

Pharmacovigilance Setup Guide

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

Explains pharmacovigilance setup for a pharma company — adverse event collection, assessment and reporting to PvPI/CDSCO, PSUR where applicable — with the setup (responsible person, SOPs, training) and records. Use this to monitor and report adverse events per PvPI and CDSCO requirements.

Purpose of this tool & output

Monitor and report adverse events

How the output is used

Use the guide to set up pharmacovigilance — adverse-event capture, assessment and reporting to the authority.

Important cautions

AI-generated guide; follow PvPI and CDSCO pharmacovigilance requirements.

Companion documents

- Loan Licence Agreement
- Third-Party Manufacturing Agreement
- Distribution / Stockist Agreement
- NDA Builder
- Quality Agreement Builder
- Testing / Service Agreement

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.