Cell Culture Technology

Weekly Intelligence Report

2026-05-18 | 24 articles | 7 countries

troy-technical.jp

This Week's Keyword

Biomanufacturing Shift

AI, Automation, & Supply Chain Reshaping

24	7	25-40	99
articles	countries	%	%
Total Articles Analyzed	Source Countries	Plant Capacity Boost (AI)	hcDNA Reduction (AAV)

All 24 Articles This Week — 5-Axis Evaluation Matrix

How to read columns — Tech Novelty: degree of breakthrough Market Proximity: closeness to commercialization Market Impact: industry-wide effect Data Reliability: quantitative data & peer review US/EU Relevance: direct impact on US/European companies & supply chains

#	Article Title	Type	Tech Novelty	Market Proximity	Market Impact	Data Reliability	US/EU Relevance	Summary
#01	Thermo Fisher Bioreactor	New Product	3	4	4	2	4	Thermo Fisher launched a single-use bioreactor and bioprocess design center to streamline cell/gene therapy manufacturing.
#02	FDA CMC Guidance	Regulatory Update	1	4	4	3	4	FDA finalized flexible CMC guidance for cell and gene therapies, expediting development and patient access.
#03	CGT Industrialization	Market Overview	2	3	4	2	4	Conference highlighted CGT industrialization via automation, modular facilities, and AI for quality control.
#04	Meatly Cultivated Meat	Corporate Strategy	3	3	4	3	4	Meatly secured $14M for Europe's largest cultivated meat facility in London, targeting pet food with reduced costs.
#05	Advanced PCR Strategies	Technology Analysis	3	4	3	2	4	Advanced PCR (dPCR, dcPCR) is crucial for precise DNA quantification in cell/gene therapy quality control.
#06	CDMO Sector Expansions	Corporate Strategy	2	4	4	2	4	CDMOs Andelyn Biosciences launched an LVV platform, and Made Scientific partnered with RoosterBio for MSC/EV manufacturing.
#07	Aldevron & Minaris Plasmid	Corporate Strategy	1	4	4	2	4	Aldevron and Minaris renewed their lentiviral plasmid agreement, bolstering CGT raw material supply chain.
#08	Bioscibex SW1NGO Bioreactor	New Product	3	4	3	2	4	Swiss Bioscibex ships SW1NGO single-use bioreactor-incubators to streamline bioprocess seed trains.
#09	Roche & NVIDIA AI Factory	Technology Adoption	4	3	4	3	4	Roche and NVIDIA launched an AI factory with Omniverse digital twins to optimize GLP-1 pharma manufacturing, boosting capacity.
#10	Cytiva ELEVECTA Cell Line	New Product	4	4	4	3	4	Cytiva's ELEVECTA cell line received FDA AMT designation for AAV manufacturing, reducing host cell DNA by 99%.
#11	Korean Biotech Giants	Corporate Strategy	1	4	3	3	4	Samsung Biologics sees record growth but faces labor risks, while Celltrion expands global CDMO presence.
#12	CellFiber & Locus Cell MSC	Technology Adoption	3	4	4	2	3	CellFiber and Locus Cell established commercial-scale UC-MSC manufacturing using advanced 3D culture technology.

#	Article Title	Type	Tech Novelty	Market Proximity	Market Impact	Data Reliability	US/EU Relevance	Summary
#13	BIOSECURE Act & Korea	Regulatory Impact	Low	High	High	Med-High	High	US BIOSECURE Act is shifting biopharma supply chains from China to South Korean API and oligo CDMOs.
#14	Korea Pre-Approval Therapy	Regulatory Update	Low	High	High	Med-High	Med-High	South Korea approved its first 'pre-approval therapy' plan for advanced regenerative medicine, broadening patient access.
#15	Helios ARDS Therapy & CDMO	Corporate Strategy	Med	Med-High	Med-High	Med	Med-High	Helios advances ARDS therapy approval and builds a new Kobe manufacturing hub for regenerative medicine CDMO.
#16	Ajinomoto Culture Medium	New Product	High	Med-High	High	Med-High	High	Ajinomoto developed a novel culture medium supplement to significantly boost gene therapy drug productivity.
#17	Terumo BCT & Steminent MSC	Corporate Strategy	Med-High	High	Med-High	Med	High	Terumo BCT and Steminent partnered to automate MSC manufacturing for late-stage clinical commercialization.
#18	AIST Culture Media Analysis	Research	High	Med	High	High	High	AIST developed a novel AI-driven multifluorescent polymer sensor for rapid, holistic cell culture media quality analysis.
#19	ProBio & Curocell CAR-T	New Product	High	High	High	High	High	ProBio and Curocell received BLA approval for their next-gen CD19 CAR-T therapy, initiating commercial production in Korea.
#20	SuperMeat Funding	Corporate Strategy	Med-High	Med-High	Med-High	Med-High	High	SuperMeat secured $6M to accelerate cultivated chicken commercialization for Swiss market entry, partnering with Ajinomoto.
#21	Form Bio FormManufacturing	New Product	High	High	High	Med	High	Form Bio launched FormManufacturing, an AI-driven platform to optimize genetic medicine design and manufacturing.
#22	Pharma Membrane Filter	Market Overview	Low	High	Med-High	Med-High	Med-High	Market report highlights growth in pharmaceutical membrane filtration driven by continuous bioprocessing and regulations.
#23	3D Bioprinting Organoids	Technology Analysis	High	Med	High	Med	High	Advanced 3D bioprinting techniques are driving progress in organoid and tissue development for drug discovery.
#24	Lonza Q1 Performance	Corporate Strategy	Low	High	High	High	High	Lonza reported strong Q1 2026, driven by CDMO growth and strategic transformation into a pure-play biopharma partner.

High Med-High Med Low | Yellow highlight = featured article

Three Questions That Demand Your Decision This Week

❶ Is your biomanufacturing strategy AI-ready?

Roche and NVIDIA are deploying digital twins to boost plant capacity by 25-40% and cut lead times by 15-20% (#09). Form Bio also launched an AI platform for genetic medicine optimization (#21). Are your operations leveraging AI to this extent, or are you falling behind in efficiency and speed?

❷ How exposed is your supply chain to geopolitical shifts?

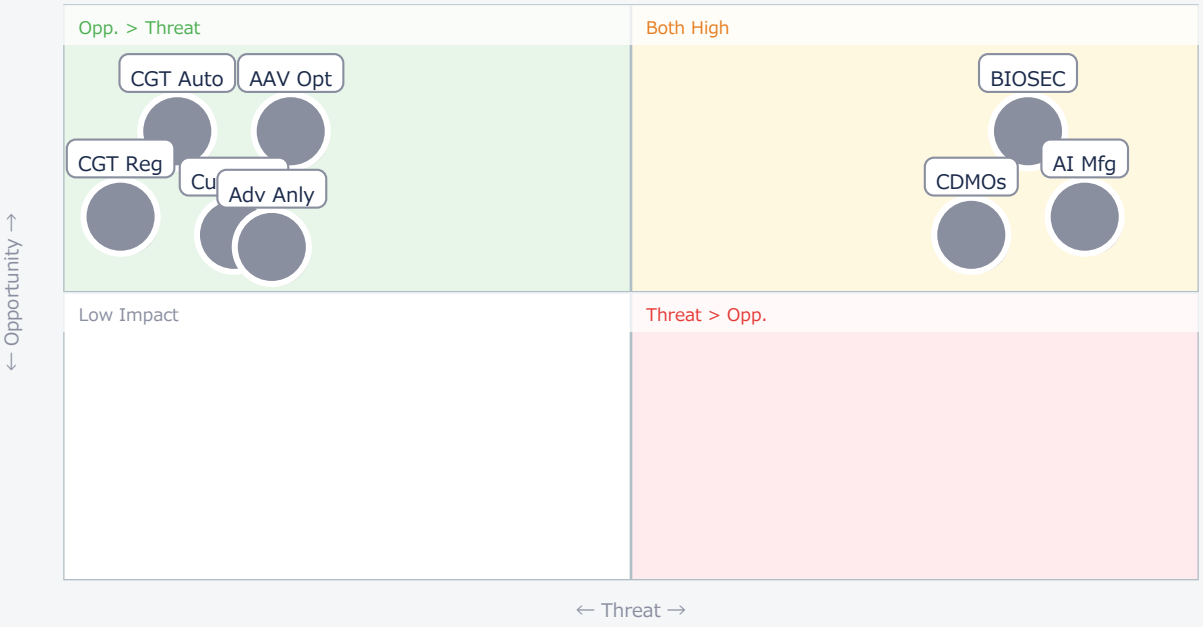
The US BIOSECURE Act is forcing a rapid diversification of biopharma supply chains away from China, creating massive opportunities for South Korean CDMOs in API and oligonucleotide manufacturing (#13). Have you identified and secured alternative, compliant suppliers for critical raw materials before 2028 restrictions tighten?

❸ Can your CGT manufacturing match new regulatory flexibility?

The FDA's finalized guidance on CMC flexibility for cell and gene therapies aims to expedite market access (#02). South Korea has also approved its first 'pre-approval therapy' plan (#14). Are your internal processes and CDMO partners agile enough to leverage these new pathways for faster commercialization, or will competitors gain a critical time-to-market advantage?

