# CAPA Classification and Documentation

Auditing Platform

CAPA Classification and Documentation

## Why is CAPA classification and documentation needed?

- The CAPA (Corrective and Preventive Action) process is essential for establishing structured control over issues as they arise and for implementing measures to prevent their recurrence.
- In more detail:
    - **Control**: Allows for prioritization based on severity, ensuring critical issues are addressed promptly.
    - **Prevention**: Facilitates thorough analysis of root causes to implement preventive measures.
    - **Compliance**: Ensures adherence to regulatory requirements and quality standards.
    - **Continuous Improvement**: Enables the systematic monitoring of trends and patterns in data to identify areas for ongoing quality enhancement and to proactively address potential issues before they escalate.

## Audit observations: What was missing?

- Lack of details in SOP regarding the severity classification of CAPA incidents (i.e. minor, major, critical).
- Absence of formal documentation for any incidents occurring.

## Recommendations:

- Amend the CAPA Management process / SOP to include the definition of classification and terminologies used to describe and evaluate non-conformances
- Develop a template for logging non-conformances, corrective and preventive actions, along their root cause evaluation
- Implement a CAPA tracker to allow tracking of CAPA actions and their completion versus due dates.