Lonza

# Global Laboratory & PAT Systems Quality Lead

## 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 Laboratory & PAT Systems Quality Lead (f/m/d) will head the team responsible for quality and GxP compliance of global computerized systems in the areas of QC laboratories and process analytical technology areas. She/he will work hands-on in implementation projects, together with LIQ and project teams, to cover QA and compliance aspects of the systems involved, providing expert guidance and decisions to the implementation project teams. The incumbent will liaise between the QMS/LIQ leadership and QC/PAT-related projects and assume, together with the team, responsibility for a compliant QC/PAT systems landscape.

Key responsibilities:

- Lead the laboratory & PAT systems QA group as part of the global information quality organization.
- To drive and manage quality and GxP compliance of the global lab notebook, CDS, LIMS, and other systems in a GMP environment and coordinate development, projects, and changes to the systems, as well as defend the systems during regulatory inspections and customer audits
- Accompany PAT & laboratory implementation projects as project QA
- Ensure that changes to the systems are appropriately communicated, implemented, and trained.
- Drive training and standardization efforts across the Lonza QC organization with respect to the relevant systems
- Drive further development and deployment of the systems to other sites as an active member of the project teams

Key requirements:

- Master, Bachelor or equivalent qualification in Computer Science and/or vocational experience in Computer System Validation and Quality Assurance.
- Experience with participation in validation projects relating to GMP processes and computer systems projects
- Expertise in laboratory computer system environments, quality requirements and their application to GMP processes focusing on QC, analytical development, and process analytical technology.
- Knowledge of GMP documentation requirements for the validation of computer systems in the pharmaceutical industry
- Project experience and a strong quality mindset
- Good interpersonal skills and ability to interact positively with all functions in a complex project organization
- Strong verbal and written communication skills with well-structured communication

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.