

QA Expert - Project Delivery (CAPEX) - R61360

Job Description Summary

Senior QA Specialist (Hybrid) - Qualification Utilities

Location: VISP

Hybrid Working Model (3 days in the office, 2 days WFH)

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:

To support the strategic growth investment of the company in Visp, Switzerland, we are looking for an experienced quality leader responsible for the **equipment & facilities qualification** aspects of our CAPEX projects portfolio, with focus on utilities.

Key responsibilities:

- Owns all quality related responsibilities for the commissioning and qualification (C&Q)) activities of dedicated new facilities, equipment and utilities (main focus) related to the GMP manufacturing of biologics & APIs.
- Representative of Quality in the CAPEX project organization in regard to qualification of facilities, utilities, equipment and systems (incl. computerized systems).
- · Reviews and releases of qualification documents and SOPs.
- Be a Subject Matter Expert (SME) and provides guidance and recommendations to internal or external customers.
- Participate in developing action plans to correct deficiencies to ensure the adequate microbiological quality of the lab facilities, utilities, and procedures.

Key requirements

- Bachelor, Master's degree or PhD in biotechnology, chemistry, life science or related field
- Significant experience in the GMP regulated pharmaceutical industry; preferable in a role within a
 Quality Unit.
- · Strong background in cGMP.
- Broad knowledge in qualification of equipment, facilities, utilities (biopharmaceuticals & APIs) and related Guidelines (e.g. ASTM, ISPE, GAMP).
- Experience interacting with various interfaces within the organization and with regulatory agencies (Swissmedic, FDA etc.).
- · 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.