



QA Specialist Batch Record Review - R60711

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.

The QA Specialist reports to the QA Automation Manager (Team Lead), under the organization of the QA Head of Large Scale Mammalian Business Unit. The QA specialist will be working in close collaboration with different quality and multiple operations functions in order to ensure cGMP-compliant manufacturing activities and documentation within IBEX®.

A well-organized, agile and eager individual with basic GMP knowledge who possess a professional fluency of English and at least a basic level of German completes the profile.

Key responsibilities:

- Review of the executed electronic batch records in MES Syncade.
- Involvement in MES Syncade Recipe change management.
- Collaborate with Operations team to clarify ambiguities in the executed batch records.
- Support in the management of Quality Records (CAPAs, Deviations/Investigations) for Batch Record review related observations.
- Write, revise and approve SOPs.
- Support in batch release by ensuring the completeness of the documentation package.
- Interacting with the customer in batch record review and automation related topics.
- Collect and evaluate KPI data on a regular basis.
- Contribute to a constantly evolving continuous improvement work culture.

Key requirements:

- Bachelor degree in Biology, Biotechnology, Life Science or similar educational background.
- Basic understanding of GMP and bioprocess manufacturing.
- Ability to identify non-compliance and gaps from quality standards.
- Language Skills: Professional Fluency in English and basic German proficiency (A2), or willing to learn.
- Structured, precise and well-organized working attitude; open-minded & pragmatic for new ideas and suggestions; agile, highly motivated and dynamic drive.

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.