

## Senior QA Specialist Qualification

## **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.

- Representative of QA Qualification in the project organization for new facilities or other projects in regard to qualification of facilities, utilities, equipment and systems
- Coordinating different QA interests during the project phase e.g. process, cleaning or other relevant QA objectives
- Driving implementation of new qualification strategy and being a strong decision maker when needed
- Compiling, reviewing and releasing Qualification Documents (URS, Qualification Plan & Report, DQ/IQ/OQ/PQ Reports and more) as also supporting and approving quality risk analysis (e.g. FMEA)
- Performing assessments and approvals of technical changes requests during the different phases of a project and lifecycle and their relevance to the qualification of facilities, equipment, utilities and systems
- · Representing qualification topics during customer audits and regulatory inspections
- Being responsible to drive CAPA and Effectiveness Checks items to completion and timely closing as well ensuring deviations are appropriately investigated and recorded in Deviation Reports

## Key requirements:

- · Master/Bachelor degree in Engineering, Chemistry, Biotechnology or a related field
- Significant experience in the pharmaceutical industry, ideally in a QA role would be an advantage
- · Good understanding of the applicable cGMP regulations would be an advantage
- · General knowledge of engineering and manufacturing processes
- · Ability to oversee project execution to identify non-compliance from quality standards
- Fluent language skills in German and English is required

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.