

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

Guidance documents for CTGTP

Here is the list of guidance documents with relevant forms and templates to help you meet the regulatory requirements for dealing in cell, tissue and gene therapy products (CTGTP).

Is my product a Cell, Tissue or Gene Therapy Product?

Answer a few questions in our self-help tool to find out if your product is considered a CTGTP in Singapore.

LET'S GO

Product notification, registration or variation

Class 1 CTGTP Notification

[Class 1 CTGTP Notification Guide](#)

- [Documentary Requirements for Class 1 CTGTP Notification and Updates](#)  229 KB

Class 2 CTGTP Registration

[Class 2 CTGTP Registration Guide](#)

- [NDA Checklist for Class 2 CTGTP \(ICH CTD Format\) !\[\]\(31b03e46ee8a80a1f1467b8c03bd76e8_img.jpg\) 136 KB](#)
- [NDA Checklist for Class 2 CTGTP \(ACTD Format\) !\[\]\(7d9665ff04f9d2270c38081c6215a724_img.jpg\) 134 KB](#)
- [Checklist for Registration of Class 2 CTGTP containing materials of animal origin !\[\]\(7cea648fec4dfc1e99934873e9173b69_img.jpg\) 30 KB \(if applicable\)](#)

Class 2 CTGTP Variation Applications

[Major Variation \(MAV-1\) Guide](#)

- [MAV-1 Checklist for Class 2 CTGTP \(ICH CTD Format\) !\[\]\(4e333a6106fc298d0ae6dff272a736ef_img.jpg\) 60 KB](#)
- [MAV-1 Checklist for Class 2 CTGTP \(ACTD Format\) !\[\]\(97089f8e07e24e31baa67366e358a709_img.jpg\) 59 KB](#)

[Minor variation \(MIV\) Guide](#)

- [MIV Checklist for Class 2 CTGTP !\[\]\(97faa0168e491544be255cfcab218e9b_img.jpg\) 379 KB *\(updated 15 January 2026\)*](#)

Other useful links:

- [Pre-market consultation for Class 2 CTGTP](#)
 - [Book your CTGTP pre-market consultation](#)
- [GMP conformity assessment for overseas manufacturers of CTGTP](#)
- [Risk Management Plan \(RMP\) submission](#)
- [CMC Requirements for CTGTP for Clinical Trials and Product Registration !\[\]\(33006de4dd11f8c729ca8ca0fde0352f_img.jpg\) 525 KB](#)
- [Points to consider for Class 2 CTGTP Labelling !\[\]\(d5f9ffa97ddb414b7e96feb8ad710c8e_img.jpg\) 216 KB](#)
- [Guidance on CTGTP Registration and Variation Applications in Singapore !\[\]\(d900cae4f5a7d73d67b6a98ff3e7bb9a_img.jpg\) 507 KB *\(Updated 15 January 2026\)*](#)

⊖ Dealer's licensing and certification

Dealer's licensing and certification

Good Distribution practice (GDP) guides


- [Guidance Notes on Good Distribution Practice](#)  263 KB

Good Manufacturing Practice (GMP) guides

HSA guides

- [HSA Guidelines on Good Manufacturing Practice for CTGTP](#)  854 KB

PIC/S guides

- [Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File \(PIC/S PE 008-4\)](#) 

⊖ Special Access Routes (SAR)

Special Access Routes (SAR)

- [Import and supply of unregistered Class 2 CTGTP](#)

- [Import and supply of registered Class 2 CTGTP on consignment basis](#)


⊖ Safety monitoring and product recall

Safety monitoring and product recall

Post-Marketing Vigilance Requirements for CTGTP

- [Guidance for Industry_Post-marketing Vigilance Requirements for Therapeutic Products and CTGTP](#) 
- [Singapore-Specific Annex \(SSA\)](#) 
- [Safety Notification Form](#)

Reporting product defects and recall CTGTP

- [Product Defect Reporting and Recall Procedures for Therapeutic Products and Cells, Tissue and Gene Therapy Products](#) 
- [Video guide on product defect reporting and recall](#) in Singapore. This video brings you through the considerations on whether a product defect needs to be reported to us, and the steps to report the defect or recall the product.
- [Online Product Defect Reporting Form](#)
- [Online Product Recall Completion Form](#)

⊖ Clinical trials

Clinical trials

Refer to our [clinical trials section](#) for the guidance documents.

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