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Quality System Audit

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

Builds a quality system self-audit — area by area (documentation, deviation and CAPA, change control, complaints, recall, training, data integrity) with checks, a Good/Fair/Poor scorecard and priority fixes. Use this to audit your quality system end to end. For a facility-focused GMP audit use the GMP Self-Audit Checklist.

Purpose of this tool & output

Audit your quality system end to end

How the output is used

Use it to audit your quality management system end to end and get a prioritised list of gaps to fix.

Who should vet it

A qualified QA professional to confirm the findings and priorities before you act.

Important cautions

AI-generated audit; align to GMP and your PQS.

Companion documents

- QC Laboratory SOP
- Stability Study Protocol
- Analytical Method & Validation
- Certificate of Analysis (COA)
- OOS / OOT Investigation
- Quality Manual Builder

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.