# 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 organisational 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