Lonza

Senior QA Specialist, Analytics (f/m/d)

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.

As a Senior Quality Assurance (QA) Specialist for Analytics, you will ensure the Quality oversight on GMP-relevant activities carried out by the Quality Control and Analytical Development (AD) departments, also for externally formulated drugs (external DP final samples). This includes the review and approval of SOPs, analytical methods/specifications and validation plans/reports assuring their compliance to Lonza's standards, customer's requirements and health authority expectations (Pharmacopoeias). Moreover, as a Quality and Compliance representative, you are a key member of cross-functional project teams, e.g. for process transfers and new product introductions.

Key responsibilities:

- Represents the QA concerns to the Quality Control (QC) department and ensures that GMP requirements are met and SOPs are followed.
- Control and release of GMP relevant documents of the QC
- Review and approval of SOPs, analytical test methods, method transfer protocols/reports and method validation protocols/reports, and OOx iLab investigation issued by the QC/AD departments.
- QA supervision for OOXs events during investigation in QC/AD: Review and approve Out-of-Specifications/-Expectations/-Trend results
- Write or revise SOPs in your area of expertise and be the owner of these documents.
- Ensures compliance with GMP in the areas of stability testing and reference standards
- Cooperation, review and approval of deviations (DRs), Investigations (INV), changes (CRs) and CAPAs within analytics (QC)
- Support inspection/audit
- Ensure compliance of Lonza QC test methods with Pharmacopoeias where applicable.

Key requirements:

- Bachelor's or Master's degree in chemistry, biotechnology, life science or a related field
- Significant experience in the pharmaceutical industry; preferably in a QC or QA function
- Founded analytical expertise and experience with analytical method validation
- Strong background in cGMP regulations; including. USP, European and Japanese Pharmacopoeia
- Auditing experience and experience in interaction with health authorities (FDA, Swissmedic, etc.)
- Excellent verbal and written communication in English. German language knowledge is 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.