

 A Singapore Government Agency Website [How to identify](#) 

# Therapeutic Product Registration

Find out how to register your therapeutic product and manage the product registration here.

## Registration overview

Understand the therapeutic product registration process before you register your product.

## Submission of Drug Master File

Follow this guide to find out the processes for the submission and processing of a Drug Master File for a therapeutic product registration.

## Submission of Plasma Master File

Follow this guide to find out the processes for the submission and processing of a Plasma Master File for a therapeutic product application.

## eCTD submissions for Therapeutic Products

Submit documents in a standardised electronic format for therapeutic product registration.

## Summary Reports of Benefit-Risk Assessment

Provides information about the evaluation of New Drug Applications (NDA-1) and shares the considerations behind the approval of the therapeutic product.

## GMP evidence for overseas drug substance (DS) manufacturers

Overseas drug substance manufacturers will need to provide evidence of GMP compliance to support product registrations or variations in Singapore

## GMP conformity assessment of overseas drug product (DP) manufacturers

Overseas manufacturers who intend to register therapeutic products in Singapore may be subjected to a Good Manufacturing Practice (GMP) conformity assessment by HSA.

## Lot release for imported vaccines

Submit a notification to us on the lot release information of imported registered vaccines before you supply them in Singapore.

## Pre-submission Consultation Mechanisms

The range of mechanisms that enable companies to self-help include the use of guidelines, flow charts, frequently asked questions (FAQ) and self-help tools as alternatives to pre-submission meeting.

## RMP submission for product registration

Find out when a risk management plan (RMP) submission is required and the documents to be submitted.

## Special Access Routes (SAR)

In specific situations, we may allow the import or the supply of therapeutic products via Special Access Routes (SAR).

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