

# Building a new advanced manufacturing industry: commercial scale cellular therapies



*Industrialising biology: Cell Therapies is developing advanced manufacturing techniques for patient specific cellular therapies*

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Using human cells as therapeutic agents is set to transform healthcare, delivering breakthrough cures to diseases that small molecules and biologics have struggled to address. Genetically modifying a patient's immune system T-cells (so-called CAR-T therapy) is demonstrating 90% complete and durable remission in chemotherapy resistant leukaemia with a single treatment. Modifying a patient's haematopoietic stem cells to insert properly functioning genes for haemoglobin production appears to be able to 'cure' transfusion dependent thalassaemia.

A whole new manufacturing and supply industry must be created if thousands of patients are to benefit from these breakthrough therapies. Traditional pharmaceuticals are inert, largely temperature stable and can be manufactured centrally in batches of thousands or millions of doses to sit on a pharmacy shelf until needed. Cellular therapies are patient specific, living products that are inherently fragile, have very short shelf-lives unless stored in liquid nitrogen and are highly variable. A clinical prescription initiates and just-in-time, time critical production process with

each batch producing a single product for one patient. Today these processes are very manual and very expensive.

Cell Therapies Pty Ltd, a subsidiary of Peter MacCallum Cancer Centre in Melbourne, has more than a decade of experience manufacturing cellular therapies for clinical trials and small scale commercial use. The team at Cell Therapies are now turning their attention to large volume production, aiming to provide the essential infrastructure necessary to deliver these advanced manufacturing products across Asia. Using current manufacturing processes to scale-out these therapies quickly leads to unmanageable outcomes. Even a small product treating 5,000 patients per year could need 60-70 biosafety cabinets in clean room environments and 500-700 staff and if even one production run fails, a patient dies.

Cell Therapies has launched an "Autologous Production for the Future" program to develop advanced manufacturing systems to solve the scale-out problem. This requires a systems view of the complete supply chain, a "needle-to-needle" view of each product's journey. The cell collection and processing process needs to be optimised, "closed" and automated. Facility design offers further optimisation opportunities. Information systems to manage the huge volume and complexity of thousands of batches each year are needed. Automation and simplification of QC assays, which make up 25% of product costs, are a key area for innovation. Drawing inspiration from other perishable goods, just in time production industries, Cell Therapies aim to reduce the cost of cellular therapies by 70% while improving consistency, scalability and predictability.

An advanced manufacturing eco-system is developing around these new therapies. Cell Therapies already collaborates with Invetech Ltd in Melbourne for process automation, the CRC for Cell Therapy Manufacturing in Adelaide for cost reducing processes and Peter Mac for optimising cell collection by apheresis. Australia has a genuine opportunity to be more than a local manufacturing hub – it can also become an advanced manufacturing leader in this field. 🏗️