

When GMP is required in Australia for Clinical Trials in Biologicals

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Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

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Purpose and executive takeaway

Use this deck to decide when GMP obligations are triggered, what evidence sponsors should hold, and when to engage TGA early.

1 **Pathway does not remove GMP**

CTN and CTA are trial-authorisation routes; they do not remove Australian GMP or licence obligations.

2 **Product type drives the code**

Medicines generally follow PIC/S GMP; cell and tissue biologicals generally follow the BTC Code.

3 **Class 4 needs early mapping**

Map every donor, processing, testing, release, storage and distribution step before supply.

Current practical focus: Class 4 biologicals, investigational medicinal products, overseas manufacture and sponsor evidence packages.

Always verify the latest TGA guidance and product-specific requirements before trial start.



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Regulatory context at a glance

Question	Why it matters	Practical implication
What is the product?	Product type changes the applicable code and approvals.	Confirm classification before protocol and supply-chain lock-in.
Where is each step performed?	Australian steps may need a TGA licence; overseas steps need GMP evidence.	Map sites for collection, testing, processing, packaging, release, storage and distribution.
Which trial pathway applies?	CTN relies on HREC/site governance; CTA adds TGA dossier evaluation.	Neither pathway removes GMP or sponsor obligations.
Which GMP code applies?	PIC/S generally applies to medicines; BTC Code to many cell/tissue biologicals.	Dual-scope products may need both codes for different steps.

The Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and TGA-adopted GMP codes set the operating frame.



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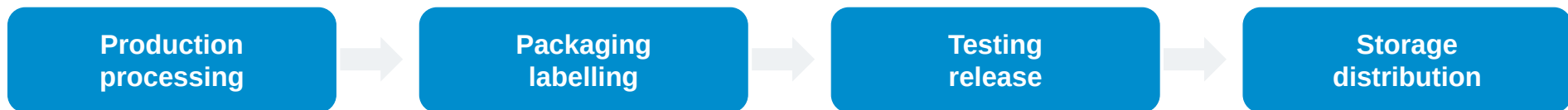
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What counts as manufacture for clinical trial materials

A GMP trigger is any controlled activity that can affect product quality, safety, identity, potency or efficacy.



For biologicals, the manufacturing chain can also include donor screening/testing, collection, transport, manipulation, cryopreservation and chain-of-identity controls.

Usually not licensed at the clinical site

Reconstitution, dilution or preparation strictly per sponsor instructions for immediate use; dispensing by the site pharmacist.

Usually licensed manufacture

Central relabelling, packaging, non-routine manipulation, GMP-critical testing or release performed away from the authorised site.



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General rule for clinical trial materials in Australia

Manufactured in Australia

1. Therapeutic goods for *initial experimental studies in human volunteers* are exempt from TGA manufacturing licence requirements.
2. A TGA manufacturing licence is generally required for other therapeutic goods, including most products for later-stage clinical trials and commercial supply.
3. All therapeutic goods must comply with applicable standards, including relevant TGOs.
4. The licence must cover the relevant product type, manufacturing site and activities
5. Manufacturers must comply with the applicable GMP requirements.

Manufactured overseas for supply in Australia

1. TGA does not issue a manufacturing certificate to the overseas site for CTN/CTA supply. However appropriate GMP should be observed.
2. The sponsor must hold current evidence of acceptable GMP compliance.
3. TGA may request the evidence during review, inspection or compliance activity.

Practical rule: map the manufacturing step first; then determine the licence, GMP code and evidence needed for that step.



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CTN vs CTA: GMP still applies

CTN

HREC approval and site governance review. TGA is notified; data are not pre-reviewed by TGA.

CTA

TGA evaluates a dossier before the trial proceeds, including relevant quality and manufacturing information.

Both pathways

Require a sponsor, GCP compliance and product quality oversight across the supply chain.

Neither CTN nor CTA exempts the manufacturer from GMP or licensing/certification requirements.

Use CTA when TGA evaluation is required; use CTN only when the sponsor and HREC hold sufficient supporting evidence.

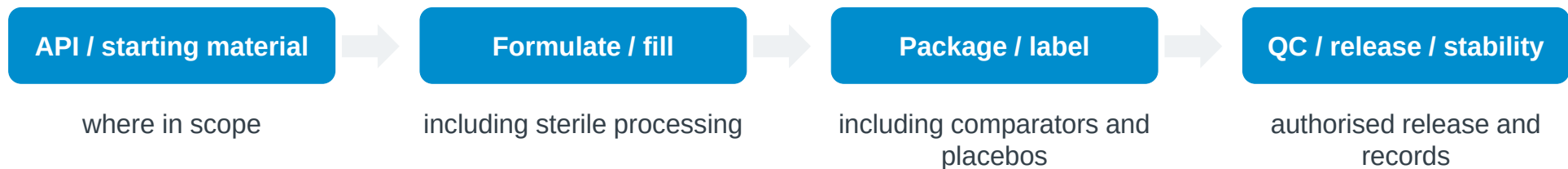


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Medicines used in clinical trials (IMPs)

Australian manufacture of IMPs generally needs both GMP compliance and a TGA manufacturing licence for the activities in scope.