Opportunities vs. Threats for US/European Companies

Opportunity vs. Threat Matrix for US/European Companies



Item	Quadrant	↑ Opportunity	↓ Threat
● CGT Auto	Opp.	Streamline mfg	Slow adoption
● CGT Reg	Opp.	Faster approval	Missed speed
● BIOSEC	Critical	Diversify supply	Geopolitical risk
● AI Mfg	Critical	Optimize mfg	Competitor lead
● CultMeat	Opp.	New food market	Regulatory hurdles

AAV Opt	Opp.	Boost yield/qual	Lagging tech
CDMOs	Critical	Expand services	Asian competition
Adv Anly	Opp.	Better QC	Missed insights

Deep Dive ① — Next-Gen CAR-T Commercialization

#19 | 2026/05/11 | ProBio CDMO | Tech Novelty●●●●○ Proximity●●●●● Market Impact●●●●○ Data Reliability●●●●○ US/EU Relevance●●●●○

ProBio CDMO and Curocell secured BLA approval for Anbal-cel, a next-generation CD19-targeted CAR-T cell therapy for relapsed/refractory DLBCL. Clinical trials showed an 82% overall response rate, enhanced by Curocell's OVIS™ platform suppressing immune checkpoints.

ProBio achieved Korea's first GMP certification for a lentiviral vector facility, enabling seamless commercial manufacturing. This milestone highlights South Korea's growing innovation and capability in advanced therapies, offering a new treatment option for critical unmet needs.

▶ Strategic Analyst's Perspective

Strategic Analyst's Perspective: The 82% response rate for Anbal-cel is impressive and suggests a highly effective therapy, likely due to the OVIS™ platform. This commercialization in South Korea is a significant [Opportunity] for Asian CDMOs to gain market share and expertise in advanced cell therapies, potentially challenging US/EU dominance. For US/EU OEMs & device manufacturers, this represents a [Threat] of increased competition from Asian players with robust manufacturing capabilities and innovative platforms. Technical barriers for CAR-T remain in cost and scalability, but this approval shows progress. Next actions: [R&D;] Evaluate OVIS™ platform's technical advantages by Q3 2026. [Business Dev] Explore potential licensing or partnership opportunities with Curocell or similar Asian innovators by Q4 2026. [Strategy] Assess competitive landscape shifts in CAR-T manufacturing by end of year.

Deep Dive ② — AI & Digital Twins for Pharma Manufacturing

#09 | 2026/05/08 | IntuitionLabs | Tech Novelty●●●●○ Proximity●●●○○ Market Impact●●●●● Data Reliability●●●○○ US/EU Relevance●●●●●

Roche partnered with NVIDIA to establish a 3,500+ GPU AI factory, deploying Omniverse digital twins for an upcoming GLP-1 manufacturing facility. This integrates AI and simulation to optimize entire production lines, from chemical processes to robotics.

Industry analysts project this digital twin adoption could boost plant capacity by 25–40% and cut design/validation lead times by 15–20%. This signals a major technological leap in pharmaceutical development and manufacturing, moving towards proactive, predictive optimization.

▶ Strategic Analyst's Perspective

Strategic Analyst's Perspective: The projected 25-40% capacity increase and 15-20% lead time reduction are highly ambitious but plausible given the power of AI/digital twins for complex systems. The main technical barrier is the integration of diverse data streams and the development of accurate simulation models. This is a massive [Opportunity] for US/EU OEMs & device manufacturers to lead in next-gen pharma manufacturing, and for Technology licensors and IP holders to develop and license AI/simulation platforms. Conversely, it's a significant [Threat] to companies that fail to invest in and adopt these advanced technologies, risking obsolescence and loss of competitive edge. Next actions: [Executive] Mandate a cross-functional task force to evaluate AI/digital twin adoption roadmap by Q3 2026. [R&D;] Pilot digital twin projects for critical manufacturing lines by Q1 2027. [Procurement] Identify key AI/simulation platform providers and talent by Q4 2026.

Deep Dive ③ — AI-Driven Culture Media QC Breakthrough

#18 | 2026/05/13 | AFPBB News | Tech Novelty●●●●● Proximity●●○○○ Market Impact●●●●○ Data Reliability●●●●● US/EU Relevance●●●●○

Japan's AIST developed a novel analytical technology for cell culture media quality using multifluorescent polymers and AI. This sensor detects holistic fluorescent patterns, which machine learning then uses to identify subtle differences and changes.

Unlike conventional component-by-component analysis, this innovation simplifies pre-culture quality checks, prevents costly culture failures, and enhances overall biomanufacturing product quality. This represents an academic breakthrough with high reliability data.

▶ Strategic Analyst's Perspective

Strategic Analyst's Perspective: This AIST breakthrough is highly novel and the concept of holistic media analysis via AI is very realistic, addressing a critical pain point in biomanufacturing. The primary technical barrier is translating this lab-stage research into robust, high-throughput commercial instruments. This presents a significant [Opportunity] for US/EU Materials & component suppliers to integrate this technology into their media offerings or for Technology licensors to develop and license analytical platforms. However, it's a [Threat] if US/EU companies are slow to adopt or develop similar advanced QC methods, leading to higher failure rates or inconsistent product quality compared to competitors. Next actions: [R&D;] Initiate internal research or academic partnerships to replicate/advance this technology by Q4 2026. [Procurement] Monitor emerging analytical solutions for culture media quality, engaging with AIST or similar research groups by Q1 2027. [Strategy] Assess the long-term impact on biomanufacturing cost and quality control paradigms.

Other Notable Articles

#01 Thermo Fisher Bolsters Cell Therapy Manufacturing with New Single-Use Bioreactor and Integrated Bioprocess Hub (Simply Wall St)
Tech Novelty●●●○○ Proximity●●●●○ Market Impact●●●●○

New single-use bioreactor and bioprocess hub from a US leader streamlines CGT manufacturing, enhancing scalability.

#02 FDA Finalizes Guidance on CMC Flexibility for Cell and Gene Therapies, Expediting Access to Advanced Treatments (Regulatory Focus)
Tech Novelty●○○○○ Proximity●●●●● Market Impact●●●●●

FDA's flexible CMC guidance for CGT is a critical regulatory update, accelerating market access for US/EU developers.

#04 Meatly Secures $14M Series A to Build Europe's Largest Cultivated Meat Facility in London (Green Queen Media)
Tech Novelty●●●○○ Proximity●●●○○ Market Impact●●●●○

UK firm Meatly's funding for Europe's largest cultivated meat plant signals major progress in alternative protein scale-up.

#13 BIOSECURE Act Reshapes Biopharma Supply Chains, Driving API and Oligo CDMO Expansion in South Korea (CHOSUNBIZ)
Tech Novelty●○○○○ Proximity●●●●● Market Impact●●●●●

US BIOSECURE Act is a game-changer, forcing supply chain diversification and boosting Korean CDMOs for critical raw materials.

#25 Lonza Reports Strong Q1 2026 Performance, Driven by Robust CDMO Growth and Strategic Transformation into Pure-Play Biopharma Partner (Lonza)
Tech Novelty●○○○○ Proximity●●●●● Market Impact●●●●○

Lonza's strong Q1 and pure-play CDMO focus highlight the critical role of specialized partners in biopharma manufacturing.

Recommended Actions This Week

Action recommendations based on article evaluation matrix and opportunity/threat analysis.

Immediate (this week)

- [Executive] Review implications of FDA's new CMC guidance (#02) for all ongoing CGT programs and pipeline assets.
- [Procurement] Initiate an urgent audit of all Chinese-sourced API and oligonucleotide suppliers in light of the BIOSECURE Act (#13) and identify immediate alternatives.

Short-term (1 month)

- [R&D;] Form a cross-functional team to assess the feasibility and ROI of integrating AI/digital twin technologies into a pilot manufacturing line (#09, #21).
- [Strategy] Benchmark current biomanufacturing automation levels against new single-use bioreactor systems and integrated bioprocess hubs (#01, #08).
- [Business Dev] Investigate potential partnerships or acquisitions of cultivated meat technology firms, especially those targeting European markets (#04, #20).

Medium-long term (quarter+)

- [R&D;] Launch internal projects or academic collaborations to develop advanced culture media analysis technologies, leveraging AI and novel sensors (#18).
- [Legal/IP] Monitor global regulatory shifts, particularly 'pre-approval therapy' models (#14), and assess their impact on future market entry strategies.
- [Procurement] Develop a robust, diversified CDMO strategy, considering specialized Asian partners for viral vectors and cell therapies to mitigate supply chain risks (#06, #07, #11, #15, #24).

