Lonza

Senior QA Specialist 2, 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.

For our QA Analytics Team we are currently looking for a dedicated person who would like to work as a Senior QA Specialist, Analytics (f/m/d) in a fast growing and innovative environment. 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. 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. 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 :

- Representing the QA concerns to the Quality Control (QC) department and ensuring that cGMP requirements are met, as well as 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, 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 area of expertise and ownership of these documents
- Ensuring compliance with cGMP 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)
- Participating in customer Audits and Inspections

Key requirements:

- Bachelor or Master degree in chemistry, biotechnology, life science or 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; incl. USP, European and Japanese Pharmacopoeia
- Auditing experience and experienced in the 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.