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South Koreaâ??s Cell and Gene Therapy Surge

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South Koreaâ??s cell and gene therapy (CGT) landscape is highly dynamic, as observed from regulatory approvals, clinical development, and manufacturing activity. The Ministry of Food and Drug Safety (MFDS) has approved 15 CGT products to date, including 12 cell therapies and three gene therapies, indicating a conducive environment for CGT development. However, it is important to note that most developments and approvals have been concentrated in regenerative stem cell therapies, with comparatively fewer developments in more complex ones, such as in vivo gene editing and in vivo engineered cell therapies.

South Korea's CGT ecosystem is diverse and expanding, with a good mix of both early-stage startups, large pharma collaborations, and globally renowned Contract Development and Manufacturing Organisation (CDMOs).

Startups such as ENCell, Helixmith, TiCARos, and SillaJen are advancing a diverse CGT therapy pipeline, including stem cell therapies, CAR-T therapies, and engineered oncolytic viruses for oncology and rare disorders. Many indigenous gene therapy candidates are rapidly moving across phases of clinical development, and a good example is ENCell, which received approval from the MFDS for a phase 2a clinical trial for its allogeneic umbilical cord-derived mesenchymal stem cells(MSCs) EN001 for Charcot-Marie-Tooth disease. The same candidate is also moving further in clinical trials for sarcopenia.

Helixmith's lead candidate, Engensis (VM202), is a non-viral DNA therapy in Phase 3 trials for multiple neurodegenerative indications. SillaJen, a relatively well-established biotech, is also advancing its oncolytic virus-based immunotherapies, with its platform technology enabling targeted cancer treatment through engineered viruses.

Several engineered cell therapies in development, and TiCARos, a developer of next-gen CAR-T and CAR-NK therapies, received an MFDS approval in January 2026 to carry out Phase 2 clinical trials for its follicular lymphoma (FL) candidate TC011.

In addition to a promising clinical pipeline, there is a notable shift in biotech R&D, where several biotech companies are reprioritising their portfolios and shifting their focus toward CGT development and commercialisation. For instance, CHA Biotech's recent decision to deprioritise traditional vaccine development and pivot toward CGT and CDMO expansion highlights a broader trend in South Korea- to reallocate resources toward high-value, advanced modalities. With this renewed focus on CGTs, CHA Biotech aims to improve access to CGTs and reduce the costs of these products to 1/10th of current costs.

Alongside startups, large biopharma players are crucial to build Korea's global position in advanced modality manufacturing, with Samsung Biologics, Celltrion, and global CDMOs such as Thermo Fisher strengthening their capabilities in the nation. Thermo Fisher Scientific established a Cell and Gene Therapy Vision Centre in South Korea in May 2025, aimed at supporting biopharma companies across the CGT value chain, from R&D to manufacturing and commercialisation. Bayer is expanding its CGT efforts across the Asia-Pacific region, with Korea chosen as a strategic clinical development hub and market to improve patient access. This combination of agile startups and industrial-scale players helps establish a balanced ecosystem to foster both innovation and commercialisation.

Capacity Expansion, Workforce Training, and Digitalisation are Transforming CGT Manufacturing

South Korea is well known for its advanced biomanufacturing capability, and the nation is building capacity, along with investments in automated, AI-integrated processes to support CGT manufacturing. A recent example is Karis Bio's partnership with Cellino to support first-in-human trials and scale up production of its personalised iPSC cells for cardiovascular diseases using Cellino's automated platform.

CGT workforce training is one of the most critical bottlenecks of CGT manufacturing, and collaborations such as the one between Terumo Blood and Cell Technologies and the Osong Medical Innovation Foundation (KBIOHealth), focused on workforce training programmes for MSCs and CAR-T manufacturing, aim to standardise training protocols and address talent gaps.

Bio-clusters such as Songdo and Osong are evolving into integrated ecosystems to support combining R&D, manufacturing, and clinical development. Infrastructure expansion is happening in parallel to build capacity to meet the growing demands for CGT and other advanced modalities. Samsung Biologics is one of the world's largest CDMOs, providing end-to-end biologics development and manufacturing services, with capacity exceeding 845,000 litres, where more than 90 per cent of manufacturing takes place locally across the five plants in South Korea. The company is further investing in capacity expansion within Korea and the US.

Other CDMOs such as Matica Biolabs, a CHA Biotech subsidiary, are also building end-to-end CGT manufacturing capability, and recently entered an agreement with TiCARos to manufacture material for CAR-T candidate TC091.

These developments point toward a broader transformation of South Korea's biomanufacturing landscape, which is not only focused on capacity expansion but also capability building to align with the dynamic and complex needs of CGTs.

Hub for Clinical Trial Infrastructure

In addition to R&D and product development, South Korea is a growing hub for clinical trials for cell therapies, with a wide network of clinical trial centres. Seoul alone accounts for a large number of clinical studies worldwide. Many biotech companies are participating in multiregional clinical trials and global regulatory filings for their CGT candidates. In 2025, Novotech partnered with Acrostar and Kyungpook National University Hospital to strengthen the clinical trial footprint in South Korea. Such partnerships are enhancing South Korea's ability to support both domestic innovation and global trials, enabling companies to generate reliable data in a relatively compressed timeframe.

The Role of Innovation Clusters

South Korea's bio-clusters, particularly Songdo, Pangyo Techno Valley, and Osong Medical Industrial Complex, are evolving into integrated ecosystems to support research, clinical development, and manufacturing. Songdo Bio-Cluster is a global manufacturing hub with companies like Samsung Biologics, Cytiva, and Celltrion building capabilities and accelerating momentum.

CHA Biotech's collaboration with the Cambridge Innovation Centre (CIC) to establish the Cell Gene Biobank (CGB), an innovation hub in Pangyo Techno Valley, is a major step toward building a local innovation hub at par with global standards. The facility, which aims to begin operations in Q2 2026, will support open innovation by providing shared lab space, equipment, and networking opportunities, thereby lowering entry barriers for early-stage biotech companies and accelerating commercialisation. In addition to lab space, the startups will also have access to CHA's CDMO sites in Europe and the US, along with its affiliated CRO network.

Poised to Emerge as one of the Global CGT Leaders

South Korea's ambition to become a top destination for CGTs is visible in its efforts to transition from a manufacturing-centric model to an innovation-driven ecosystem. With continued investment in R&D, manufacturing infrastructure, and workforce development, it is well-positioned to become a global leader in CGT and other advanced modalities.

Despite rapid progress, South Korea's CGT sector faces few challenges, including intensifying competition from the US and China. In addition, regulatory frameworks need to be more flexible to enable accelerated translation of advanced CGTs, especially those involving in vivo gene editing and those acting on the germline. The revised Advanced Regenerative-Bio Act, implemented in 2025, allows broader application of regenerative therapies and will nurture the development of such therapies. However, the Advanced Regenerative-Bio Act only permits ex vivo gene editing, while in vivo editing needs careful evaluation. By largely limiting gene editing to ex vivo approaches and only somatic cells, the framework does not fully accommodate the next wave of CGTs. Regulatory evolution needs to keep pace with scientific advances for South Korea to launch next-generation CGT candidates.

At the same time, deeper collaboration within the APAC region and broader global CGT ecosystem will be critical. Strategic R&D collaborations, manufacturing agreements, and clinical trial partnerships will support the nation in amplifying its strengths and mitigating gaps for large-scale commercialisation.

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