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Overseas Product Registration

Pharma, Chemicals & Life Sciences

Document type: Licence / statutory filing · 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

Outlines overseas product registration for an exporter — dossier (CTD), local agent, fees, timelines and GMP evidence — with market-specific variations and the documents to prepare. Use this to register products in export markets. Each country has its own process; engage regulatory experts.

Purpose of this tool & output

Register products in export markets

How the output is used

Use it to plan an overseas product registration — the dossier format, India-side certificates and country requirements — before you file with the foreign authority.

Who receives it

The drug regulatory authority of the destination country (for example US FDA, EMA or the national authority); India-side you also need CDSCO documents.

How to submit / file it

File the country-specific dossier (CTD or ACTD) with the foreign authority; India-side obtain the required CoPP, free-sale certificate and manufacturing-licence copies.

Fees & charges

Country-specific registration fees, often substantial, plus consultant and testing costs.

Who should vet it

A regulatory consultant experienced in the target market and, where required, a local agent.

Important cautions

AI-generated outline; each country has its own process, engage regulatory experts.

Companion documents

- Pharma Export Setup Guide
- Pharma Export Documentation
- WHO-GMP Certification Guide
- COPP / Free Sale Certificate Guide
- Pharma Export Costing
- Pharma Export Contract