Lonza

Engineer Chemistry, Biotechnology as QA Manager Qualification - cGMP (m/f/d)

Lonza AG Visp

Lonza is one of the world's leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets. We harness science and technology to create products that support safer and healthier living and that enhance the overall quality of life.

Not only are we a custom manufacturer and developer, Lonza also offers services and products ranging from active pharmaceutical ingredients and stem-cell therapies to drinking water sanitizers, from the vitamin B compounds and organic personal care ingredients to agricultural products, and from industrial preservatives to microbial control solutions that combat dangerous viruses, bacteria and other pathogens.

Further information can be found at www.lonza.com.

QA Manager Qualification

- CH – Visp

At Lonza, we invest in great people. We encourage our employees to challenge themselves and we offer an environment that fosters creativity and success. Headquartered in Basel, Switzerland, we operate production, R&D, and business sites around the world, including Europe, North America, and Asia.

***Our vision**: We strive to be the leading supplier using science and technology to improve the quality of life.*
***Our mission**: We work with passion, using advanced technologies, to transform life science into new possibilities for our customers.*

Do you want to help us as we shape the future of this great organization?

Job Description Summary

Key accountabilities

Owns all quality related responsibilities for the daily qualification activities of facilities, equipment, utilities and systems (incl. CSV) related to the cGMP manufacture of pharmaceutical products

- Representative of QA Qualification in project organization for new facilities, extensions or other projects in regards to qualification of facilities, utilities, equipment and systems
- Coordinate the different QA interests e.g. process, cleaning or other relevant QA objectives
- Identify new QA relevant topics e.g. as part of project of new technologies and work actively on their development into new or already established QA strategies or standards
- Act as decision-maker if new or changed QA strategies or standards are identified e.g. during the Engineering-Phase of a project and/or after the facilities, equipment and utilities are given into operation
- Support the transfer from the project into production phase and support the takeover of QA Operation
- Compiles, reviews and releases Qualification Documents (URS, Qualification Plan & Report, DQ/IQ/OQ/PQ Reports, etc.)
- Representative of QA Qualification during FAT's and attend Supplier Qualification Audits as SME (willingness to travel required)
- Performs assessments and approvals of technical changes requests and their relevance to the qualification of facilities, equipment, utilities and systems
- Supports and approves quality risk analysis (e.g. FMEA)
- Responsible to drive CAPA and Effectiveness Checks items to completion and timely closing
- Writes of revises SOPs in his area and ensures that documents are correct and adhere to SOPs and future customer's requirement
- Represents specific areas as Subject Matter Expert (SME) and provides guidance's and recommendations in these areas to internal or external customers

Qualifications and skills required

- Bachelor's or Master's degree in Engineering, Chemistry, Biotechnology, or related field
- Min. 5 years of experience in the pharmaceutical industry, ideally in a QA role
- Good understanding of the applicable cGMP regulations as well as general knowledge of engineering and manufacturing processes
- Auditing experience is an asset
- Excellent verbal, written and interpersonal communications skills in German and English
- Strong problem-solving and attention to quality is a must
- Requires independent decision making regarding quality and compliance
- Ability to work in partnership as an active member of a team and/or cross functional working groups
- Ability to prioritize and manage work to critical project timelines in a fast-paced environment
- Provide exceptional customer service by developing excellent working relationships with clients both external and internal

Lonza. The place to Go, Stay and Grow.

Vollzeit, Festanstellung Fachkraft Aktualisiert am 04.10.2019