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CellCultureTechnology — Selected Articles

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Articles: 24

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#21 SuperMeat Secures $6M in Funding, Accelerating Commercialization of Cultivated Chicken for Swiss Market Entry

#22 Form Bio Launches FormManufacturing: An AI-Driven End-to-End Platform for Genetic Medicine Design and Manufacturing Optimization

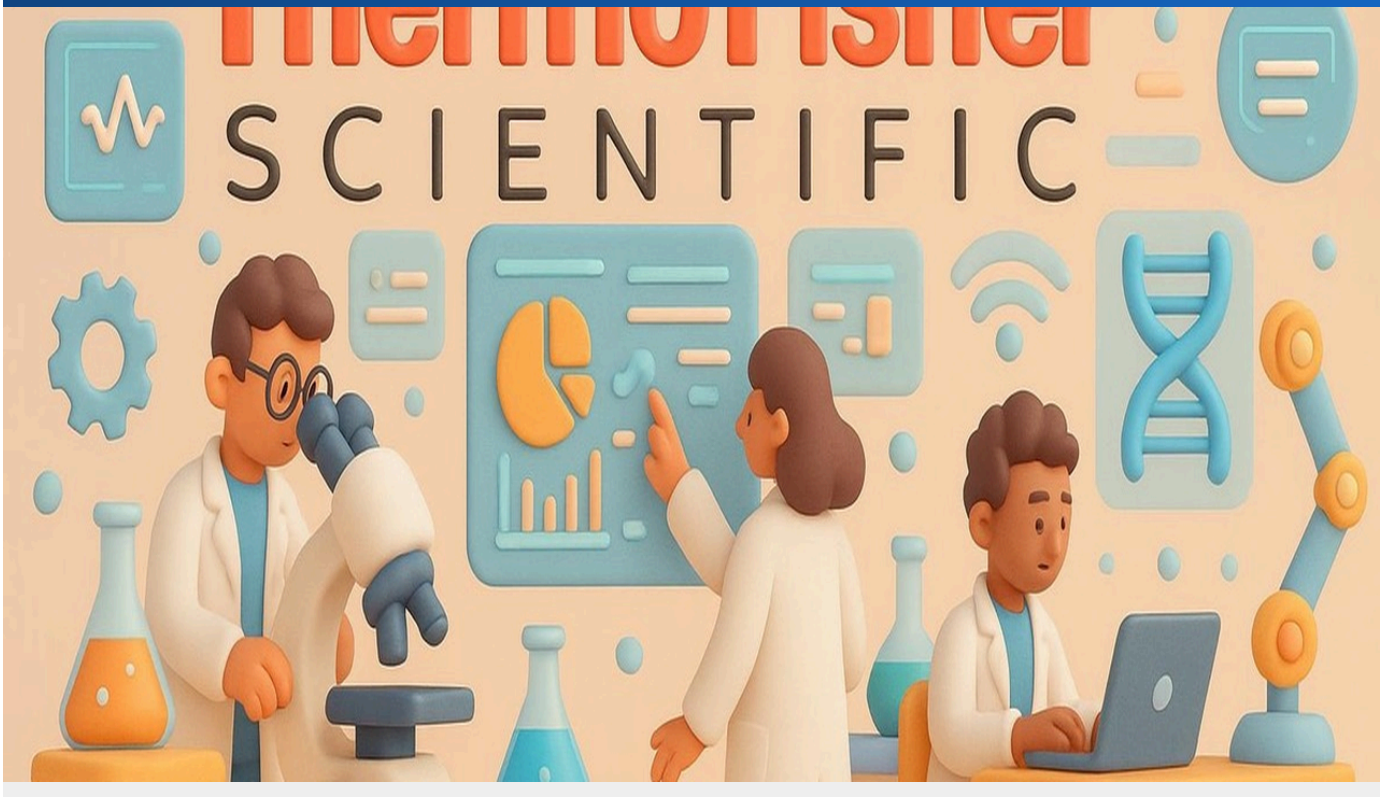
#23 Pharmaceutical Membrane Filtration Market: Size, Share, and Growth Forecast to 2034 – A Straits Research Overview

#24 Advanced 3D Bioprinting Techniques Drive Progress in Organoid and Tissue Development for Regenerative Medicine and Drug Discovery

#25 Lonza Reports Strong Q1 2026 Performance, Driven by Robust CDMO Growth and Strategic Transformation into Pure-Play Biopharma Partner

Thermo Fisher Bolsters Cell Therapy Manufacturing with New Single-Use Bioreactor and Integrated Bioprocess Hub

Published May 08, 2026 Simply Wall St USA



OVERVIEW

Thermo Fisher Scientific has launched the Gibco CTS DynaXS Single Use Bioreactor, engineered for scalable and precise cell therapy manufacturing, alongside a new U.S. Bioprocess Design Center. This strategic expansion offers developers an end-to-end solution for cell and gene therapy (CGT) workflows, from early research to commercial production, streamlining process design, cGMP compliance, and scaling operations. These advancements reinforce Thermo Fisher's market position as a comprehensive bioproduction partner, critical for accelerating the commercialization of advanced therapies.

IN DEPTH

Background and Strategic Imperatives

The cell therapy landscape is rapidly expanding, driven by breakthroughs in oncology and regenerative medicine. However, the path from discovery to commercialization is fraught with manufacturing challenges, particularly concerning scalability, cost-efficiency, and stringent regulatory compliance. Companies like Thermo Fisher Scientific are actively addressing these bottlenecks by developing integrated solutions that span the entire bioproduction workflow.

Thermo Fisher's recent announcements underscore a strategic commitment to the cell and gene therapy (CGT) sector. The introduction of a new single-use bioreactor and the establishment of a dedicated bioprocess design center are poised to significantly impact how cell therapies are developed, scaled, and brought to market.

Key Innovations and Offerings

The newly launched **Gibco CTS DynaXS Single Use Bioreactor** is designed to facilitate the transition of cell therapy manufacturing from research-grade to clinical and commercial scales. Key features include:

- **Scalability:** Enables seamless expansion across various volumes, from process development to cGMP manufacturing, crucial for diverse cell therapy applications.
- **Precise Control:** Offers advanced control over critical process parameters, ensuring consistent product quality and yield, which is paramount for sensitive cell products.
- **Flexibility:** Its adaptable design supports a broad range of cell types and culture strategies, allowing developers to optimize processes for specific therapeutic modalities.
- **Regulatory Readiness:** Engineered with cGMP requirements in mind, the system integrates features that simplify documentation and accelerate regulatory submissions.

Complementing this product launch is the inauguration of a flagship **U.S. Bioprocess Design Center** in Plainville, Massachusetts. This facility will serve as a hub for collaborative development, offering customers expertise in process design, cell line optimization, media development, and analytical services. The center aims to provide end-to-end support, fostering innovation and de-risking the complex journey of biologics development.

Technical Significance and Market Outlook

These initiatives are technically significant as they address fundamental limitations in current CGT manufacturing. Single-use bioreactors mitigate cross-contamination risks and enhance operational flexibility, making them ideal for the personalized and often small-batch nature of cell therapies. The integrated design center further streamlines development by providing a centralized resource for optimizing highly variable biological processes. This holistic approach, from media and cell line development to advanced single-use systems and analytics, can significantly reduce development timelines and manufacturing costs.

From a market perspective, Thermo Fisher's expanded footprint in CGT positions it as a critical enabler for the broader biopharmaceutical industry. By offering comprehensive solutions, the company aims to capture a larger share of the rapidly growing CGT market, which is projected to reach tens of billions of dollars within the next decade. For investors, these strategic investments signal a deepening commitment to high-growth sectors, enhancing the company's long-term value proposition and cementing its role in bringing life-saving cell therapies to patients worldwide.

Source: https://simplywall.st/stocks/us/pharmaceuticals-biotech/nyse-tmo/thermo-fisher-scientific/news/thermo-fishers-new-cell-therapy-bioreactor-and-bioprocess-hu

FDA Finalizes Guidance on CMC Flexibility for Cell and Gene Therapies, Expediting Access to Advanced Treatments

Published May 08, 2026 Regulatory Focus USA

OVERVIEW

The U.S. FDA has issued final guidance outlining flexible Chemistry, Manufacturing, and Controls (CMC) requirements for cell and gene therapy (CGT) products, recognizing their inherent complexities compared to traditional biologics. This guidance advocates for phase-appropriate GMPs, risk-based comparability studies, and tailored release criteria to streamline development and regulatory review. The aim is to accelerate patient access to safe and effective CGT products for serious conditions with unmet medical needs, providing crucial clarity for sponsors.

IN DEPTH

Background and Regulatory Imperative

Cell and gene therapy (CGT) products represent a paradigm shift in medicine, offering transformative potential for previously intractable diseases. However, their unique characteristics—such as living components, individualized manufacturing, and limited shelf life—present significant challenges for traditional Chemistry, Manufacturing, and Controls (CMC) frameworks. Regulators, including the U.S. Food and Drug Administration (FDA), have been working to adapt existing guidelines to foster innovation while ensuring product safety, quality, and efficacy.

This drive culminated in the FDA's recent issuance of a final guidance document. It provides immediate advice to sponsors on CMC flexibilities specifically tailored for CGT products submitted for Biologics License Applications (BLAs), aiming to bridge the gap between scientific advancement and regulatory practicality.

Key Provisions of the Guidance

The new FDA guidance emphasizes a flexible, risk-based approach to CMC requirements, acknowledging the dynamic nature of CGT development. Key components include:

- **Phase-Appropriate CGMPs:** Sponsors are encouraged to implement Current Good Manufacturing Practices (CGMPs) commensurate with the stage of product development. This allows for a less stringent application of certain requirements during early clinical phases, gradually increasing in rigor as products advance towards commercialization.
- **Risk-Based Comparability Studies:** For manufacturing process changes, the guidance supports a risk-based approach to comparability studies. This means the scope and depth of these studies should be proportionate to the potential impact of the change on product quality, safety, and efficacy, leveraging a thorough understanding of the product and process.
- **Tailored Release Acceptance Criteria:** Investigational CGT products can have release acceptance criteria that evolve with development, reflecting accumulating knowledge and data. This flexibility allows for adjustments as understanding of the product matures.

- **Quality by Design (QbD) Principles:** The guidance implicitly supports QbD, encouraging sponsors to build quality into the product and process from the outset, which facilitates the adoption of flexible CMC strategies.

These provisions are designed to reduce the regulatory burden where appropriate, allowing developers to focus resources on critical aspects of product quality and patient safety.

Industry Impact and Future Outlook

The FDA's final guidance is expected to significantly impact the CGT industry by providing much-needed clarity and predictability in the regulatory pathway. By formalizing CMC flexibilities, the agency aims to streamline development programs, reduce time-to-market, and lower the associated costs of bringing these complex therapies to patients. This is particularly crucial for smaller biotech firms and academic institutions that might lack the extensive resources of large pharmaceutical companies.