Site preparation boundary

Immediate reconstitution, dilution or preparation under sponsor instructions may not require a separate TGA manufacturing licence.

Early-phase nuance

Certain Phase I / first-in-human medicines / biologicals may be licence-exempt; sponsors should still maintain appropriate GMP controls and evidence.

If packaging or relabelling is performed away from the trial site, treat it as manufacture and confirm licensing.



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Biologicals overview and Class 4 definition

The biologicals framework covers many human cell and tissue-based products and applies a risk-based classification from Class 1 to Class 4.

Class 1
lowest risk

Class 2

Class 3

Class 4
highest risk

Class 4 examples / triggers

More-than-minimal manipulation, non-homologous use, allogeneic products, complex processing or higher-risk cell and gene therapy attributes.

Important boundary

Vaccines, recombinant proteins and many biotech products are regulated as medicines rather than biologicals.

Decision point

Confirm classification early with TGA because it determines the trial pathway, GMP code, licence scope and evidence package.



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Which GMP code applies?

Medicines

PIC/S Guide to GMP for Medicinal Products as adopted by TGA.

Applies to formulation, sterile filling, testing, packaging, labelling and release activities for medicines.

Human cell / tissue biologicals

Australian BTC Code for human blood, blood components, human tissues and human cellular therapy products.

Covers donor through release, including collection and traceability.

Combination products

Both codes may apply to different parts of the supply chain.

Example: vector manufacture under PIC/S; cell processing under BTC Code.

TGA defines the licence scope: product type, site, process step and code must all align.



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When GMP is required for Class 4 biologicals

Manufacture in Australia

TGA licence required for GMP-relevant steps unless a specific exemption applies. Scope should cover donor testing, collection, processing, cryostorage, QC, release and distribution.

Manufacture overseas

Sponsor holds acceptable GMP evidence for all steps, including donor-related processes and critical testing. Consider import, biosecurity and OGTR requirements.

Clinical site preparation

Thaw and immediate administration may sit outside licensing. Washing, selection, activation or other manipulation may be manufacture.

Class 4 control starts at donor eligibility and ends only when the final product and records are reconciled.



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Exemptions and clinical-site boundaries

Exemptions are narrow, product-specific and should not be assumed for Class 4 clinical trials.

May fall outside a TGA manufacturing licence

Same-patient, same-clinical-procedure, minimal-manipulation uses that meet strict criteria.

Immediate administration strictly under sponsor instructions.

Dispensing at the trial site within the approved protocol.

Requires confirmation or licensed control

Most Class 4 autologous products.

Centralised processing, cryopreservation, storage before release or GMP-critical testing.

Any site manipulation beyond simple preparation.

If the exemption is material to trial start-up, confirm it before contracts and site activation.



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Specific GMP expectations for Class 4 biologicals

1 Quality system

Change control, deviation/CAPA, supplier qualification and risk management.

3 Aseptic processing

Validated cleanrooms, environmental monitoring, media fills and personnel qualification.

5 QC and release

In-process controls, release testing, sterility/rapid microbiology and potency/identity.

7 Cold chain

Validated cryostorage, shipping lanes, transport and excursion handling.

2 Donor eligibility

Validated screening/testing, deferral criteria and traceability from donor to recipient.

4 Identity and custody

Auditable chain of identity and chain of custody throughout the process.

6 Qualified release

Independent release or equivalent function separated from production.

8 Data integrity

Complete batch records, reconciliations and review-ready evidence.

Expectation: controls are validated, documented, auditable and proportionate to patient risk.



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Cell and gene therapy clinical trials: decision points

Trial stage / product	Licence and GMP position	Likely pathway consideration
First-in-human / Phase I medicine	Potential licence exemption for certain early-phase medicines; maintain GMP controls.	CTN or CTA depends on risk and need for TGA evaluation.
Class 4 biological / ex vivo gene-modified cells	High-risk controls across donor, processing, release and traceability; confirm exemptions.	CTA may be required; confirm pathway early.
Beyond first-in-human or expanded studies	Australian manufacture generally needs a TGA licence for the relevant step.	CTN is common with adequate evidence; CTA if TGA evaluation is needed.

Do not treat “first-in-human”, “hospital-based” or “autologous” as shorthand for no GMP. The safe approach is to map the product, class, trial stage and every manufacturing step.

Confirm product-specific requirements with TGA before trial submission or site activation.

Activities that frequently trigger licensing for biologicals

Donor-controlled collection

Collection is performed under sponsor manufacturing control.

Manipulation beyond preparation

Washing, selection, activation or other process steps at site.

