Senior QA Specialist Automation/EBR/BRR

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.

In Visp we are looking for a QA Specialist Automation, EBR and Batch Record Review (f/m/d) (100 %) to build up our Vibe-X QA Operations team. You will report to a QA Vibe-X Operations team lead and work closely with various quality and operations functions to ensure the buildup and execution of cGMP compliant manufacturing and documentation processes in Vibe-X.

Responsible for the project specific QA work regarding GMP products manufactured in the Vibe-X area, in particular:

Key responsibilities:

- Partner with internal customer for quality topics linked to set-up eBR in the Vibe-X project.
- Checking and approval of master production records and electronic master batch records (EMBR); checking for consistency with approval documents, process descriptions, transfer documents, test plans, parameter lists, etc.
- Review of executed batch records within the defined timeline.
- Review of minor deviations, investigations and CAPAs within the defined due dates.
- Ensure that the batch records are closed and archived when all the activities batch related are completed.
- Contribute to the management and tracking of Key Performance Indicator (KPI) and Quality metrics and support QA department for internal and external meetings (batch tracker meetings, deviation review board, IPT, etc).
- Perform other duties as assigned.

Key Requirements:

- Bachelor or Master of Science in chemistry, biotechnology, life sciences or another related field is an advantage
- Experience in the GMP-regulated pharmaceutical/API industry
- Ability to recognize non-compliance and gaps in quality standards
- Structured, precise and well-organized work attitude; open-minded to new ideas and suggestions; agile, highly motivated and dynamic

Preference for a candidate that worked with electronic batch records (execution and/or review)

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.