Globally, this move aligns with a broader trend among regulatory bodies to adapt to the unique challenges of advanced therapies. For instance, the European Medicines Agency (EMA) and other major regulators have also introduced adaptive pathways and scientific advice mechanisms to support CGT development. The FDA's action is anticipated to foster greater innovation and accelerate the delivery of potentially curative CGT products to patients suffering from serious or life-threatening conditions with limited treatment options, thereby fulfilling a critical unmet medical need.

Source: https://friendsofcancerresearch.org/news/regulatory-focus-fda-finalizes-guidance-on-cmc-flexibilities-for-cell-and-gene-therapies/

Collected: May 15, 2026 | Automated Research System (Gemini API)

Industrializing Cell & Gene Therapy Manufacturing: Key Takeaways from Advanced Therapies USA Conference

Published May 12, 2026 BioProcess International USA

OVERVIEW

The Advanced Therapies USA conference highlighted the critical shift in cell and gene therapy (CGT) manufacturing towards large-scale industrialization through process consolidation, closed automation, and modular facilities. Discussions emphasized integrating AI-driven real-time quality systems and adopting Quality by Design (QbD) from early development to ensure consistent product quality and reproducibility. This strategic focus aims to reduce operational complexity, accelerate commercialization, and improve patient access to advanced therapies by mitigating batch-to-batch variability, particularly for iPSC-derived treatments.

IN DEPTH

Background and the Urgency for Industrialization

The burgeoning field of cell and gene therapies (CGTs) holds immense promise for treating a wide array of diseases. However, translating these complex, often personalized, treatments from research breakthroughs to widely available commercial products faces significant manufacturing hurdles. The Advanced Therapies USA conference in May 2026 underscored a pivotal transition: moving beyond mere feasibility to establishing robust, scalable, and cost-effective manufacturing processes. The consensus was clear—industrialization is no longer optional but an urgent imperative for the sustainable commercialization of CGTs.

Traditional CGT manufacturing often relies on manual, open processes, leading to high variability, elevated costs, and limited scalability. The conference highlighted the industry's collective effort to overcome these challenges through strategic advancements in bioprocessing.

Key Discussions and Technical Advances

Central to the conference discussions were several interconnected strategies for achieving industrial-scale CGT manufacturing:

- **Process Consolidation and Closed Automation:** Speakers emphasized the need to reduce operational complexity by integrating discrete unit operations into streamlined, automated workflows. Implementing closed-system automation minimizes human intervention, thereby significantly reducing contamination risks and enhancing process reproducibility, critical for regulatory compliance.
- **Modular Facilities:** The development of modular, flexible manufacturing facilities was a key theme, allowing for rapid deployment and adaptable production capacities. This approach is particularly beneficial for accommodating the diverse and evolving needs of various CGT products.

- **Real-time Quality Systems and AI Integration:** The integration of artificial intelligence (AI) with real-time Process Analytical Technologies (PATs) was presented as essential for continuous quality monitoring and reducing batch-to-batch variability. For therapies derived from induced pluripotent stem cells (iPSCs), automated, closed-loop bioreactors are crucial to maintain phenotypic stability, shifting from end-of-process quality control to in-process assurance.
- **Early Manufacturing Readiness (Quality by Design - QbD):** A recurring motif was the importance of considering manufacturing readiness early in the development cycle, rather than as an afterthought. Adopting a Quality by Design (QbD) framework ensures that manufacturability, scalability, and quality attributes are engineered into the product and process from discovery, thus preventing costly delays in later stages.

Industry Impact and Outlook

The industrialization of CGT manufacturing carries profound implications for the entire biopharmaceutical ecosystem. Enhanced efficiency, reduced costs, and improved product consistency will not only accelerate regulatory approvals but also make these life-saving therapies more accessible and affordable for patients globally. This shift is crucial for CGTs to transition from bespoke treatments to a standard of care.

Furthermore, the focus on intensifying downstream purification and implementing advanced PATs reflects a maturing industry driven by the need for robust, high-quality products. The strategies discussed at the Advanced Therapies USA conference provide a clear roadmap for the CGT sector to achieve sustainable growth, meet global demand, and solidify its position as a cornerstone of modern medicine. This concerted effort towards industrialization is expected to establish new benchmarks for next-generation biopharmaceutical manufacturing.

Source: https://www.bioprocessintl.com/cell-therapies/industrialization-for-cgt-scalability-highlights-from-the-advanced-therapies-usa-conference

Meatly Secures $14M Series A to Build Europe's Largest Cultivated Meat Facility in London

Published May 08, 2026 Green Queen Media UK

OVERVIEW

British food tech firm Meatly has raised £10 million ($14.1 million) in Series A funding to construct a 20,000-liter cultivated meat pilot plant in London, set to become Europe's largest. The company, which focuses on cultivated chicken for pet food, has achieved significant cost reductions, bringing its protein-free growth medium to £0.22 per liter and bioreactor costs down tenfold. This investment underscores growing investor confidence in the cultivated meat sector and signals a major step towards commercial-scale production in Europe, with products slated for launch next year.

IN DEPTH

Background and the Cultivated Meat Industry Landscape

Cultivated meat, produced by growing animal cells in a bioreactor, presents a sustainable alternative to conventional livestock farming, promising reduced environmental impact and ethical benefits. However, its widespread commercialization has been hindered by substantial manufacturing costs, particularly associated with cell culture media and bioreactor infrastructure, as well as the inherent challenges of scaling production efficiently.

Meatly, a UK-based food tech company founded in 2021 (originally as Good Dog Food), has emerged as a key innovator in this space. By strategically focusing on the pet food market, which often has different regulatory and consumer acceptance pathways than human food, Meatly aims to accelerate its path to commercial viability. The company has demonstrated a consistent focus on technological advancements to dismantle these economic barriers.

Significant Funding and Production Expansion

Meatly recently announced the successful closure of its Series A funding round, securing £10 million (approximately $14.1 million). This capital injection is earmarked primarily for the construction of a 20,000-liter cultivated meat pilot plant in London. Upon completion, this facility will be the largest of its kind in Europe, representing a significant leap in the region's cultivated meat production capacity.

The funding round saw participation from new investors, including Oyster Bay Venture Capital, Clean Growth Fund, and JamJar Investments, alongside existing backers. This robust investment signals a renewed and growing investor confidence in the cultivated meat sector, particularly noteworthy given previous periods of fluctuating funding in the industry.

Cost Reduction and Path to Commercialization

A cornerstone of Meatly's strategy and success has been its systematic approach to cost reduction, which directly addresses the most significant barriers to cultivated meat commercialization:

- **Reduced Media Costs:** The company has achieved a breakthrough by lowering the cost of its chemically defined, protein-free growth medium to an unprecedented £0.22 per liter. This drastically cuts one of the largest expenditure categories in cultivated meat production, a critical step towards price parity with conventional meat.
- **Bioreactor Cost Efficiency:** Meatly has also reported a tenfold reduction in bioreactor costs, alleviating the capital intensity typically associated with scaling bioreactor-based biomanufacturing.
- **Regulatory Milestones:** In a landmark achievement for the European market, Meatly secured regulatory approval from the UK's Animal & Plant Health Agency in 2024, becoming the first company in Europe permitted to sell cultivated pet food. This regulatory success is a crucial prerequisite for market entry and large-scale commercial operations.

With these advancements, Meatly plans to launch new products from 2027, addressing the surging demand for sustainable protein alternatives. This development not only positions Meatly as a leader but also serves as a significant milestone for the broader cultivated meat industry in Europe, demonstrating the tangible progression from pilot to commercial-scale production.

Source: https://www.greenqueen.com.hk/meatly-lab-grown-cultivated-meat-pet-food-funding-facility-london/

Collected: May 15, 2026 | Automated Research System (Gemini API)

Advanced PCR Strategies Critical for Precision and Safety in Cell and Gene Therapy Development

Published May 12, 2026 Biocompare USA

OVERVIEW

Polymerase Chain Reaction (PCR) technologies are pivotal across the entire lifecycle of cell and gene therapy (CGT) product development, from early gene target validation to comprehensive quality and safety assessments. While quantitative PCR (qPCR) remains foundational, digital PCR (dPCR) and direct-count PCR (dcPCR) are enabling unprecedented precision in DNA quantification, crucial for vector copy number (VCN) assays and residual DNA detection. These advanced methods enhance process optimization and regulatory compliance, accelerating the delivery of safer and more efficacious CGTs.

IN DEPTH

Background and the Pervasive Role of PCR in CGT

The burgeoning field of cell and gene therapies (CGTs) promises revolutionary treatments for numerous diseases. However, the inherent complexity of these living therapies necessitates exceptionally precise and sensitive analytical tools at every stage of development and manufacturing. Polymerase Chain Reaction (PCR) technology, by its ability to specifically amplify DNA sequences, has become an indispensable component throughout the CGT lifecycle, spanning initial research, process optimization, and stringent quality control.

PCR's versatility allows for critical applications such as evaluating gene targets, confirming gene-editing efficiencies, assessing gene delivery techniques, and establishing robust assays for identity, purity, quality, and safety attributes of CGT products.

