# QA for QC Manager

## 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.

This is an exciting role in a state-of-the-art Biologics Drug Substance production facility, entering into commercial phase, where all QC testing is outsourced to external vendors. It is a great opportunity to expand and develop external vendor management and internal/external stakeholder management skills. The role is in a business that is growing and which is a key strategic site for internal and external stakeholders.

Key responsibilities:

- Is involved as QC subject matter expert with internal and external stakeholders, in relation to technical transfers and ongoing manufacture, including definition of specifications for raw materials, In-process samples and Biologic Drug Substance, reviewing and approving these documents.
- Reviews and approves SOPs, analytical methods, sampling protocols, and method validation plans/reports issued by the QC department. Assessing OOX events, reviewing the associated raw data and investigations/deviations, creating/assessing CAPA and performing effectiveness checks.
- Ensures that the change management process for evaluating new or revised analytical methods and specifications is applied and that required associated validation or qualification activities are defined and carried out.
- Performs internal and external audits. Supports and participates in customer audits and health authority inspections.

Key requirements:

- Bachelor, Master's degree or PhD in chemistry, biotechnology, life science or related field.
- At least 5 years of experience in the pharmaceutical industry, preferably in a QC or QA function with experience in QC Analytical method transfer and validation. With a strong background in cGMP regulations, incl. USP, European and Japanese Pharmacopoeia.
- Internal Auditing experience and experience in the interaction with health authorities (FDA, Swissmedic, etc.).
- Resilient, Solution-oriented and strongly team-minded.
- Structured, focused and well-organized working attitude; open-minded for new ideas and suggestions; agile, highly motivated and dynamic drive.
- Excellent verbal and written English skills, German language knowledge advantageous.

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.