

Non-conformances

Auditing Platform

Non-conformances

Why is capturing of non-conformances needed?

- To allow to formal control over all occurring issues and to prevent their re-occurrence
- To analyze patterns of non-conformities and to continuously improve internal processes

Audit observations: What was missing?

- Formal process lacking for capturing, evaluating, and documenting daily non-conformances.
- Absence of systematic documentation for minor incidents, which are not captured in a CAPA and Change Management processes.
- Clear guidelines and documentation for managing non-conformities missing, resulting in limited assignment and follow-up on corrective and preventive measures.

Recommendations:

- Write a procedure/SOP (or include this as a separate chapter of the CAPA Management SOP) outlining the handling of non-conformances, defining responsibilities, and how root cause analyses are conducted to ensure corrective as well as preventive measures are taken to eliminate and prevent the non-conformances in the future.
- Implement a template or form for recording non-conformances, root cause analysis, and CAPA definition, ensuring necessary signatures are obtained on the document.
- Consider if identified incidents need to be formally documented in the department specific risk register and evaluated within the annual risk register review.