Diverse PCR Applications Across the CGT Development Pipeline

The utility of PCR in CGT development is multifaceted and integral to addressing key analytical needs:

- **Early Research and Discovery:** In foundational stages, PCR is crucial for validating gene targets, confirming the efficacy and specificity of gene-editing tools (e.g., CRISPR/Cas9 off-target analysis), and assessing initial gene delivery methods for early-stage constructs.
- **Process Development and Optimization:** As CGT products advance, PCR-based assays become critical for establishing identity (confirming cell type and transgene presence), purity (detecting adventitious agents or undesirable cell populations), quality (assessing transgene expression or functional integrity), and safety (screening for mycoplasma, adventitious viruses, and residual host cell DNA).
- **Vector Copy Number (VCN) Determination:** For CGT products utilizing integrating viral vectors (e.g., lentivirus, AAV), precise quantification of the therapeutic gene's integration into the cellular genome is vital. PCR-based VCN assays are employed to define acceptable integration levels, which directly correlates with therapeutic efficacy and safety.

- **Residual DNA and Adventitious Agent Detection:** Regulatory bodies demand rigorous testing for residual host cell DNA and potential viral contaminants. Highly sensitive PCR methods are key to ensuring that these critical quality attributes meet regulatory thresholds, preventing potential immunogenicity or oncogenicity.

Evolution of PCR Technologies for Enhanced Precision

While quantitative PCR (qPCR) remains a cornerstone, newer PCR methodologies have significantly advanced analytical capabilities in CGT:

- **Digital PCR (dPCR):** Unlike qPCR which relies on standard curves for relative quantification, dPCR partitions samples into thousands of individual reactions, allowing for the direct, absolute quantification of DNA molecules. This offers superior precision and sensitivity for low-abundance targets, making it ideal for accurate VCN determination, residual DNA detection, and characterization of rare genetic events without reliance on standard curves.
- **Direct-Count PCR (dcPCR):** Further extending the capabilities of dPCR, dcPCR methods enhance partitioning to enable true counting of DNA molecules without statistical estimations based on Poisson distribution. This provides even greater accuracy and confidence in absolute quantification, which is invaluable for stringent quality control and comparability studies in CGT manufacturing.

Technical Significance and Future Outlook

The adoption of these advanced PCR strategies is technically critical for developing robust and compliant CGT products. The enhanced sensitivity and precision offered by dPCR and dcPCR are particularly vital for detecting minute quantities of contaminants and accurately quantifying rare genetic integrations, ensuring the safety and consistent quality of cell and gene therapies. As the CGT pipeline matures and more products enter late-stage clinical trials and commercialization, these sophisticated PCR tools will continue to be central to meeting evolving regulatory expectations and guaranteeing therapeutic efficacy and patient safety worldwide. The global shift towards personalized medicine relies heavily on such precision analytics.

Source: https://www.biocompare.com/Editorial-Articles/625387-Choosing-the-Right-PCR-Strategy-in-

Cell-and-Gene-Therapy-Development/

CDMO Sector Sees Strategic Expansions: Andelyn Biosciences Launches LVV Platform, Made Scientific Partners with RoosterBio

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OVERVIEW

The biopharmaceutical contract development and manufacturing (CDMO) sector is experiencing significant strategic advancements, with Andelyn Biosciences unveiling its 'LVV curator platform' for standardized lentiviral vector (LVV) manufacturing. Concurrently, cell therapy CDMO Made Scientific and human mesenchymal stem cell (MSC) supplier RoosterBio have forged a partnership to integrate RoosterBio's MSC and extracellular vesicle (EV) manufacturing platforms into Made Scientific's services. These moves highlight efforts to streamline cell and gene therapy (CGT) production from process development to commercial-scale GMP manufacturing, enhancing scalability and comprehensive service offerings.

IN DEPTH

Background and Evolution of the CDMO Landscape

The rapid expansion of the biopharmaceutical industry, particularly within the cell and gene therapy (CGT) sector, has underscored the critical importance of Contract Development and Manufacturing Organizations (CDMOs). The manufacturing of CGT products demands highly specialized expertise, advanced facilities, and stringent adherence to regulatory requirements, leading many pharmaceutical and biotechnology firms to rely on CDMO partners. This dynamic environment fosters both competition and collaboration among CDMOs, accelerating the introduction of innovative technologies and service models.

Recent industry news highlights several key players bolstering their capabilities and forming strategic alliances to meet the evolving demands of this complex market.

Key Developments and New Service Offerings

This industry roundup features significant progress from the following entities:

- **Andelyn Biosciences' LVV curator platform:** Andelyn Biosciences, a CDMO specializing in cell and gene therapies, has launched its 'LVV curator platform.' This standardized lentiviral vector (LVV) manufacturing solution is designed to support both clinical and commercial adeno-associated virus (AAV) programs through a modular approach. The platform aims to enhance consistency and efficiency in vector manufacturing, addressing a crucial bottleneck in CGT production.
- **Made Scientific and RoosterBio Strategic Partnership:** Cell-therapy CDMO Made Scientific and RoosterBio, a prominent supplier of human mesenchymal stem cells (MSCs) and bioprocess services, have announced a strategic collaboration. This partnership integrates RoosterBio's well-established MSC and extracellular vesicle (EV) manufacturing platforms into Made Scientific's CDMO service offerings. This comprehensive integration will cover the entire spectrum of cell product manufacturing, from initial process development to commercial-scale GMP (Good Manufacturing Practice) production.

Industry Impact and Outlook

These announcements illustrate the CDMO industry's drive towards specialization and integration to address the complex manufacturing needs of cell and gene therapy products. Andelyn Biosciences' standardized platform is expected to improve the scalability and reproducibility of viral vector manufacturing, helping developers overcome critical bottlenecks in transitioning from clinical trials to commercialization. This is particularly relevant given the high demand for reliable vector supply.

The partnership between Made Scientific and RoosterBio emphasizes the importance of vertical integration within the cell therapy supply chain. MSCs and EVs hold immense promise in regenerative medicine, and this collaboration provides an efficient pathway to accelerate the development and commercialization of these advanced therapies. Offering an end-to-end service, from process development to GMP manufacturing, will significantly de-risk the development process for clients and potentially reduce time-to-market.

Collectively, these developments indicate a maturing CGT manufacturing ecosystem that is becoming more efficient and reliable. CDMOs will continue to play a central role in supporting the growth of this sector, contributing to the realization of future therapies through technological innovation and strategic partnerships. The increasing sophistication of CDMO offerings is essential for navigating the technical and regulatory complexities of advanced biotherapeutics on a global scale.

Source: https://www.dcatvci.org/top-industry-news/supplier-news-siegfried-vetter-made-scientific-more/

Collected: May 15, 2026 | Automated Research System (Gemini API)

Aldevron and Minaris Renew Lentiviral Plasmid Agreement, Bolstering Critical Supply for Advanced Cell and Gene Therapies

Published May 12, 2026 BioBuzz USA

OVERVIEW

Aldevron and Minaris have renewed their lentiviral plasmid licensing agreement, significantly expanding access to scalable plasmid solutions essential for advanced cell and gene therapy (CGT) developers. This collaboration reinforces the supply chain for proprietary off-the-shelf lentiviral plasmids used in CAR-T, TCR-T, and other gene-modified cell therapies, with Aldevron supplying various quality grades including cGMP. The partnership aims to simplify supply chains, reduce manufacturing risks, and accelerate development timelines from discovery through clinical application, addressing a critical need for high-quality raw materials in the rapidly evolving CGT sector.

IN DEPTH

Background and the Pivotal Role of Plasmids in CGT

The rapid advancements in cell and gene therapies (CGTs) are opening new avenues for treating intractable diseases. However, the commercialization of these innovative treatments heavily relies on robust and reliable raw material supply chains for manufacturing. High-quality plasmid DNA, in particular, is an indispensable component for producing viral vectors (e.g., lentiviral vectors) used to deliver therapeutic genes into cells. Plasmids serve as the foundational starting material for viral vector manufacturing, and their quality and consistent supply directly influence the safety, efficacy, and scalability of CGT products.

In this context, partnerships that can efficiently and scalably supply high-quality plasmids are of paramount importance to the global CGT development community.

Overview of the Renewed Agreement and Key Provisions

Aldevron, a global leader in the production of DNA, RNA, and proteins for genomic medicine, and Minaris, a global cell and gene therapy (CGT) contract development and manufacturing organization (CDMO) and biosafety testing provider, have announced the renewal of their lentiviral plasmid licensing agreement.

The primary objective of this renewed collaboration is to expand access to scalable plasmid solutions for advanced therapy developers, featuring several key provisions:

- **Enhanced Supply:** The agreement strengthens the availability of a proprietary, 'off-the-shelf' lentiviral plasmid system that is widely utilized in gene-modified cell therapy applications, including CAR-T, TCR-T, and other emerging therapeutic modalities. This ensures a consistent and readily available source for critical raw materials.
- **Diverse Quality Grades:** Aldevron will continue to manufacture and supply the plasmid system across various quality grades, encompassing research-use, GMP Source™ (a higher quality grade suitable for early clinical development), and full cGMP production. This multi-grade offering provides CGT developers with flexibility to meet regulatory requirements at different stages of development.

- **Streamlined Supply Chains:** By consolidating a critical raw material supply through a proven partnership, the agreement aims to simplify supply chains for CGT developers, reducing the complexity and risk associated with managing multiple vendors.

Industry Impact and Future Outlook

The renewal of this strategic partnership carries several significant implications for the cell and gene therapy sector. Firstly, securing a reliable supply of high-quality plasmids is a key factor in significantly accelerating CGT product development timelines. By mitigating raw material procurement risks, which often constitute a bottleneck in manufacturing processes, companies can allocate more resources towards core research and clinical development.

