Project Manager Quality Assurance

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.

We are looking for an established and experienced professional working as an indirect leader and within the QA project team. The Project Manager Quality Assurance specifies quality requirements for manufacturing processes and ensures that manufactured products comply with national and international requirements and cGMP standards over their entire life cycle. By acting as an objective source of independent advice the Project Manager Quality Assurance protects the organization's reputation in regard of product safety, product quality & cGMP compliance.

Key responsibilities:

- Representing the department Quality Assurance in cross-functional teams and ensuring and managing interfaces to different internal and external stakeholder
- Assesses, reviews and approves quality records such as deviations, change controls, CAPAs, investigations, effectiveness checks, and extensions in line with valid SOPs
- Authors, reviews and approves GMP-relevant documents and SOPs in the ownership of QA
- Supports and participates in internal, customer and regulatory audits
- Support customer communications, manage interactions in case of changes, deviations, out of specifications etc.
- Review and approval of executed batch records, prepares batch release package for the Responsible Person / FvP, including recommendation on disposition status
- Review and approval Master Batch Records
- Support continuous improvements programs to establish effective Quality Management Systems

Key requirements:

- Bachelor or Master Degree in life sciences (e.g. chemistry, biotechnology, pharmacy or a related field)
- Significant work experience in the GMP-regulated industry; preferably in the following units: Production, QC or QA
- Broad knowledge in Quality standards (e.g. ICH Q7, 21 CFR Part 11)
- Availability to occasionally provide quality support outside of working hours
- English and German language skills (written and spoken) are 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.