

WHO-GMP Certification Guide

Pharma, Chemicals & Life Sciences

Document type: Licence / statutory filing · Generated 15 Oct 2026

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

Explains WHO-GMP certification for a manufacturer — what it is, its benefit for exports, the application to the state licensing authority and the inspection — with prerequisites (GMP compliance, documentation) and the process. Use this to get WHO-GMP for export credibility. Confirm the current process with your state licensing authority.

Purpose of this tool & output

Get WHO-GMP for export credibility

How the output is used

Use it to prepare for WHO-GMP certification — the site master file, Schedule M gaps and inspection readiness — before you apply to the state licensing authority.

Who receives it

The State Licensing Authority / State FDA that issues the WHO-GMP certificate and CoPP after inspection.

How to submit / file it

Apply to the state FDA with the site master file, product list and Schedule M compliance evidence; a WHO-GMP inspection of the plant follows.

Fees & charges

A government fee per certificate or product plus inspection costs.

Who should vet it

A GMP or regulatory consultant and your qualified QA head.

Important cautions

AI-generated guide; confirm current process with your state licensing authority.

Companion documents

- Pharma Export Setup Guide
- Pharma Export Documentation
- Overseas Product Registration
- COPP / Free Sale Certificate Guide
- Pharma Export Costing
- Pharma Export Contract

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.