Secondly, the simplification of the supply chain contributes to reduced manufacturing costs and improved overall efficiency. Aldevron's provision of plasmids across different quality grades enables flexible selection based on development stage, optimizing resource utilization and minimizing waste.

From a global perspective, establishing such stable infrastructure is essential for meeting the escalating demands of CGT development worldwide. This partnership forms a crucial foundation that supports innovation and commercialization across the industry, enabling CGT products to reach patients more rapidly. The continued collaboration between Aldevron and Minaris is expected to play a vital role in shaping the future of advanced therapeutic modalities.

Source: https://biobuzz.io/news/aldevron-and-minaris-renew-lentiviral-plasmid-agreement-to-accelerate-cell-and-gene-therapy-development/

Collected: May 15, 2026 | Automated Research System (Gemini API)

Swiss Biotech Bioscibex Begins Shipments of Novel SW1NGO Single-Use Bioreactor-Incubators, Streamlining Bioprocess Seed Trains

Published May 08, 2026 Startupticker.ch Switzerland

OVERVIEW

Swiss biopharmaceutical startup Bioscibex has begun delivering its innovative SW1NGO single-use bioreactor-incubators to initial customers, marking a significant milestone. This system is designed to streamline traditionally manual, multi-step bioprocess seed train operations, reducing labor, mitigating contamination risks, and promoting sustainability through reduced plastic usage. The official European launch is slated for the ESACT conference in June 2026, targeting large biopharma companies and CDMOs seeking enhanced operational efficiency.

IN DEPTH

Background and Challenges in Bioprocess Manufacturing

The manufacturing of biopharmaceuticals, particularly the initial cell culture expansion phase known as 'seed train' operations, has traditionally been a labor-intensive and multi-step process. These manual, often open, procedures inherently carry a high risk of contamination and are time-consuming. Furthermore, the reliance on numerous disposable plastic components contributes to environmental concerns, driving an industry-wide push for more efficient, safer, and sustainable bioprocessing solutions.

Swiss biopharmaceutical startup Bioscibex has developed an innovative solution to address these critical challenges, aiming to transform the efficiency and sustainability of upstream bioprocesses.

Introduction of the SW1NGO Bioreactor-Incubator and Initial Shipments

Bioscibex has achieved a significant commercial milestone by commencing the delivery of its novel SW1NGO bioreactor-incubators to its first customers. This innovative single-use system is engineered to simplify and automate key aspects of bioprocess manufacturing.

Key features and benefits of the SW1NGO system include:

- **Streamlined Seed Train Operations:** The system is specifically designed to significantly simplify and automate the traditionally complex and manual seed train processes. This minimizes human intervention, reducing operational variability and potential errors.
- **Reduced Contamination Risk:** As a closed, single-use system, the SW1NGO drastically lowers the risk of microbial contamination from external sources, thereby enhancing the overall reliability and safety of the manufacturing process.
- **Environmental Sustainability:** The system aims to optimize plastic usage, contributing to a reduction in environmental footprint compared to conventional multi-use or less optimized single-use systems, aligning with growing industry demands for green biomanufacturing.

- **Improved Efficiency:** By reducing manual labor, the SW1NGO contributes to lower operational costs and faster processing times, ultimately boosting overall manufacturing efficiency.

The official European launch of the SW1NGO is strategically planned for June 2026 at the ESACT (European Society for Animal Cell Technology) conference, a major gathering for cell culture and bioprocessing professionals. This event will provide a platform for widespread product visibility and engagement with key stakeholders.

Industry Impact and Future Outlook

Innovative systems like the SW1NGO are poised to become critical tools for large biopharma companies and Contract Development and Manufacturing Organizations (CDMOs) looking to resolve manufacturing bottlenecks and enhance their competitive edge. The system directly aligns with the modern biopharmaceutical manufacturing imperatives of efficiency, safety, and sustainability.

This technology is expected to accelerate the standardization and automation of cell culture processes, potentially leading to reduced biopharmaceutical costs and faster time-to-market. Bioscibex's SW1NGO is anticipated to establish itself as a key component in shaping next-generation biomanufacturing, further solidifying Switzerland's reputation as a hub for biotechnology innovation. Its ability to offer a comprehensive, integrated solution for upstream processing represents a notable advancement in the pursuit of industrialized bioproduction.

Source: https://www.startupticker.ch/index.php/en/news/bioscibex-ships-first-sw1ngo-bioreactors-incubators

Collected: May 15, 2026 | Automated Research System (Gemini API)

Roche and NVIDIA Launch AI Factory with Omniverse Digital Twins to Optimize GLP-1 Pharma Manufacturing

Published May 08, 2026 IntuitionLabs USA

OVERVIEW

Roche has partnered with NVIDIA to establish a 3,500+ GPU AI factory, deploying Omniverse digital twins for an upcoming GLP-1 manufacturing facility. This initiative integrates AI and simulation to optimize entire production lines—from chemical processes to robotics—predicting and preventing costly faults. Industry analysts project that this digital twin adoption could boost plant capacity by 25–40% and cut design/validation lead times by 15–20%, signaling a major technological leap in pharmaceutical development and manufacturing.

IN DEPTH

Background and the Digital Transformation in Pharma

The pharmaceutical industry faces immense pressure to accelerate drug development, reduce manufacturing costs, and ensure product quality amidst increasing demand and complexity. Traditional drug discovery and manufacturing processes are often lengthy, capital-intensive, and prone to unforeseen challenges. Artificial intelligence (AI) and advanced simulation technologies, particularly digital twins, are emerging as powerful tools to address these bottlenecks, transforming the entire pharmaceutical value chain from R&D to commercial production.

Digital twin technology, which creates virtual replicas of physical systems or processes, enables real-time monitoring, simulation, and optimization, thereby offering unprecedented opportunities for efficiency gains and risk reduction in complex manufacturing environments.

Roche and NVIDIA's AI Factory: Pioneering Digital Twins in GLP-1 Manufacturing

Pharmaceutical giant Roche has announced a groundbreaking partnership with NVIDIA to establish a state-of-the-art AI factory, powered by over 3,500 GPUs. This ambitious initiative will deploy NVIDIA's Omniverse digital twin platform to optimize the operations of an upcoming GLP-1 (Glucagon-like peptide-1) manufacturing facility. This move marks a significant technological leap, positioning AI and simulation as central pillars alongside traditional chemistry and biology in drug development.

The deployment of digital twins aims to:

- **Simulate Entire Production Lines:** Replicate the entire manufacturing process in a virtual environment, encompassing complex chemical reactions, robotic automation, material flow, and potential equipment faults. This holistic simulation allows for comprehensive testing and validation before physical implementation.
- **Optimize Performance:** By analyzing vast amounts of real-time and simulated data, engineers can identify bottlenecks, predict potential failures, and fine-tune process parameters. This optimization can lead to substantial improvements in throughput, yield, and overall operational efficiency.

- **Prevent Costly Rework:** Virtual prototyping and scenario planning enable the identification and resolution of design flaws or operational inefficiencies in the digital realm. This proactive approach significantly reduces the need for expensive physical rework, shortening design and validation lead times.

Industry analysts anticipate that widespread adoption of digital twins in pharma manufacturing could lead to a 25–40% increase in plant capacity and a 15–20% reduction in design and validation lead times, translating into accelerated market access for critical therapeutics.

Technical Significance and Future Outlook

This collaboration is technically profound, as it leverages cutting-edge AI and high-performance computing to create a living, breathing digital replica of a complex biopharmaceutical plant. The ability to simulate intricate chemical and biological processes, coupled with physical robotics, provides an unparalleled testbed for innovation. It's a move from reactive problem-solving to proactive, predictive optimization.

