Quality Assurance Manager Operations Drug Substance

Job Description Summary

Today Lonza is a global leader in life sciences. We are more than 15,000 employees in more than 100 locations around the world. 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 have recently been confirmed as the global manufacturing partner for Moderna's vaccine against the novel coronavirus, providing a tenfold manufacturing capacity increase. As other businesses face increasing economic uncertainty, we are fortunate to have opportunities for expansion. Through this new collaboration, our work will have a significant, direct and long-term impact on the management of this global pandemic.

Key responsibilities:

- Be involved in all facility start-up activities as well as process transfers
- Responsible for defining the bill of material and be involved in all activities required to qualify raw materials
- Facilitate discussions within internal cross-functional teams such as MSAT (Manufacturing Science & Technology), Manufacturing and Quality Control
- Review and approve manufacturing recipes
- Perform batch record reviews in the Manufacturing Execution System
- Review and approve Discrepancy Records and Change Requests
- Support the definition of preventive and corrective measures (CAPAs), approve them and track their timely implementation and effectiveness
- Release Drug Substance batches
- Review and approve SOPs and project related documents; support and approve quality risk analysis (e.g. FMEA)
- Write or revise SOPs in your area of expertise
- Support cGMP training programs to ensure staff is trained
- Be involved in customer audits as well as in regulatory inspections and support all activities to ensure inspection readiness of the department
- Actively support the Quality culture as a role model

Key requirements:

- Bachelor in Biotechnology, Biology, Chemistry or other natural science; Master or PhD would be preferred
- Profound working experience in the area of biopharmaceutical manufacturing
- Knowledge of biotechnological manufacturing processes (especially microbiological biotech processes) as well as in cGMP
- Good communication skills
- Strong team orientation
- Structured, focused and well-organized working attitude, solution-oriented
- Open-minded for new ideas and suggestions
- Fluency in English, German would be an advantage

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.