Periodic review and revision process

Auditing Platform

Periodic review and revision process

Why is the definition of the life cycle of QMS documents needed

- Establish clear procedures for document creation, approval, review, and archiving.
- Ensure document integrity, reliability, and compliance throughout their lifecycle.
- Facilitate standardized document management processes within the CTU.
- Align periodic review cycle with industry/ GCP best practices, typically within at least a 3-year timeframe.

Audit observations: What was missing?

Periodic review cycle for documents was too long (5 years) and not aligned with GCP best practices.

Recommendations:

- Amend SOP to reflect a periodic review cycle of at least every 3 years.
- Implement standardised procedures for document management, including document identification and approval.
- Implement also standardised procedures that define the
    - editing rights for document revision.
    - training period for the revised document to ensure proper understanding of the changes.
    - appropriate individuals are informed about the new document version and receive the necessary training.