QA Manager Qualification, Validation and EM (Environmental Monitoring) (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.

For Ibex® Solutions (www.ibex.lonza.com), our recently launched unique biological manufacturing and development concept in Visp, Switzerland, we have multiple openings. Become part of this exciting opportunity and join our team by applying for the position as QA Manager Qualification/Validation/EM (Environmental Monitoring) for Ibex®.

The QA Manager Qualification/Validation/EM is ensuring that all processes for facility, equipment, utilities and systems qualification/validation comply with cGMP requirements and internal/external quality standards over the entire life cycle. As a Quality and Compliance representative, he/she will be a key member in cross-functional technical project teams.

Key responsibilities:

- Own all Quality and Compliance related responsibilities for the qualification, validation and routine monitoring of the facility, utilities and systems
- Coordinate Quality and Compliance objectives during the different project phases (e.g. zone concept, process, cleaning, Environmental Monitoring (EM), etc.)
- Identify emerging QA relevant topics, communicate to the Ibex™ QA organization (e.g. new technologies) and work actively on their development into new or already established Quality and Compliance strategies and/or standards
- Review and approve Qualification Documents (e.g. Operational Qualification (OQ)/ Performance Qualification (PQ) Plan and Reports, etc.)
- Review and approve technical change requests during the different phases of a project and assess their relevance to the qualification of the facility, utilities and systems and ensure investigations and deviations are appropriately investigated and documented
- Responsible to drive CAPA (Corrective And Preventive Actions) and Effectiveness Check items to completion and timely closure
- Represent EM topics during internal/customer audits and regulatory inspections
- Write or revise SOPs in your area of SME and act as owner of such documents

Key requirements:

- Bachelor, Master Degree or PhD in Biotechnology, Pharmacy, Microbiology, Chemistry, Engineering, or related field
- Significant experience in the area of biopharmaceutical manufacturing in an EM function as well as strong background in cGMPs
- Broad knowledge of engineering and manufacturing processes
- Good communication skills and interaction with all kind of interfaces within the organization and with Health Authorities (Swissmedic, FDA etc.)
- Sound experience in representing Quality and Compliance in projects
- Strong team orientation
- Fluency in English, German would be an asset

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.