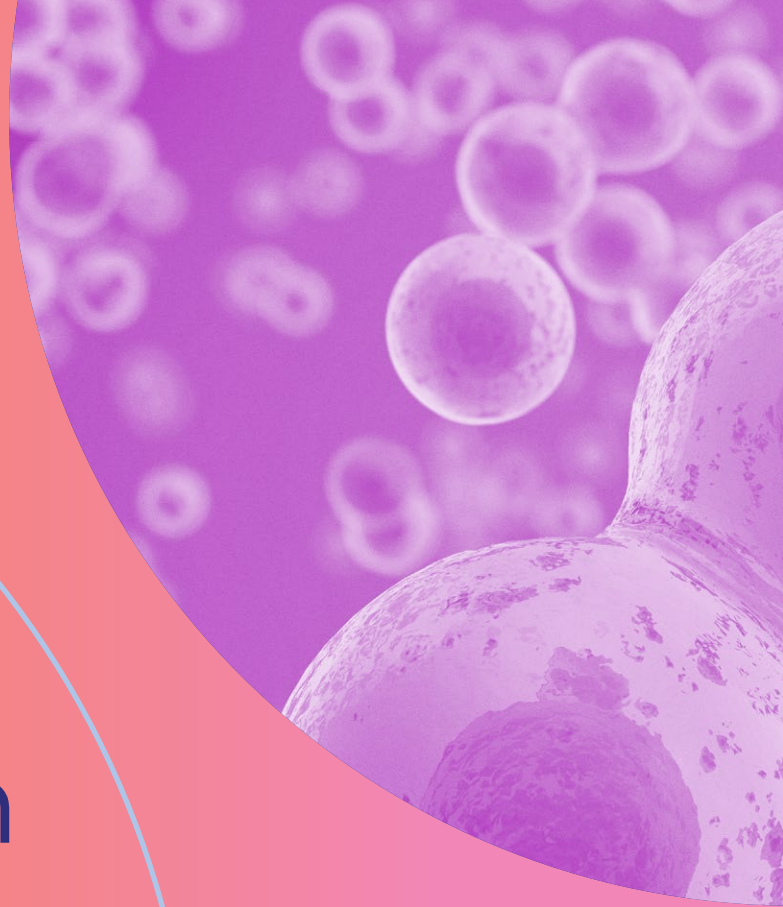




magellan
STEM CELLS

Cellular Therapy

From Concept
to Commercialisation





We are one of Australia's few TGA-licensed, GMP-certified CDMOs for cell therapies; we have built a strong reputation in MSC manufacturing, supported by Phase 3-ready facilities and robust GMP infrastructure.

Our specialist knowledge in MSCs forms the foundation of a broader capability that extends to iPSCs, NK cells, CAR-T, exosomes, and other advanced cell types – making us the ideal partner from concept to commercialisation.

Our History

- License granted
April 2025
- Inspection
Dec 2023
- Construction finished
Feb 2023
- Construction start
Mid 2022
- Site purchased
Jan 2022
- GLP established for
early Phase
2014
- Preclinical
since 2009



Why Partner with us?

At Magellan Stem Cells, we see ourselves as an extension of your team.

We offer a collaborative, flexible partnership model that adapts to your program's needs – whether you require donor material, small scale pre-clinical development, process optimization, full scale tech transfer into GMP, or Regulatory support. Our goal is to deliver not just a service, but a seamless pathway to clinical and commercial success.

Client Journey Focus



Concept to Clinic

End-to-end Cell therapy support from idea to Phase 3.



Quality without Compromise

Rigorous GMP standards, global compliance mindset.



Collaborative Partnership

Flexible solutions tailored to your therapy.

Outcome and Impact Driven



Trusted Partnership

Transparent collaboration built on trust and results.



Speed to Patients

Accelerating therapies into clinical trials.



Unmatched Quality

Reliable, reproducible GMP manufacturing.

Our Services

01

Biobanking

- MCB & WCB generation
- Cell Characterisation

02

Process development

- Process optimisation for GMP
- Aseptic Process validation
- Scale up Process development

03

GMP Manufacturing

- Tech transfer Framework
- Aseptic protocol development and validation
- Engineering runs
- GMP manufacturing (small to large scale)
- Downstream processing

04

Quality Assurance and control MCB & WCB generation

- Validation Protocol and SOP development
- TGA Audit support if required
- QC method validation

05

Regulatory Dossiere Support

- CMC document support and advice

06

Storage & Logistics

- Validated Control rate freezing
- Liquid Nitrogen Freezer
- Domestic & International shipping. Room temp to coldchain

Quality Test Menu

	Test Item	Details
1	ELISA	Biomolecule quantification assay used to detect proteins, antibodies and hormones.
2	FACS (flow cytometry)	Uses light scattering and fluorescence to sort and characterizes cell populations for expressed markers, size, phenotype and cell life cycle analysis.
3	Endotoxin	Detects bacterial endotoxins that may cause adverse immune reactions.
4	Mycoplasma	Sensitive assay for detecting hidden mycoplasma contamination
5	Cell differentiation Capability	Confirms Cells identity & Multipotency though differentiation assays
6	Cell Count & Viability	Ensure accurate dosing and cell health prior to release
7	Ph	Tests product acidity or basic properties
8	EM (environmental monitoring)	Continuous assessment of cleanroom air and surfaces to ensure GMP compliance.
9	Gram stain	Rapid screen for bacterial or fungal contamination
10	Growth Promotion tests	Confirms culture media/EM plates can support microbial growth.
11	Bioburden	Detect and quantifies microbial contamination in cell products and solutions.
12	qPCR	Sensitive genetic assay for detecting viral or microbial contaminant.

