

CDSCO Regulatory Primer

Pharma, Chemicals & Life Sciences

Document type: Plan / SOP / strategy / guide · Generated 27 Aug 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

Provides a CDSCO and drug-regulation primer — the framework (Drugs and Cosmetics Act and Rules, central CDSCO and state licensing authorities, new drugs rules), the key approvals (manufacturing licence, product permission, import, new drug approval) and the authorities (CDSCO, state FDA, DCGI). Use this to get oriented. Regulations are technical, so engage a regulatory professional.

Purpose of this tool & output

Understand India drug regulation

How the output is used

Use the primer to understand how India regulates drugs — the authorities, licences and approvals — before you plan your own compliance.

Important cautions

AI-generated primer; regulations are technical, engage a regulatory professional.

Companion documents

- Drug Manufacturing Licence Guide
- 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.