

GMP Self-Audit Checklist

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 GMP self-audit checklist — area by area (facility, documentation, production, QC, warehouse, personnel, validation) with checks, common observations and corrective-action readiness. Use this to be inspection-ready for CDSCO and customer audits. For a full GMP implementation roadmap use the GMP Implementation Guide.

Purpose of this tool & output

Be inspection-ready for CDSCO and clients

How the output is used

Use the checklist to self-inspect your unit against Schedule M and GMP before a CDSCO or customer audit and to close gaps first by risk.

Who should vet it

A qualified QA head or a GMP/regulatory consultant, before you rely on it for a CDSCO or customer audit.

Important cautions

AI-generated checklist; align to Schedule M and applicable GMP standards.

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.