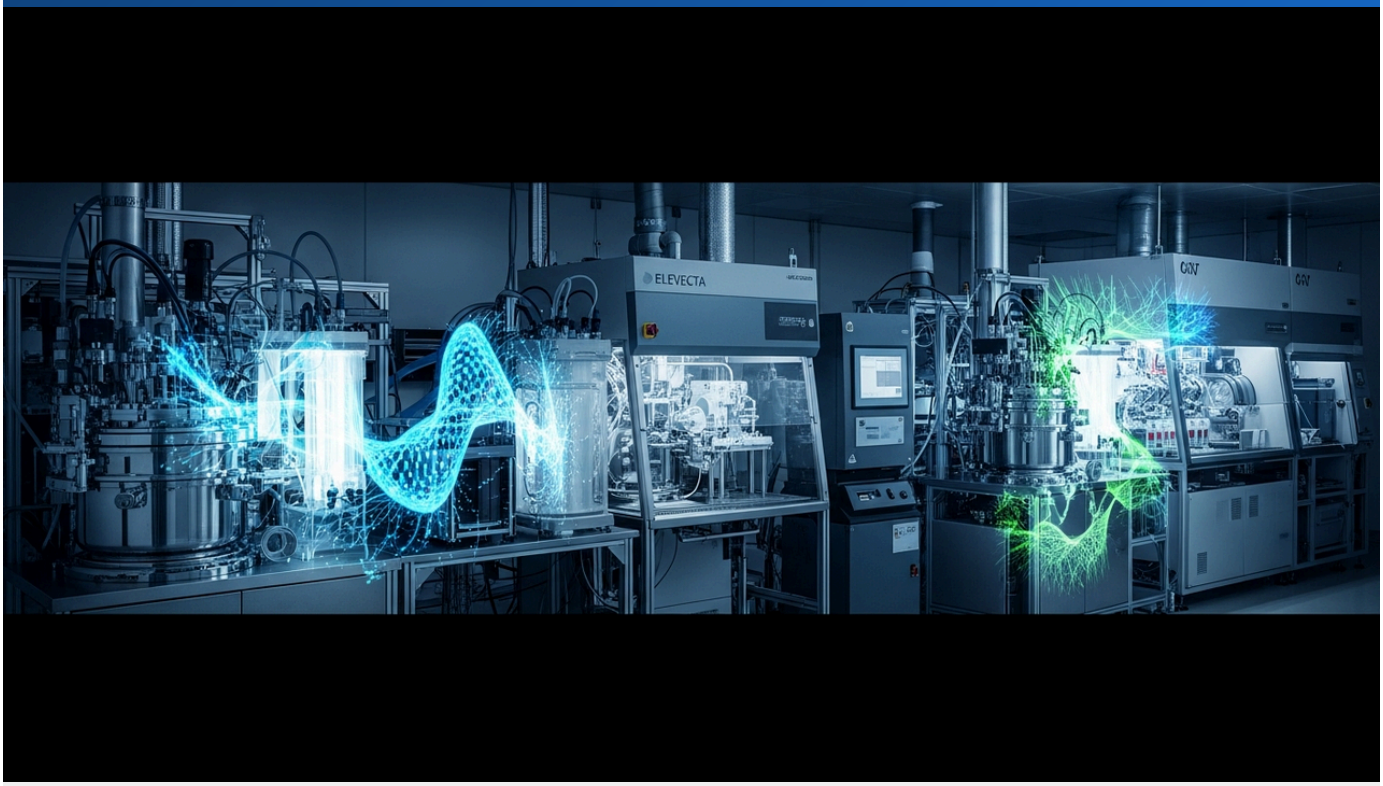
Looking ahead, Roche is exploring 'agentic research workflows,' where AI agents could autonomously design and conduct experiments. This vision includes the potential for closed-loop robotics labs, where AI models generate hypotheses, program robots to execute experiments, interpret results, and iterate on designs without human intervention. Such advancements could dramatically accelerate the pace of drug discovery and development, making the creation of new therapeutics more efficient and predictable than ever before.

This initiative sets a new benchmark for digital transformation in the pharmaceutical industry, demonstrating how AI can redefine manufacturing efficiency, quality, and innovation, ultimately benefitting patients worldwide through faster access to vital medicines.

Source: https://intuitionlabs.ai/articles/roche-nvidia-ai-factory-glp-1-digital-twins

Cytiva’s ELEVECTA Cell Line Receives FDA AMT Designation, Pioneering Next-Gen AAV Manufacturing with 99% Host Cell DNA Reduction

Published May 14, 2026 BioPharma BoardRoom USA



OVERVIEW

Cytiva, a Danaher company, has secured FDA Advanced Manufacturing Technology (AMT) designation for its ELEVECTA transient cell line, designed for adeno-associated virus (AAV) manufacturing. This pioneering technology reduces encapsidated host cell DNA (hcDNA) by up to 99% compared to commercial alternatives, addressing a critical AAV quality attribute and streamlining regulatory pathways. The AMT designation facilitates earlier, more frequent FDA engagement, promising accelerated resolution of technical and regulatory challenges for customers and advancing high-quality AAV production.

IN DEPTH

Background and Challenges in AAV Manufacturing

Adeno-associated viruses (AAVs) are indispensable vectors in gene therapy, owing to their robust safety profile and efficient gene delivery capabilities. They are critical tools for developing treatments for a wide array of diseases. However, the production of AAV vectors at large scale and with high quality remains a significant challenge for the industry. Specifically, residual host cell DNA (hcDNA) in final AAV products is a major concern, as it can impact product safety (e.g., potential for immunogenicity, insertional mutagenesis) and efficacy. Regulatory bodies worldwide are increasingly demanding stringent control and reduction of residual DNA.

In response to these challenges, companies like Cytiva have been intensely focused on developing next-generation AAV manufacturing technologies aimed at improving process efficiency and enhancing product quality.

Cytiva's ELEVECTA Cell Line and FDA AMT Designation

Cytiva, a Danaher company, has announced that its ELEVECTA transient cell line, specifically developed for adeno-associated virus (AAV) manufacturing, has received an Advanced Manufacturing Technology (AMT) designation from the U.S. Food and Drug Administration (FDA). This designation is among the first for a gene therapy technology provider, underscoring ELEVECTA's innovative potential in AAV production.

Key characteristics and benefits of the ELEVECTA cell line include:

- **Substantial Host Cell DNA (hcDNA) Reduction:** The ELEVECTA cell line has demonstrated the capability to reduce encapsidated hcDNA by up to 99% compared to currently available commercial cell lines. This significant reduction addresses a critical quality attribute in AAV manufacturing and aligns with evolving regulatory expectations for enhanced control over residual DNA.
- **Improved Manufacturing Efficiency:** Lower hcDNA levels can simplify downstream purification processes, potentially leading to increased overall manufacturing efficiency and cost-effectiveness. This is crucial for scaling up production to meet commercial demand.

- **Clearer Regulatory Pathway:** The FDA's AMT designation recognizes technologies that significantly improve the quality, reliability, and robustness of advanced therapy manufacturing. This designation offers Cytiva and its customers the benefit of earlier and more frequent engagement with the FDA, facilitating the proactive resolution of technical and regulatory considerations during the development process.

Industry Impact and Future Outlook

The FDA’s AMT designation for the ELEVECTA cell line represents a significant milestone in the evolution of gene therapy manufacturing. It not only validates Cytiva’s technological prowess but also signifies a broader industry movement towards establishing new standards for producing higher quality and safer gene therapy products. For customers utilizing ELEVECTA, this designation provides reduced uncertainty in developing new AAV manufacturing processes and navigating regulatory approvals. Early engagement with the FDA can de-bottleneck development processes, ultimately helping to bring gene therapies to patients more quickly.

Technical advancements in AAV vector manufacturing, such as those demonstrated by ELEVECTA, are indispensable for accelerating the commercialization of gene therapies and enabling the delivery of effective treatments for a greater number of diseases. Cytiva's achievement sets a new benchmark for quality and efficiency within the global gene therapy manufacturing ecosystem, reinforcing the importance of innovative platforms that address critical product quality attributes.

Source: https://www.biopharmaboardroom.com/news/82/4712/cytiva-secures-fda-amt-designation-for-elevecta-cell-line-advancing-next-generation-aav-manufacturing.html

Collected: May 15, 2026 | Automated Research System (Gemini API)

South Korean Biotech Giants Diverge: Samsung Biologics Faces Labor Risks Amid Record Growth, Celltrion Boosts Global CDMO Expansion

Published May 11, 2026 aju press South Korea

OVERVIEW

South Korea's leading biotech firms, Samsung Biologics and Celltrion, show divergent paths: Samsung Biologics achieved record Q1 2026 performance with 25.8% revenue growth due to full plant utilization but faces significant labor dispute risks. Meanwhile, Celltrion is aggressively expanding its global market presence with products like Jimpenetra and strengthening its CDMO business, securing over $800 million in new contracts and surpassing 1 trillion won in Q1 backlog for its CDMO subsidiary. These strategies highlight distinct approaches to navigating the global biopharmaceutical market amidst complex operational and expansion challenges.

IN DEPTH

Background and the South Korean Biopharmaceutical Landscape

South Korea has emerged as a formidable player in the global biopharmaceutical Contract Development and Manufacturing Organization (CDMO) sector, driven by significant investments and technological advancements. Samsung Biologics and Celltrion stand as the two titans of the nation's biotech industry, each pursuing distinct strategies and navigating unique challenges within an expanding global market. The increasing demand for biologics, including cell and gene therapies and biosimilars, continues to fuel opportunities for CDMOs, yet intensifying competition, supply chain vulnerabilities, and labor relations remain critical considerations for sustained growth.

Samsung Biologics: Record Performance Amidst Labor Challenges

Samsung Biologics reported its highest-ever quarterly performance in the first quarter of 2026, showcasing robust financial health. The company achieved revenues of 1.2571 trillion Korean Won and an operating profit of 580.8 billion Won, marking a substantial year-over-year increase of 25.8% in revenue and 35.0% in operating profit, respectively. This impressive growth was primarily attributed to the full operational utilization of its first four manufacturing plants and the accelerated ramp-up of its fifth facility, demonstrating the effectiveness of its capacity expansion strategy.

However, this period of record growth is overshadowed by ongoing labor disputes. The potential for strikes could significantly impact the company's performance in the second quarter and complicate future order acquisitions. Maintaining stable manufacturing operations and fostering positive labor relations are crucial for Samsung Biologics to sustain its long-term growth trajectory and global reputation as a reliable CDMO partner.

Celltrion: Global Expansion and CDMO Reinforcement

In contrast, Celltrion is adopting a differentiated strategy, focusing on aggressive global market penetration with its proprietary products and a significant reinforcement of its CDMO business. The company is actively expanding its footprint in the U.S. and European markets with its biosimilar product, Jimpenetra.

A pivotal element of Celltrion's strategy is its dedicated CDMO subsidiary, established late last year, which aims to achieve 3 trillion Won in revenue by 2031. This subsidiary offers comprehensive drug development and production services. Celltrion has already secured substantial contracts, including a $473 million agreement with Eli Lilly and another worth up to 375.4 billion Won for biopharmaceutical raw material manufacturing. These deals have pushed its cumulative Contract Manufacturing Organization (CMO) order backlog past 1 trillion Won in Q1, signaling strong market confidence in its integrated offerings.

