QA Senior CSV Compliance Lead (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.

In order to support the strategic growth investment of the company in Visp, Switzerland, we are looking for an experienced quality leader responsible for the CSV aspects of our CAPEX projects portfolio.

The Senior CSV Compliance Lead takes a great responsibility at our site in Visp, Switzerland. Visp is known as the sun center of Switzerland and is located in the Swiss Alps. Working in this extraordinary environment the Senior CSV Compliance Lead supports groups comprised of plant engineering, manufacturing management, quality assurance ant IT. The individual also functions as backup to the team lead.

Key responsibilities:

- Owning all quality related responsibilities for the Computerized System Validation (CSV): activities of dedicated new facilities, equipment and utilities related to the GMP manufacturing of biologics & APIs
- Representing the quality department in the CAPEX project organization in regards to CSV
- Being the backup of the team lead and taking over following responsibilities such as representing the team towards different stakeholders (manufacturing management, QA, QC, and IT)
- Reviewing and releasing CSV documents and SOPs
- Being a Subject Matter Expert (SME) and providing guidance and recommendations to internal or external customers

Key requirements:

- Bachelor or Master Degree in life science or computer science
- Several years of experience in Quality Assurance with main focus on CSV, automation and IT-compliance
- Significant experience in the GMP regulated pharmaceutical industry; preferable in a role within a Quality Unit
- Broad knowledge in CSV, Data Integrity and related guidelines (21 CFR Part 11, EU GMP Annex 11, GAMP5 and the underlying principles of each)
- Experience in interaction with all kind of interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.)
- Working knowledge within electronic document management systems
- Fluency in English, German would be 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.