

Lonza

QA Manager Microbial Control & Sterility Strategy (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.

The QA Manager for Microbial Control & Sterility Strategy (f/m/d) 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:

- Ensuring an end-to-end microbial control concept is developed for Drug Product manufacturing (aseptic filling) facilities and is captured in local documents (incl. specifications, SOPs, etc.)
- Defining a Drug Product manufacturing (aseptic filling) sterility strategy and reflecting this strategy in written rationales and SOPs
- Supporting investigations and approving deviations related to microbiology and sterility assurance e.g. EM (Sterility failure or Media-fill failure).
- Reviewing and approving SOPs, deviation reports and change requests associated with Sterility Assurance and microbiological control.
- Supporting the preparation and follow-up of customer audits and regulatory inspections
- The position includes a management responsibility for a team of 5 – 8 direct reports

Key requirements:

- Bachelor Degree, 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 and 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.