Lonza

Functional Specialist

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.

Lonza in Visp is looking for a Commissioning, Qualification and Validation (CQV) Functional Expert.

Key responsibilities:

- Responsible to apply/implement Commissioning, Qualification and Validation (CQV) approach, standardized CQV procedures and provide oversight on CQV activities of Lonza's CAPEX projects at a SGIE project level.
- Responsible for ensuring that SGIE projects are compliant with the global CQV guidelines, aligned with local/site level procedures and detect/resolve potential gaps in line with Lonza's continuous improvement vision.
- Provide leadership of CQV activities at a project level, acting as subject matter expert (SME) for any and all CQV activities. Support the SGIE project teams in business-related quality and compliance topics, including project risk analysis.
- Leverage work being done at global level, to engage specialized companies for CQV activities to support SGIE CAPEX projects.
- Apply applicable, globally developed Framework Agreements with local or global partners to assure adequate staffing, enhance efficiency, and reduce operational costs of CQV activities.
- Ensure CQV activity compliance with all pertinent safety policies, rules and regulations.

Key requirements:

- Solid experience in Commissioning, Qualification and Validation incl. CSV with good experience in management of pharmaceutical projects. Familiarity with biologics (mammalian, CGT) as well as chemical manufacturing technologies desirable
- Profound experience in regulated pharmaceutical industry and/or engineering company
- Knowledge of ISPE guidelines with proven experience on projects. Proven experience in an EMA / FDA regulated environmental with good knowledge of current ICH, PIC/S, EU and US regulatory requirements and their implementation.
- Experience in People Management (internal and external) with respect to organizational aspects, coaching and project management
- Language: Good command of English and proven knowledge in German necessary

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.