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Quality Manual Builder

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

Drafts a pharmaceutical quality manual structure — quality policy, the pharmaceutical quality system elements (documentation, change, deviation, CAPA, complaints, recall, self-inspection) and responsibilities. Use this to document your quality management system. Align it to your PQS and Schedule M.

Purpose of this tool & output

Document your quality management system

How the output is used

Use the builder to document your quality management system in a structured quality manual adapted to your unit.

Important cautions

AI-generated structure; align to your PQS and Schedule M.

Companion documents

- QC Laboratory SOP
- Stability Study Protocol
- Analytical Method & Validation
- Certificate of Analysis (COA)
- OOS / OOT Investigation
- Document Control & Data Integrity

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.