

## QA Contamination Prevention Manager (f/m/d)

## **Job Description Summary**

This role is based in BioAtrium, which is a joint venture and part of Ibex® Solutions (<a href="www.ibex.lonza.com">www.ibex.lonza.com</a>). Ibex® is a modular build complex to develop and manufacture biological products. It enables companies to get access to a complete solution, gaining speed and achieving a simplified value chain. The Ibex® Complex is our contribution to the medicine of tomorrow and possibly the next step in your career? Start your career with Lonza today. Apply as QA Contamination Prevention Manager (f/m/d)!

## Key responsibilities:

- Ensuring the development of an end-to-end microbial control concept for the biotechnological drug substance manufacturing facilities and capturing it in local documents (incl. specifications, SOPs, etc.)
- Ensure that practices within the manufacturing facility are compliant and support microbiological control of the product
- · Ensuring a robust contamination control strategy is in place
- Supporting the Quality Oversight on activities of Environmental Monitoring and activities related to the assessment of disinfectants from microbiological expertise point of view
- Writing, Reviewing and approving SOPs, deviation reports and change requests, associated with the above-mentioned topics
- · Supporting the preparation and follow-up of customer audits and regulatory inspections
- Acting as an expert during audits / inspections, presenting aspects related to the microbial control and sterility strategies
- Enhancing the quality knowledge by following the quality standards and by visiting specific training courses / conferences

## Key requirements:

- University degree (Bachelor, Master or PhD) in pharmacy, engineering, natural science, or related life sciences discipline - preferably microbiology
- Substantial experience in the area of biopharmaceutical manufacturing and a strong background in cGMP
- Broad knowledge related to hygiene topics, environmental monitoring, disinfectant testing and microbial control strategies
- · Previous Contamination Control experience, would be an advantage
- Good communication skills and interaction with all kind of interfaces within the organization and regulatory agencies (e.g. US FDA, EMA, etc.)
- Working knowledge with MS Office, Excel, data trend creation/analysis, TrackWise®, LIMS and SAP is an advantage
- · Fluent in English, German is 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.