develop and manufacture biological products. It enables companies to get access to a complete solution, gaining speed and achieving a simplified value chain.
The Ibex® Complex is our contribution to the medicine of tomorrow and possibly the next step in your career? Start your career with Lonza today. Apply as Quality Process Validation Manager.
As a member of the QA department, the QA Process Validation Manager is responsible under the guidance of the QA Validation Group Lead to design, plan and oversight process validation activities and studies intended to demonstrate the suitability and robustness of biotechnological manufacturing processes. Thereby, he/she ensures that these validations/studies meet the requirements of internal instructions, regulatory expectations and industry standards.

The QA Process Validation Manager works closely with other Quality experts as well as cross functionally with Development, MSAT and Manufacturing. In addition, he/she will act as key member in cross-functional technical project teams and will support the site as subject matter expert during inspections by authorities or customer audits.

Key accountabilities and duties

- Issues process validation/study protocols and reports (incl. hold time studies and leachable & extractable studies)
- Ensures that internal/external GMP standards and regulatory requirements related to process validations are adhered to in projects
- Participates in or moderates cross-functional Risk Assessments to define the scope of validation/study activities
- Assesses validation data for conformance to protocol acceptance criteria and supports the investigation and evaluation of deviations from the plans as well as the definition of associated corrective measures
- Issues, reviews or approves SOPs and project related documents
- Is involved as Subject Matter Expert in the execution of Discrepancy Records and Change Requests
- Acts as author of parts of Annual Product Quality Reviews
- Participates and supports regulatory inspections and customer audits
- Supports cGMP training programs

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Qualification and Skills required

- Bachelor, Master degree or PhD in chemistry, biotechnology, life science or related field.
- 3+ years of experience in the GMP regulated pharmaceutical industry; preferable in a role within the Quality Unit.
- Strong background in cGMPs
- 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.).
- Languages: English and German is 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.