Group Leader QA Qualification

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

The Group Leader QA Qualification is responsible for managing the Quality Assurance (QA) qualification group which includes the QA monitoring group. Together this group is responsible for ensuring that all GMP plants, facilities and utilities are qualified to current GMP standards. The Group Leader is responsible for personnel management of this group, for providing expert support and guidance and for ensuring that the appropriate level of service is provided to Operations. In addition the Group Leader is a member of the QA management team and thus responsible for maintaining and improving GMP systems and compliance on the Visp site.

Job Description

Management of qualification and monitoring activities in GMP areas

- Maintenance and improvement of the existing systems to ensure lean, effective systems
- Works with other departments to reinforce and embed a culture of quality and ensuring compliance with current GMP and ISO regulations
- Identifies any areas of compliance vulnerability end ensures preparedness for inspections within the field of responsibility
- Preparation, review and approval of relevant VMPs, SOPs and other qualification documents
- Ensuring that deviations are adequately investigated and documented and QA approval of major deviations in qualification/EM
- Ensuring that qualification and monitoring activities are professionally and competently presented in audits and inspections
- Provide guidance on the scope and depth of qualification activities to project teams

Management of resources

- Prioritizing projects and providing support for all qualification activities in GMP areas
- Establishing productive working relationships and technical support for other QA groups
- Ensuring that all monitoring is performed according to plan
- Ensuring that adequate resources are available to support major projects
- Ensuring that reports are written and approved on time

Oversight of technical changes

- Oversight and maintenance of system for technical changes in SAP
- Ensuring GMP compliance for technical changes
- Ensuring timely and appropriate communication between qualification and operations groups regarding technical changes

Education

Doktorat: Biotechnologie, Doktorat: Chemie, Master: Biotechnologie, Master: Chemie

Work Experience

Quality (Advanced)

Skills

Experience in engineering/operations is a plus., Good knowledge and understanding of all technical aspects of manufacturing plants., Good understanding of GMP and GMP-compliant systems., Personnel management (leadership, priority setting, timely decision making etc.), ability to motivate, develop and inspire his/her team members, talent development, ability to work in multi-functional teams, ability to explain and present complex systems in audits and inspections, innovative, able to work to timelines under pressure, good communication skills., Preferably at least 5 years' experience in the pharmaceutical, biotechnology or related industry with significant exposure to GMP or closely related environment.

Language(s)

Deutsch, Englisch