





Asia Pacific's leader in manufacturing and delivery of cellular therapies: the essential infrastructure behind a new industry

Cell Therapies Pty Ltd ("CTPL"): benefits for customers

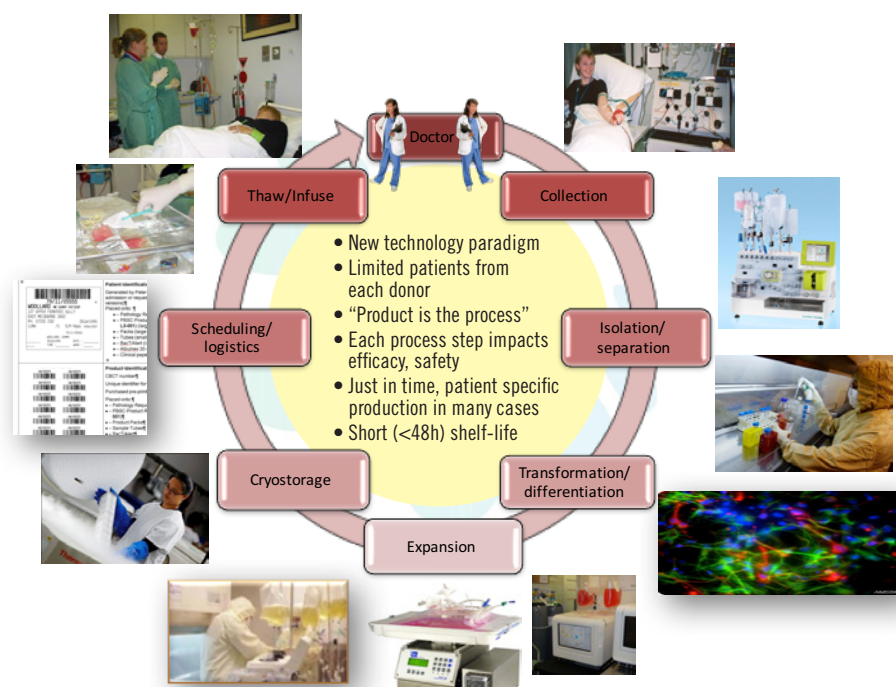
- Asia Pacific hub for cell processing and product distribution – essential infrastructure to maximise commercialisation options
- Needle-to-needle solution offering control from starting materials/collection through processing to transplant – all under one quality system
- Access to >850 million potential patients: accelerated trial recruitment, large market
- Global compliance and consistency: seamless linking with other manufacturing sites
- One partner from translation to commercialisation
- Single gateway to / from Asia Pacific including Japan – flexible business models; one stop solution

Capability highlights: international compliance – regional manufacturing and distribution

- 15+ years' experience in TGA regulated cGMP contract manufacturing for clinical trials AND distribution of standard of care products
- Facilities in Melbourne and Japan (through PharmaBio alliance)
- Fully cGMP and PIC/S compliant facilities: sterling quality track record
- Majority owned by Peter MacCallum Cancer Centre – internationally recognised centre of excellence
- World class clinical and research links throughout Australia
- Access to Australia's streamlined clinical trial approval process, R&D tax concessions and other government funding programs, and Japanese conditional approval pathway

Needle-to-needle production system

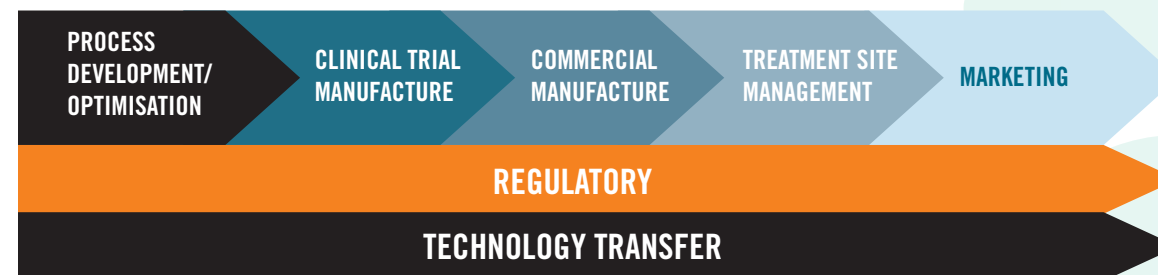
"Needle to needle" process is CTPL's unique experience and expertise



