

Senior QC Specialist - ChemOps

Job ID
REQ-10024312
Jan 20, 2025
Switzerland

Summary

As a Senior QC Specialist in the QC Services team of ChemOps CH you will oversee all tasks associated with the qualification of laboratory equipment. You will also be responsible for topic related to data integrity and CSV, as well as consulting with the laboratory personnel, IT and QA for the continuous improvement of the laboratory processes involving instruments and electronic data.

About the Role

Major accountabilities:

- Qualification activities for laboratory equipment, from simple instruments to computerized systems.
- Change Management for laboratory equipment.
- Interfacing with laboratory and QA for equipment related issues/inquiries.
- Interfacing with IT for definition of firewall rules, operating systems and software permissions, etc.
- Technical audit trail review.
- Management of local projects, as well as leading local rollout of global projects related to QC equipment.
- Archival of systems as virtual machines and periodic testing
- Management of the inventory in SAP
- Involvement in assessments and investigations
- Update of procedures and forms.
- Assessment of pharmacopeias general chapters
- Participation to health authorities and customer audits as SME

Key performance indicators:

- Timely handling of deviations and other quality relevant tasks.
- Timely update of SOPs.
- Timely execution of trainings.
- Qualification of laboratory equipment according to plan defined with the stakeholders.
- No avoidable safety incidents.
- Project delivered according to predefined quality, scope, costs, and schedule.

Minimum Requirements:

Work Experience:

- Proven experience in the qualification and operation of computerized and non-computerized laboratory equipment under GMP.
- Good knowledge of analytical techniques.

- Being able to effectively communicate at a technical level with both laboratory and IT.
- Good IT knowledge (Windows permissions, active directory, networks, VMware virtual machines).
- Knowledge of CDS / LIMS
- Very good knowledge of GMP, GAMP and data integrity principles.

Skills:

- Be open to continuous learning.
- Proactive thinking and decision making.
- At least 5 y experience in GMP environment.
- Knowledge of laboratory equipment and operations in a laboratory.
- Smart risk taking.

Languages :

- English: very good in speaking and writing.
- German: very good in speaking and writing.

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