

QMS responsibilities

Auditing Platform

QMS responsibilities

Why is the delegation of QMS responsibilities needed?

- ensure effective implementation and maintenance of a process-oriented and risk-based QMS within the CTU.
- provide dedicated oversight and supervision of QMS processes.
- facilitate planning and continuous improvement.
- ensure adherence to applicable standards.
- enhance overall QMS effectiveness.
- establish clear accountability, promote transparency and alignment with organizational goals.

Audit observations: What was missing?

The audit identified a lack of evidence demonstrating the delegation of responsibility and authority over the QMS to an experienced individual, such as a quality manager or quality assurance manager. This delegation was not adequately described and lacked proper documentation, for example in a job description.

Recommendations:

- Ensure alignment of the job description (JD) of the QMS responsible person with GGOP requirements
- Align the respective section in the Quality Manual or relevant SOP to clarify the respective QMS responsibilities outlined in the JD and the delegation of those tasks