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Deviation & CAPA Report

Pharma, Chemicals & Life Sciences

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This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

Background

Produces a deviation and CAPA report — description, classification (minor/major/critical), impact assessment on product quality, root cause, and corrective and preventive actions. Use this to document a deviation and fix its root cause. Deviations need QA assessment and approval.

Purpose of this tool & output

Handle deviations and fix root causes

How the output is used

Use it to document a deviation, investigate the root cause and record the corrective and preventive actions properly.

Important cautions

AI-generated report; deviations need QA assessment and approval.

Companion documents

- GMP Implementation Guide
- Manufacturing SOP Writer
- Batch Manufacturing Record (BMR)
- Cleaning Validation Protocol
- Process Validation Protocol
- Equipment Qualification (IQ/OQ/PQ)

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and processes vary by state and change over time — confirm with your state authority.