Needle-to-needle cGMP manufacturing

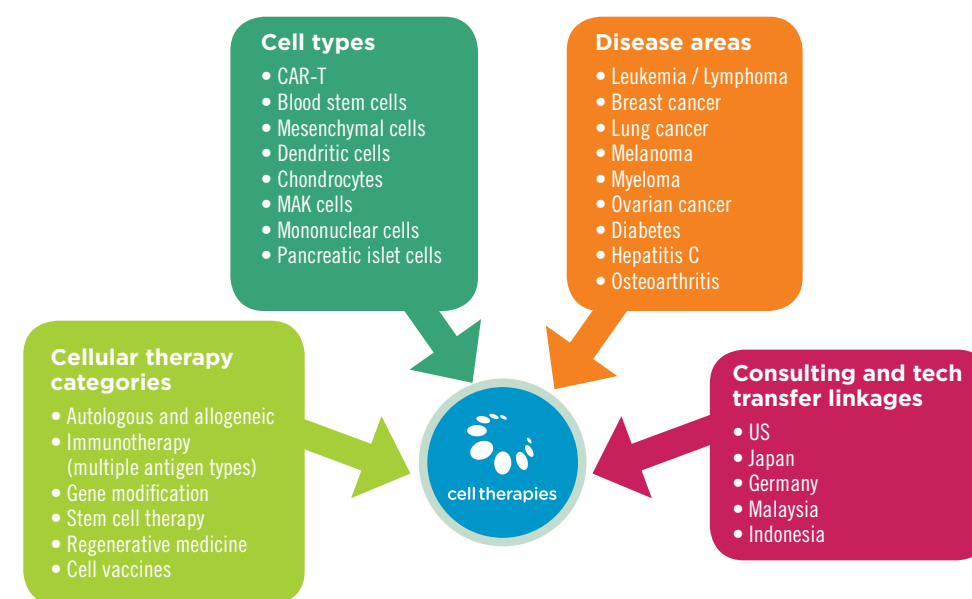
+
Location close to 850m patients
+
World class clinical & research infrastructure
=
CTPL's unique expertise and significant competitive advantage

Services



- Product and process development
- Project management and technology transfer
- cGMP cell manufacturing
- Regulatory and quality advisory services including dossier preparation
- Marketing and promotion (through specialist collaborators)
- Grant support and management
- Apheresis/collection site management
- Cell banking and cryo-preservation
- Advanced analytics including haematology/pathology and flow cytometry
- Nuclear medicine and imaging
- Logistics, storage and scheduling

