Lack of document management process

Auditing Platform

Lack of document management process

Why is the description of processes needed?

- Ensure effective document management within the organisation.
- Provide clear guidelines and instructions for creating, maintaining, approving, and controlling documents.
- Help establish consistency and compliance with regulations and quality standards.

Audit observations: What was missing?

- The review of SOPs and the CTU Organigram revealed deficiencies in document control processes.
- Lack of unique identification for documents and absence of version control.
- Failure to cover all aspects of document management, as required by GGOP.

Recommendations:

- Revise SOP scope of the “SOP on SOPs”/”SOP on QMS document management” to include process descriptions and responsibilities for the development, maintenance, approval and control of CTU controlled documents
- Expand the SOP to describe the process for all controlled documents of the CTU QMS, not only SOPs
- Include details on periodic review, training requirements (document approval, training, document validity) and version control
- Ensure consistent document identification and versioning. Assign unique document IDs (i.e. SOP-01), which remains the same, regardless of version change