

Drug Manufacturing Licence Guide

Pharma, Chemicals & Life Sciences

Document type: Licence / statutory filing · Generated 14 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 drug manufacturing licence requirements — the application to the state licensing authority, premises and equipment, competent technical staff, inspection and grant — with awareness of the relevant forms (e.g. 25/28) and prerequisites (GMP facility, qualified staff). Use this to get your manufacturing licence. Confirm current forms and requirements with your state FDA.

Purpose of this tool & output

Get your manufacturing licence

How the output is used

Use it to plan and assemble your drug manufacturing licence application — the right forms, technical staff, premises and documents — before you apply to the State Drug Controller.

Who receives it

The State Drug Controller / State Licensing Authority (SLA) under the Drugs and Cosmetics Act; new drugs and specified categories also involve CDSCO.

How to submit / file it

Apply online on the state FDA or SUGAM (CDSCO) portal with the site plan, equipment list and competent technical staff details; a joint inspection of the premises follows before grant.

Fees & charges

A government fee per product category plus inspection costs, varying by state and licence form.

Who should vet it

A pharma regulatory consultant and the qualified competent technical person named on the licence.

Important cautions

AI-generated guide; confirm current forms and requirements with your state FDA.

Companion documents

- CDSCO Regulatory Primer
- Product Permission / Registration
- Regulatory Dossier Structure
- Drug Labeling Compliance
- Regulatory Strategy Planner
- Import Licence & Registration

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.