QA Manager Microbial Control & Sterility Strategy

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.

The QA Manager for Microbial Control & Sterility Strategy directly reports to the QA Team Lead DP IBEX, works in close collaboration with Drug Product Manufacturing, members of the Manufacturing Science and Technology department, Quality Control as well as with Global Functions within Lonza's global network. He/she ensures that cGMP regulations, Lonza's internal standards and customer expectations with regards to contamination prevention strategies are fulfilled and the respective measures and controls defined and realized. As a Quality representative at our site in Visp , you are an important member of the cross-functional technical project team.

Key responsibilities:

- Ensures that an end-to-end microbial control concept is developed for Drug Product manufacturing (aseptic filling) manufacturing facilities and is captured in local documents (incl. specifications, SOPs, etc.)
- Define Drug Product manufacturing (aseptic filling) sterility strategy reflecting this strategy in written rationales and SOPs
- Support investigations and approve deviations related to microbiology and sterility assurance e.g. EM , Sterility failure or Media-fill failure.
- Reviews and approves SOPs, deviation reports and change requests associated with Sterility Assurance and microbiological control.
- Supports the preparation and follow-up of customer audits and regulatory inspections; acts as an expert during audits / inspections presenting aspects related to the microbial control and sterility strategies

Key requirements:

- List key requirements here.
- Bachelor, Master Degree or PhD in Microbiology or other Biosciences.
- Vast experience in the area of biopharmaceutical manufacturing
- Broad knowledge related to hygiene topics, environmental monitoring, disinfectant testing, microbial control/sterility strategies
- Good communication skills and interaction with all kind of interfaces within the organization and with regulatory agencies (e.g. US FDA, EMA, etc.).
- Sound experience in representing Quality and Compliance in projects.
- Excellent knowledge of written and spoken English; good German skills 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.