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Australiaâ??s Next Cell & Gene Therapy Leap: From Clinical Trials to Commercial Scale

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Dr Bev Menner, CEO of Cell Therapies Pty Ltd, explains how regulatory efficiency, manufacturing strength and growing automation could position Australia as a strategic hub for advanced therapies across Asia-Pacific.

Australia is rapidly evolving beyond its reputation as a destination for early-stage clinical trials to build a more complete cell and gene therapy ecosystem. Regulatory efficiency, R&D incentives, expanding manufacturing capabilities and strong clinical networks are helping attract global developers, while automation and digital manufacturing are becoming increasingly important to achieving commercial scale. **In this conversation with BioSpectrum Asia, Dr Bev Menner, CEO of Cell Therapies Pty Ltd,** discusses Australia's emerging role in the global CGT landscape and what it will take to translate promising therapies into scalable, accessible treatments across Asia-Pacific.

Q1. Australia is increasingly being recognised as a destination for cell and gene therapy development. What structural advantages have driven this shift, and how do you see the country's role evolving over the next five years?

Australia has built a very attractive environment for cell and gene therapy development by combining regulatory efficiency, strong research capability and commercial incentives.

One of the biggest advantages is the Clinical Trial Notification (CTN) scheme, which allows many early-phase trials to proceed following Human Research Ethics Committee approval, without the additional regulatory review processes required in some other jurisdictions. For sponsors with a well-prepared program, this can significantly shorten timelines and enable studies to start much faster.

Australia also takes a pragmatic approach to early-phase cell therapy manufacturing. While products are still expected to be manufactured to appropriate GMP standards, Phase I trials do not necessarily require production in a licensed GMP facility, which can reduce barriers to entry and help innovative therapies reach patients sooner.

The R&D Tax Incentive is another important driver, providing meaningful cash rebates on eligible R&D and manufacturing activities. For emerging biotech companies, this can make a substantial difference to how quickly programs can progress.

In addition, Australia benefits from a highly skilled workforce, strong hospital and research networks, diverse patient populations, and a favourable geographic position within the Asia-Pacific region.

Over the next five years, I believe Australia will continue evolving from being seen primarily as a fast and cost-effective location for early-phase trials to becoming a more complete cell and gene therapy ecosystem. We are already seeing growth in local manufacturing capabilities, and I expect Australia to play an increasingly important role in taking therapies from early clinical development through to commercialisation, rather than serving as just one step in the development journey.

Q2. International developers often face regulatory, manufacturing and operational challenges when entering a new market. What are the most common hurdles companies encounter in Australia, and how does Cell Therapies help overcome them?

For many international developers, the challenge is not Australia itself, but understanding how to navigate a new regulatory, manufacturing and operational environment efficiently.

Companies are often unfamiliar with Australia's clinical trial pathways, local regulatory expectations, and the practical requirements for establishing manufacturing and supply chains. There can also be uncertainty around importing biological materials, managing cold-chain logistics, protecting data and intellectual property, and identifying the right clinical and research partners to work with.

Australia's regulatory framework is well established and internationally respected, but sponsors benefit from having local expertise to help them move quickly and avoid unnecessary delays. That's where Cell Therapies adds value.

With more than two decades of experience manufacturing cell therapies and supporting clinical programs, we provide sponsors with an experienced local partner that can help coordinate manufacturing, quality, regulatory and operational activities through a single point of contact. We understand what Australian regulators, hospitals and investigators expect, and we help translate global development plans into a local context.

Importantly, sponsors don't need to build local knowledge and networks from scratch. Our established infrastructure, relationships and experience enable developers to focus on advancing their therapies while we help simplify the path to clinical development and, ultimately, commercialisation in Australia and the broader region.

Q3. As therapies become more personalised and complex, what manufacturing capabilities and infrastructure investments are becoming essential to support commercial-scale production while maintaining quality and regulatory compliance?

As the cell and gene therapy sector matures, manufacturability needs to be considered from the very beginning rather than treated as an issue to solve later. We've seen many promising therapies encounter challenges when moving from small-scale clinical production to commercial manufacturing because critical process decisions weren't made early enough.

Closed and automated manufacturing systems are becoming essential, particularly for personalised therapies. Automation helps improve consistency, reduce reliance on highly specialised labour, and minimise the risk of variability between batches, which is critical when each batch may be intended for a single patient.

We're also seeing increased focus on the entire manufacturing ecosystem, not just the production process itself. For example, the availability of starting material can become a constraint. Apheresis-derived products place demand on specialised collection centres, so organisations need to think carefully about how therapies will be sourced, manufactured and scaled in real-world settings.

Another key area is assay development. Potency assays and other product-specific analytical methods need to be developed and validated early, as they are fundamental to demonstrating product quality, consistency and regulatory compliance as programs progress.