Product and production experience



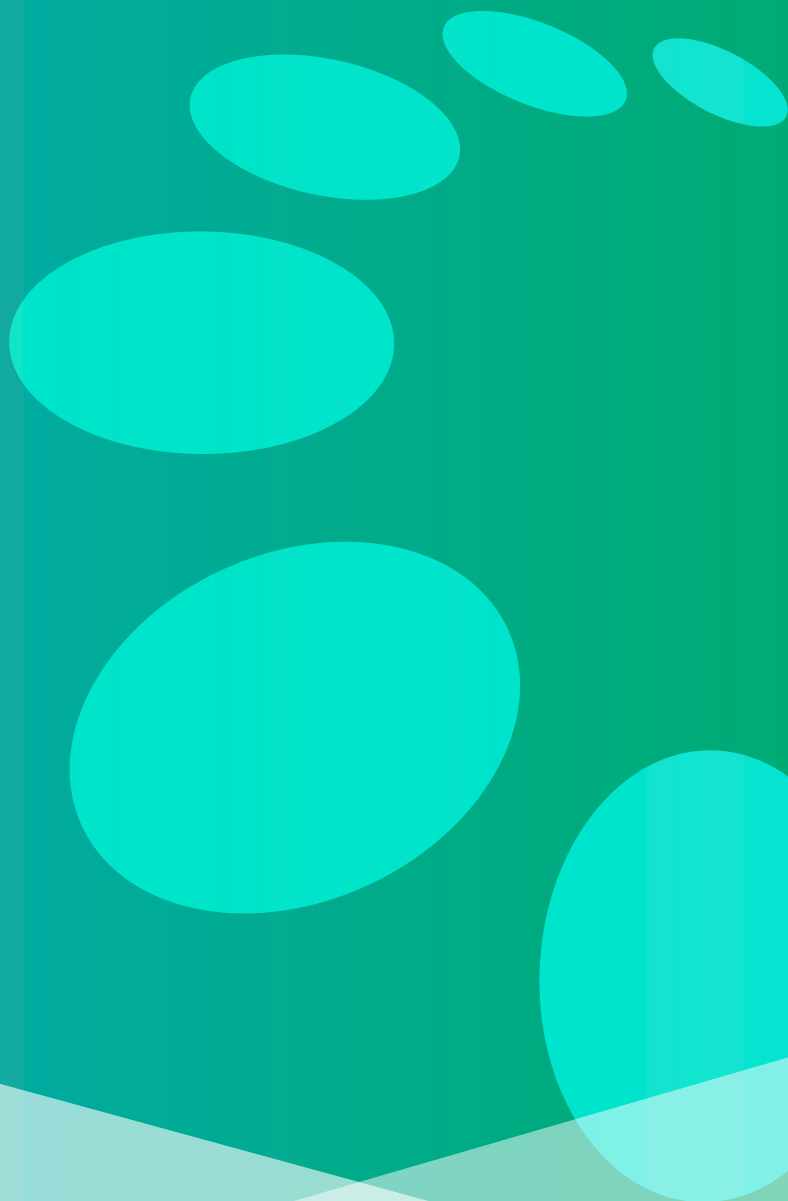
Cell Therapies Pty Ltd is well qualified

- Extensive expertise working with gene and immunotherapy products since 2001 using both lentiviral and retroviral vectors (including characterisation and safety testing)
- Manufactured and distributed Orthogen's ArthroMatrix® first generation ACI product for 10 years in Australia
- 10 clean room PIC/S compliant cGMP facility at Peter MacCallum Cancer Centre in Melbourne; biosafety levels 2 and 3
- Access to Japanese manufacturing and distribution through alliance with PharmaBio (harmonised quality systems, joint project management)
- Sterling quality track record: over 20 TGA quality audits in the past 13 years; 5 manufacturing licenses; 3 CTX approvals

- Global reputation and impact with deep regional experience: 7 manufacturing processes transferred to US, EU and Japan for late stage clinical trials; brought facilities to cGMP in Japan, Malaysia and Indonesia
- Synergistic relationship with Peter MacCallum Cancer Centre's world-class clinical and research organisations: rapid trial initiation and recruitment
- Process development IP and know-how includes quality systems, cell tracking, apheresis management, regulatory expertise, government funding support
- Deep, broad experience across cell types and processes including CAR-T, gene therapy, dendritic cells, MSCs, blood cell lineages, chondrocytes
- Extensive project portfolio and pipeline, especially in haematology / oncology and musculoskeletal indications

Service lines

- **Contract Manufacturing (CMO)**
Process development and manufacturing to support commercial and clinical supply delivering robust, cost-effective, globally scalable and regulatory compliant production processes
- **Regulatory & Clinical Consulting**
Regulatory and clinical development advisory services demonstrating “needle-to-needle” process control and efficient integration into clinical programs
- **Apheresis Management**
Establishment, coordination and monitoring of apheresis collections and collection networks resulting in a quality controlled, well-defined, consistent starting material for cell therapy and immunotherapy manufacturing



cell therapies

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Founding
Partner



Alliance
Partner