Our facility is more than just GMP space – it's a platform for your success. With flexible, scalable manufacturing suites, integrated QC labs, and Phase 3 approval, we provide a trusted environment where Cell therapies are developed with precision, speed, and uncompromising quality.

Clean Room Available

- State of the art clean rooms Grade A, Grade B, Grade C, Grade D available to suit your needs.
- **Qualified equipment available to suit your needs;**
 - Multigas incubators
 - Water bath
 - Centrifuge (refrigerated)
 - Bioreactor
 - BSC's
 - Particle counters
 - Control rate freezer
 - Fridges
 - Freezers
 - Biowelder
 - Full list available upon request.
- **Back up generator to ensure continuity of service**
Integrated Quality Control laboratories – in-house sterility, identity, and potency testing.
- **Scalability**
With adjacent warehouse capacity, our facility is designed to scale rapidly, enabling expansion into new GMP manufacturing space without disruption.





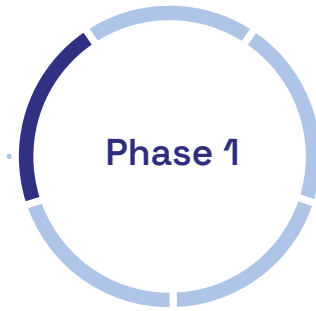
From Cell Concept to Commercialisation



Preclinical

Our team has hands-on expertise with MSCs, iPSCs, NK cells, CAR-T cells, exosomes, umbilical cord-derived cells, fibroblasts and Rna/DNA/protein-based extraction and analysis.

This breadth of experience enables us to support preclinical programs with tailored process development, scalable platforms, and robust QC methods – providing a strong foundation for smooth transition into GMP manufacturing.



Phase 1

In Phase 1, our focus is on process development and early GMP manufacturing to support first-in-human studies.

We provide tech transfer, access to partnered clinical sites, small-scale GLP/GMP production, and tailored QC assays, ensuring your therapy enters the clinic with a robust and compliant foundation.

Manufacturing Capability Preclinical and Phase 1



T Flask /Shaker Flasks /high throughput screening with DoE



2 & 4 level Cell Factory



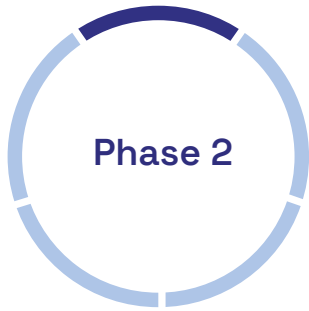
Centrifuge



Manual Filling

Project timeline Preclinical and Phase 1

Technical consultation	4 weeks				
Tech transfer		5 weeks			
Pilot study			5 weeks		
APV				7 weeks	
Engineering runs (if applicable)					3 weeks
Runs under GMP conditions					7 weeks



Phase 2

In Phase 2, we focus on scaling processes and providing access to clinical partners to ensure compliance for larger patient cohorts. Our team delivers GMP-compliant manufacturing, validated QC assays, and robust tech transfer plans, providing a smooth transition into our facility and laying the groundwork for late-stage development & GMP manufacturing compliance.



Phase 3

At Phase 3, we provide Phase 3-licensed GMP manufacturing with the capacity and rigor required for pivotal trials. Our expertise in scale-up, regulatory CMC documentation, TGA audited QMS ensures consistency, reliability, and readiness for commercial supply.



Commercial

Bioreactor 3D Cell culture technology
Process Co-development (18 months)
Manufacturing line and facility/room build up-18 months
ER, APV, Stability 12-18 months
Inspection & Audit ready-TBC
* All steps subject to Magellan internal tech transfers SOP**

Manufacturing Capability Phase 2 Onwards



Small scale
Bioreactor 3.75L



Medium scale
Bioreactor 10L



Large scale
Bioreactor 40L



Automated Fill
and Finish

Services aimed at delivering your project

Dedication account management

Our account structure is designed to keep your project on track and supported at every stage.

Each client is assigned a dedicated Account Manager with technical expertise, backed by a senior point of escalation to ensure clear communication, rapid issue resolution, and seamless project delivery.

R&D Tax Rebate

Magellan is an Australian based entity so your project may be eligible for the 43.5% Commonwealth government R&D tax rebate. We would be happy to discuss this with you as part of project planning.



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magellanstemcells.com.au
CDMO@Magellanstemcells.com.au