Finally, simplicity is often underestimated. Complex dosing and formulation strategies can create significant operational challenges at scale. Wherever possible, manufacturers should design processes that support standardisation through consistent volumes, concentrations and workflows. In our experience, therapies that are designed with scalability and operational practicality in mind are far better positioned for successful commercialisation.

Ultimately, commercial success will depend on combining robust quality systems with manufacturing processes that are efficient, reproducible and practical to scale across multiple markets.

Q4. How important is collaboration between CDMOs, healthcare providers, regulators and research institutions in accelerating cell and gene therapy innovation, and where do you see the biggest opportunities for improvement?

Collaboration is absolutely fundamental in cell and gene therapy. These therapies rely on a complex vein-to-vein process that spans patient collection, manufacturing, testing, logistics and treatment, so no single organisation can deliver successful outcomes on its own.

The strongest programs are those where CDMOs, healthcare providers, researchers and regulators work together from the outset. Early alignment helps identify potential challenges sooner, improves decision-making, and ultimately supports faster and more reliable patient access to innovative therapies.

One area where Australia has a real strength is the collaborative relationship between industry and regulators. As the only commercially licensed CDMO manufacturing CAR-T therapies in Australia, Cell Therapies works closely with the Therapeutic Goods Administration (TGA) to ensure high standards of quality and compliance while maintaining focus on patient access. That collaborative approach helps create a pathway where innovation and regulation can progress together rather than being seen as competing priorities.

There is still room for improvement, particularly through earlier engagement across the entire development pathway. Bringing manufacturers, clinical sites, apheresis centres and regulators together earlier can help address manufacturing, logistics and comparability considerations before they become barriers later in development. Greater standardisation of collection and supply chain processes would also improve consistency and efficiency across the sector.

Ultimately, the more connected the ecosystem becomes, the faster we can translate promising science into therapies that reach patients who need them.

Q5. Australia has built a strong reputation for conducting early-stage clinical trials. How can companies better leverage this ecosystem to accelerate global development programmes while ensuring efficient supply chain and logistics management?

Companies achieve the greatest value when they view Australia not simply as a location for an early-stage clinical trial, but as a strategic launch point for broader global and Asia-Pacific development.

Australia's efficient clinical trial environment, experienced investigators and internationally recognised data can help sponsors generate high-quality evidence quickly, while building the foundations for expansion into other markets. The lessons learned during early development, particularly around manufacturing, logistics and patient operations, can then be applied as programmes move into larger regional and global studies.

To do this successfully, companies need to think about supply chain design from the outset. For cell and gene therapies, robust chain-of-identity, chain-of-custody and cold-chain systems are critical. Building scalable processes early avoids the need to redesign operational systems as programmes grow across multiple countries and sites.

Another key consideration is engaging experienced development and manufacturing partners early. Organisations with established networks can help connect sponsors with the right clinical sites, service providers, logistics partners and regulatory experts, creating a more coordinated pathway from development through to commercialisation.

At Cell Therapies, we've seen the benefits of this approach firsthand. When manufacturing, clinical and supply chain planning are aligned early, sponsors can accelerate development timelines, reduce operational complexity and position themselves for successful expansion beyond Australia into the wider Asia-Pacific region and global markets.

Q6. Looking ahead, what emerging trends — automation, digital manufacturing, AI, decentralised production or advanced analytics — do you believe will have the greatest impact on the future of cell and gene therapy manufacturing in Australia and the wider Asia-Pacific region?

The trend I see having the greatest impact is automation. As cell and gene therapies move from small-scale clinical programs towards broader commercial adoption, the industry needs manufacturing processes that are more consistent, scalable and less dependent on highly specialised manual operations. Closed, automated manufacturing systems will be critical to achieving that.

Alongside automation, digital manufacturing has enormous potential. Many cell therapy manufacturing processes still rely heavily on paper-based systems, creating significant administrative and quality overhead. The adoption of electronic manufacturing execution systems and other digital platforms will improve traceability, strengthen compliance, and reduce the cost and complexity of manufacturing operations.

AI will also play an increasingly important role, particularly in process monitoring, quality management and data analysis. Cell therapy manufacturing generates large amounts of data, and AI-enabled tools can help organisations identify trends, optimise processes and make better-informed decisions more efficiently.

Another area where we expect to see progress is the standardisation of quality control testing. While many analytical approaches are already well established, there remains considerable variation between programs. Greater standardisation of assays and quality frameworks could improve efficiency while maintaining the rigorous standards regulators and patients expect.

For the Asia-Pacific region specifically, decentralised manufacturing remains an exciting long-term opportunity given the geography and logistical challenges involved in delivering personalised therapies. However, success will depend not only on technology but also on the development of the regulatory frameworks, workforce capabilities and quality systems needed to support consistent manufacturing across multiple locations.

Ultimately, the organisations that succeed will be those that combine automation, digital technologies and strong quality systems to make advanced therapies more scalable, accessible and cost-effective for patients.