SCTO PLATFORMS

CAPA Management / Non-conformities

Auditing Platform

17.10.2024

Why is a formal CAPA management process needed?

- To allow to formal control over all occurring issues and to prevent their re-occurrence

Audit observations: What was missing?

- Absence of a formal/clear process for the management of non-conformities and for capturing CAPAs (corrective and preventive measures)
- no CAPAs are assigned and followed up or process description lacks clarity
- Limited assessment and implementation of preventive actions (lack of effectiveness check).

Recommendations:

- write a procedure that defines the documentation and handling of non-conformities, the respective responsibilities
- define how root cause analyses are conducted to ensure that adequate corrective as well as preventive measures are taken to eliminate and prevent the errors in the future.
- formalize a process including:
    - The documentation and management of non-conformities and potential non-conformities
    - Determining causes for (potential) non-conformities (root cause analysis)
    - A risk analysis, assessing the impact of the non-conformity and justifying the defined measures (e.g. in case of minor non-conformities evaluating the need for corrective and preventive actions)
    - The relevance for the affected, general processes (system level)
    - The definition of corrective and preventive measures; the respective responsible person(s); the required timelines for measure completion (due dates)
    - The follow-up of measure completion
    - The effectiveness of the defined measures (follow-up observation), if necessary
    - Definition of the classification and the terminologies used to describe and evaluate non-conformances
- implement a template or form for the recording of the non-conformances, root cause analysis and CAPAs. Necessary signatures should be obtained on the document to demonstrate ownership of assigned CAPA tasks.