Director Global Quality Compliance (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 role Director Global Quality Compliance (f/m/d) supports the overall Lonza strategy to gain and maintain the license to operate. This is achieved by lowering the quality and compliance risk through audits, advising the sites to reach an optimum state of compliance. Develop, plan and execute a program of corporate GMP compliance audits/assessments for Lonza's manufacturing sites and operations with a focus on sterile and non-sterile drug products (including solid dosage forms, biologics, cell/gene therapy), biological and chemical APIs, medical devices and excipients. This also covers food, feed and dietary supplements and sites involved in software and hardware manufacture. The Director Global Quality Compliance will also act as Single Point of Contact / SPOC for assigned suppliers from a global portfolio. Ensure the uninterrupted supply of materials and services to Lonza by assessing the quality of the Suppliers and their ability to meet defined requirements utilizing tools such as Quality Risk Management (QRM), supplier assessment/audit, change management, and complaint/deviation trend management.

Key responsibilities:

- Develop audit agendas based on risk assessment principles drawing on previous audits, current regulatory trends, applicable regulations, any imminent customer submissions and stakeholder input
- Produce timely, detailed and technically correct reports following assessments/audits with appropriate references cited against each observation
- Escalate identified deficiencies and compliance risks to appropriate business, operations and quality heads and, if appropriate, feed into the Operations team for inclusion into Gap Analysis
- Advise and support the sites in devising and executing remediation actions to ensure compliance to regulatory and Lonza expectations and requirements
- Approve proposed CAPA/ remediation plans, regularly review progress & effectiveness, and continue to give support in all compliance matters
- Complete and maintain the corporate internal audit/assessment documentation and follow-up/tracking system where applicable
- Perform Supplier Quality assessments/ audits of critical Suppliers and Contractors to annual plan and follow up on agreed upon CAPAs.

Key requirements:

- University/academy degree in Biochemistry, Chemistry, Pharmacy, Microbiology, Biotechnology or equivalent
- Extensive auditing experience in GMP regulated environments, with experience specifically in some/all of:-cell and gene therapy, aseptic product, biologics and medical device manufacture
- Experience health authority FDA, SwissM; experience from inspectorate role (FDA, EMA...) is an advantage
- Experience in Supplier Qualification and Supplier Monitoring
- Strong understanding of risk assessment and risk management fundamentals/tools
- Excellent English skills, both written and spoken; German knowledge is a great advantage

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.