Lonza

Manager, QA, Contamination Control - Utilities and Cleanrooms

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.

Our site in Visp, Switzerland is growing and for the Quality Systems & Services Organization, we are currently looking for a Manager, QA, Contamination Prevention & Control (Pharmaceutical Microbiologist) - Clean Utilities Focus. The successful candidate will support the end-to-end contamination control strategies within our Biologics Business Units.

Key responsibilities:

- Design robust strategies for the design, sanitization, maintenance, and routine monitoring of clean utilities for pharmaceutical use. Ensure these utilities consistently meet their intended use criteria.
- Responsible for the microbiological quality and compliance of utility systems used in the production
 of biopharmaceuticals, ensuring all microbiological testing and monitoring activities related to utility
 systems comply with applicable regulatory requirements, including FDA, EMA, and other international
 regulatory standards.
- Conduct risk assessments to identify microbiological risks associated with utility systems and develop mitigation strategies to prevent contamination of biopharmaceuticals.
- Analyze microbiological data from utility systems, identify trends, risks, and gaps, and lead a team of
 experts to define proper mitigations.
- Provide QA oversight for utility sanitization processes, ensuring compliance with internal and external
 regulatory standards, and contribute to the site's contamination control strategy for continuous
 improvement.
- Collaborate with cross-functional teams to integrate contamination prevention and control measures for connecting utilities to process equipment.
- Conduct thorough investigations into contamination incidents and OOS (Out Of Specification) results, guiding the response to deviations and defining effective CAPAs (Corrective and Preventive Actions).
- Serve as a Clean Utilities subject matter expert during regulatory inspections and customer audits, representing the site's contamination control strategies

Key requirements:

- · Bachelor's degree in a relevant scientific discipline (preferably in microbiology).
- Substantial GMP experience in the biologics industry, with direct QA or directly relevant QC Microbiology experience.
- · Strong knowledge of contamination control principles, practices, and regulations (e.g. FDA, EMA).
- Working knowledge of microbiological testing methods, media challenges, environmental monitoring, clean room qualification and management, and microbiological control strategy required
- Excellent written and oral communication to include accurate and legible documentation skills; ability to work in a fast-paced environment; team oriented; independent work skills and a strong work ethic.
- Strong problem-solving mindset and decision-making skills.
- Strong sense of ownership and the ability to prioritize based on business needs is a must.
- Fluency in English, able to communicate in or willing to learn German.

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.