Lack of document management process

Auditing Platform

17.10.2024

Why is the description of processes needed?

- ensure effective document management within the organization.
- 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