

Pharma Regulatory Writing

Healthcare

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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 regulatory document section (Clinical Overview, Risk-Benefit Summary, PIL, SmPC, CDSCO narrative, etc.) following ICH/CDSCO conventions, with a review checklist. Use this for CTD/dossier sections; for a study synopsis use the Study Protocol Synopsis and for an India filing route use the CDSCO Submission Guide.

Purpose of this tool & output

Describe your drug or device and we draft regulatory narrative sections

How the output is used

Use the drafted narrative sections as a starting point for regulatory documents, then have a regulatory expert finalise them.

Important cautions

AI-generated regulatory writing template. All regulatory submissions must be reviewed and signed off by qualified regulatory affairs professionals and medical experts.

Companion documents

- Study Protocol Synopsis
- Patient Information Leaflet
- CDSCO Submission Guide
- Pharmacovigilance / AE Narrative
- Product Monograph Draft

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.