Central labelling / packaging

Relabelling, final packaging or blinding away from the trial site.

Cryopreservation and storage

Storage before release or shipment under validated cold-chain control.

GMP-critical testing

Sterility, mycoplasma, potency, identity or adventitious-agent testing.

External service providers

Contract labs, radiation facilities, logistics and other quality-critical parties.

Include every GMP-relevant third party in quality agreements and sponsor oversight.



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Overseas manufacture: evidence package

For overseas-manufactured trial goods, the sponsor should be able to demonstrate acceptable GMP compliance for every quality-critical step.

1 Current GMP certificate or licence

From a PIC/S member authority or equivalent competent regulator.

2 Recent audit reports and CAPA

Sponsor or qualified third-party audits with responses tracked to closure.

3 Product-specific release evidence

QP/authorised person release certification and batch documentation.

4 Validation and stability summaries

Aseptic process, shipping, cryostorage, cleaning and stability evidence.

5 Donor and collection controls

Screening/testing procedures, accreditation and traceability evidence.

6 Quality agreements

Clear responsibilities for all outsourced GMP-relevant activities.

Formal TGA GMP Clearance is often not mandatory solely for CTN/CTA supply, but a robust evidence package reduces inspection and registration risk.



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Sponsor, site and GCP interface

Sponsor accountability

Ultimate responsibility for product quality, trial conduct, records, safety monitoring and investigational product oversight.

Clinical site execution

Follow preparation instructions exactly. Escalate non-routine manipulation, deviations and temperature excursions.

Quality event handling

Manage complaints, defects, excursions and CAPA under GMP and GCP, with HREC/TGA reporting where required.

The hand-off between manufacturing controls and GCP site operations is a known risk point. Define it in the protocol, pharmacy manual and quality agreements.



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Common pitfalls to avoid

- 1 Assuming CTN or CTA removes GMP or licensing obligations in Australia.
- 2 Treating “minor” relabelling, packaging or blinding at a third party as non-manufacturing.
- 3 Leaving critical testing labs, radiation facilities or logistics providers outside quality agreements.
- 4 Weak chain-of-identity or chain-of-custody controls for autologous products.
- 5 Treating thaw, wash or activation at the clinical site as non-manufacturing without TGA confirmation.
- 6 Holding overseas GMP evidence at a corporate level but not product-, site- or step-specific level.

If the boundary is uncertain, ask before proceeding — retrofitting GMP evidence after trial start is rarely simple.



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Practical decision guide

- 1 Is the product a medicine, biological, combination product or GMO?
- 2 If it is a biological, what class applies — especially Class 4?
- 3 Where is each step performed: collection, testing, processing, packaging, release, storage and distribution?
- 4 Which steps occur in Australia, and are those entities licensed for the product and scope?
- 5 For overseas steps, is the GMP evidence current, competent-authority based and product-specific?
- 6 What will be prepared at the clinical site, and is it only immediate-use preparation?

Decision rule: when classification, pathway or site manipulation is unclear, consult TGA early.



Sponsor documentation to maintain

TGA manufacturing licences and scopes for Australian sites

Overseas GMP certificates, clearances and audit reports

Quality agreements with GMP-relevant third parties

Batch records, CoAs and authorised release documentation

Donor eligibility and traceability documentation

Shipping validation and temperature monitoring records

Deviation/CAPA, complaints and recall procedures

Evidence of site preparation instructions and pharmacy training

Keep evidence review-ready: current, product-specific, version-controlled and linked to the relevant manufacturing step.



Key references and where to get help

- 1 TGA — Clinical trials in Australia: CTN and CTA guidance
- 2 TGA — Guidance on GMP for investigational medicinal products
- 3 TGA — Australian Regulatory Guidelines for Biologicals (ARGB)
- 4 TGA — Manufacturing principles and the current TGA-adopted PIC/S Guide to GMP
- 5 TGA — Australian Code of GMP for human blood, blood components, human tissues and human cellular therapy products (BTC Code)
- 6 Other product-specific checks: OGTR for GMOs; biosecurity/quarantine and human tissue import requirements where applicable

Manufacturing Quality Branch enquiries: gmp@health.gov.au | bloodandtissues@health.gov.au

Always check the latest TGA versions and any product-specific requirements before relying on this summary.



Take-home messages

GMP applies by activity, not by pathway

CTN/CTA does not remove GMP or licensing obligations for Australian manufacture.

Class 4 biologicals need end-to-end control

Donor, processing, asepsis, release, traceability and cold-chain controls must be auditable.

Overseas supply still needs evidence

Sponsors must hold current, product-specific GMP evidence for each quality-critical step.

Start with a manufacturing map

Early classification and site/step mapping prevents trial delays and compliance gaps.

If unsure, engage TGA before supply chain decisions become locked in.

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Questions?

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For product-specific requirements, confirm with TGA before trial start.



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