CGT MANUFACTURING LANDSCAPE IN SINGAPORE:

CURRENT CHALLENGES AND FUTURE LANDSCAPE

Interest in cell and gene therapy (CGT) has grown. However, challenges remain in scaling this therapy in recent years due to a **lack of manufacturing process standardization** and **limited investments** stemming from stringent approval processes from relevant authorities. Singaporean stakeholders seek to address these issues by implementing a **standardization framework and establishing a robust local CGT manufacturing ecosystem.**

CURRENT LANDSCAPE AND CHALLENGES IN THE MARKET

The worldwide cell and gene therapy market was **valued at USD 12bn in 2022 and is projected to reach USD 82bn by 2032**, exhibiting a robust compound annual growth rate (CAGR) of 18%. Despite this significant growth on a global scale, **Singapore's contribution remains minimal due to specific challenges hindering the scaling of these therapies in the local market**. The two primary challenges are:

Difficulty in obtaining approval due to lack of standardization	▪ Unlike small molecule drugs, which are often chemically synthesized and produced at scale (constituting about 90% of pharmaceutical drugs), scaling up CGT products is challenging due to the absence of a standardized process in Singapore. ▪ Due to this lack of a standardized process, getting approval from regulatory bodies for manufacturing these products becomes extremely difficult.
Lack of investments	▪ In 2022, despite increasing interest in CGT globally, investment in the sector declined significantly, with an 87% decrease in equity offerings and a 33% drop in venture funding in Singapore. ▪ The slowdown in the 'biotech bubble' is attributed to investors prioritizing clinical validation of initial technology investments.

FUTURE LANDSCAPE: KEY RECOMMENDATIONS AND MEASURES

To address the present challenge of scaling CGT in Singapore, efforts are being made to **standardize the value chain** at every step and **establish a local ecosystem** for production. The 2 steps have been described below in detail:

1. Framework for standardization of value chain

A notable challenge in transitioning from scientific innovation to commercialization in the realm of CGTs is the inherently unpredictable and variable nature of the production process. To effectively navigate unforeseen circumstances in their value chains, the government in Singapore recommends players in the CGT sector to embrace unpredictability by working on these five key dimensions:

Quality, safety, and regulatory standards, standardization efforts for CGT must align with industry standards and Good Manufacturing Practice (GMP) frameworks.

A **robust monitoring and traceability system** that includes **chain of identity (COI) and chain of custody (COC)**. COI uses unique identifiers to trace products from donor to recipient, ensuring transparency and verifiability in the entire patient journey. COC complements COI by tracking the product's journey in detail

Enhance **resilience, introduce flexibility in processes and decisions for adaptation** to evolving situations including standardizing risk mitigation and cross-training stakeholders.

Improve **patient-centricity**, conduct 'voice of the customer' assessments to gather input from patients, physicians, and hospitals regarding the CGT patient journey.

Achieve effective **business continuity management**, it is crucial to plan for contingencies – particularly high impact scenarios – in collaboration with all stakeholders. Clear guiding principles must be established for issue escalation, and alternative arrangements for transportation and logistics should be put in place where possible.

2. Development of a local ecosystem

In pursuit of this objective, Advanced Cell Therapy and Research Institute, Singapore (ACTRIS) and SCG Cell Therapy Pvt. Ltd. have invested in establishing manufacturing facilities in Singapore in 2023.

ACTRIS sets up CGT manufacturing in Singapore	▪ **ACTRIS** has established a 2,000-sqm cell therapy facility in Singapore to address the increasing demand for CGT. ▪ ACTRIS will foster increased collaborations between the public and private sectors, enabling CGT companies in securing fastrack regulatory approvals for introducing their CGT products to Singapore.
SCG Cell Therapy company also opens a new CGT facility	▪ In addition, **SCG Cell Therapy** inaugurated a GMP-certified cell therapy facility and R&D center at its Singapore headquarters. The facility serves affiliated medical institutions globally, advancing the company's capabilities in advanced cell therapy and pluripotent stem cell technology.
ACTRIS and Agilent Technology signed an MoU for a 3 year long collaboration	▪ In September 2023, **Agilent Technologies Inc**. and **ACTRIS** entered a Memorandum of (MoU) Understanding9 for a three-year collaboration in advancing CGT. ▪ The partnership involves deploying Agilent's technologies at ACTRIS' national facility and provides early access to new platforms, aiming to enhance therapeutic development and broaden patient access to cell-based therapies in immunotherapy and precision medicine.

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