Industry Implications and Future Outlook

The divergent yet successful strategies of Samsung Biologics and Celltrion reflect the dynamic and diverse nature of South Korea's biopharmaceutical industry. Samsung Biologics' strengths lie in its massive, stable manufacturing capacity, while Celltrion's approach emphasizes product development alongside vertical integration of CDMO services. These complementary strategies collectively enhance South Korea's competitive standing in the global biopharmaceutical market.

Addressing labor issues and continuously innovating technically will be key determinants of future growth for both companies. Amidst the rising global demand for biopharmaceuticals, Korean CDMOs are poised to continue playing a critical role in the global supply chain, further expanding their influence, particularly across the Asia-Pacific region, and contributing significantly to the accessibility of advanced therapeutics worldwide.

Source: https://m.ajupress.com/amp/20260512045170812

Collected: May 15, 2026 | Automated Research System (Gemini API)

CellFiber and Locus Cell Establish Commercial-Scale Manufacturing for Human Umbilical Cord-Derived Mesenchymal Stem Cells Using Advanced 3D Culture Technology

Published May 14, 2026 PR TIMES Japan

OVERVIEW

Japan's CellFiber and its Taiwanese partner Locus Cell have successfully established a commercial-scale manufacturing process for human umbilical cord-derived mesenchymal stem cells (UC-MSC) utilizing the innovative CellFiber® technology. This advanced 3D encapsulation method protects cells within alginate gel tubes, enhancing cell function maintenance and ensuring consistent quality superior to conventional 2D cultures. Locus Cell has integrated this GMP-compliant system into its new automated smart factory in Hsinchu, Taiwan, enabling large-scale production of cell-based therapeutics and marking a significant leap toward wider cellular medicine accessibility.

IN DEPTH

Background and Challenges in Cell-Based Therapeutic Manufacturing

Regenerative medicine and cell-based therapeutics hold immense promise for treating numerous intractable diseases. However, their widespread commercialization is critically dependent on establishing large-scale, high-quality cell manufacturing processes. Mesenchymal Stem Cells (MSCs), for example, are highly susceptible to functional degradation and quality variability during traditional two-dimensional (2D) culture. Conventional methods struggle with scalability, cost-effectiveness, reproducibility, and consistency, posing significant barriers to bringing these advanced therapies to patients.

Japan's CellFiber Inc. has been at the forefront of addressing these challenges, developing its proprietary "CellFiber® technology," and collaborating with Taiwan's Locus Cell Co., Ltd. to translate this innovation into practical, commercial-scale solutions.

CellFiber® Technology and Commercial-Scale UC-MSC Production

CellFiber® technology is a next-generation three-dimensional (3D) cell culture platform that encapsulates cells within tube-like structures made of alginate gel. Key features of this innovative technology include:

- **Enhanced Cell Protection and Viability:** The alginate gel physically protects cells, mitigating stress during culture. This allows cells, such as UC-MSCs, to maintain their inherent functions (e.g., proliferation, differentiation potential, immunomodulatory properties) for extended periods with high viability, critical for therapeutic efficacy.
- **High-Density Culture and Scalability:** The tubular structure facilitates high-density cell culture, enabling easier and more efficient scale-up into bioreactors for large-scale production. This is a crucial advantage for the commercialization of cell-based pharmaceuticals.
- **Consistent Quality:** By providing a uniform culture environment, the technology helps reduce batch-to-batch variability, contributing to the production of consistently high-quality cell products—a paramount concern for regulatory approval and clinical success.

Locus Cell has successfully applied CellFiber® technology to the manufacturing process of human umbilical cord-derived mesenchymal stem cells (UC-MSC), establishing a large-scale, commercial-grade production process. This achievement was realized through the integration of the CellFiber® system into Locus Cell's newly inaugurated automated smart factory in Hsinchu, Taiwan, which is designed for Good Manufacturing Practice (GMP)-compliant cell-based therapeutic production.

Industry Impact and Future Outlook

The establishment of this commercial-scale manufacturing process by Locus Cell represents a significant advancement for the broader cell-based therapeutic industry. UC-MSCs, in particular, are garnering extensive interest due to their high regenerative capacity and immunomodulatory properties, making them promising candidates for various therapeutic applications. The efficient and high-quality production of UC-MSCs using CellFiber® technology is expected to have several impacts:

- **Accelerated Therapy Accessibility:** By reducing manufacturing costs and improving supply stability, cell-based therapies utilizing UC-MSCs could become more accessible and affordable for a wider patient population.
- **Enhanced Quality Control:** The ability to consistently supply high-quality cells increases the success rate of clinical trials and facilitates regulatory approvals, a critical hurdle for novel therapies.
- **Strengthened International Competitiveness:** This collaboration between Japanese and Taiwanese companies in establishing cutting-edge cell manufacturing technology reinforces the international competitiveness of the regenerative medicine industry in the Asia-Pacific region.

Looking ahead, this technology is anticipated to be applicable to various other cell types, contributing to the overall development of the cell-based pharmaceutical industry. It also serves as a testament to Japan's technological leadership in the regenerative medicine sector on a global scale, pushing the boundaries of what is possible in advanced biomanufacturing.

Source: https://prtimes.jp/main/html/rd/p/000000028.000067783.html

BIOSECURE Act Reshapes Biopharma Supply Chains, Driving API and Oligo CDMO Expansion in South Korea

Published May 09, 2026 CHOSUNBIZ South Korea

OVERVIEW

The U.S. BIOSECURE Act is catalyzing a significant shift in biopharmaceutical supply chains away from China, creating substantial opportunities for South Korean contract development and manufacturing organizations (CDMOs). Initially focused on large biologics CDMOs, this impact now extends to small-molecule active pharmaceutical ingredient (API) and high-value oligonucleotide (oligo) contract manufacturing. With restrictions on Chinese firms tightening from 2028, South Korean companies like ST Pharm are seeing steady inquiries and are poised to become critical alternative hubs, particularly for essential RNA-based therapeutic components.

IN DEPTH

Background and the Impetus of the BIOSECURE Act

The U.S. BIOSECURE Act represents a pivotal legislative initiative aimed at de-risking the biopharmaceutical supply chain by reducing reliance on Chinese biotechnology companies. This act, driven by geopolitical and economic security concerns, threatens to restrict U.S. federal funding to entities that engage with certain Chinese biotech firms, compelling global pharmaceutical companies to reassess and diversify their supplier strategies.

Initially, discussions around the act's impact primarily centered on large biologics CDMOs, given the dominant role of Chinese players like WuXi Biologics in antibody drug production. However, its ripple effects are now broadening to encompass the manufacturing of small-molecule active pharmaceutical ingredients (APIs) and high-value oligonucleotides, thereby opening new strategic avenues for South Korean CDMOs.

Expanded Opportunities for South Korean CDMOs

The BIOSECURE Act is positioning South Korean CDMOs as critical alternative hubs within the pharmaceutical supply chain, particularly in:

- **API Contract Manufacturing:** Beyond the large biologics CDMOs, domestic API contract manufacturers such as Yuhan Chemical Inc. and ST Pharm are gaining prominence. These companies are experiencing consistent inquiries from global drugmakers, with potential for significant new order wins in the second quarter of 2026 as firms seek to diversify their API sources.
- **Oligonucleotide CDMO:** ST Pharm, in particular, is strategically focusing on high-value oligonucleotide CDMO services. Oligonucleotides are essential components for RNA-based therapies, including mRNA vaccines and antisense oligonucleotides, and their manufacturing requires highly specialized expertise and facilities. This niche positions Korea as a key alternative for these complex and critical raw materials.

While the BIOSECURE Act grandfathers existing contracts with Chinese entities until 2032, it is anticipated to impose strict limitations on Chinese corporations' participation in new U.S. projects and contract renewals starting in 2028. This impending regulatory shift is a primary driver behind the steady increase in inquiries directed towards Korean companies.

Industry Impact and Future Outlook

This restructuring of the biopharmaceutical supply chain is expected to have long-term implications for the global ecosystem. South Korea, with its advanced manufacturing capabilities, stringent quality control systems, and strategic geographic location, is well-positioned to strengthen its role as a crucial alternative manufacturing hub to China.

- **Diversification and Resilience:** Pharmaceutical companies globally are moving to diversify their supplier base to mitigate future risks, making South Korea an increasingly attractive and reliable partner. This enhances the resilience of the global pharmaceutical supply chain.
- **Technological Innovation and Specialization:** Korean CDMOs are expected to accelerate their technological innovation and capacity expansion in high-value, specialized areas such as oligonucleotide synthesis, further solidifying their expert niche.
- **Geopolitical Significance:** Biopharmaceutical manufacturing is increasingly recognized as vital for national and economic security. Regulations like the BIOSECURE Act will continue to drive the strategic reorganization of global supply chains, emphasizing the importance of securing critical manufacturing capabilities within allied nations.

South Korean CDMO firms are poised to capitalize on this geopolitical inflection point, showcasing their manufacturing prowess and technological leadership to the world. They will likely continue to expand their strategic partnerships and exert greater influence in the global biopharmaceutical market, particularly in Asia, ensuring a more diversified and secure future for advanced therapy production.

Source: https://biz.chosun.com/en/en-science/2026/05/10/MVGIDK7JGZAKTBL2NDKDFT63I4/

South Korea Approves First 'Pre-Approval Therapy' Plan for Advanced Regenerative Medicine, Significantly Broadening Patient Access

Published May 10, 2026 Newsweek Japan South Korea

OVERVIEW

South Korea's government has approved its inaugural advanced regenerative medical treatment plan under a groundbreaking 'pre-approval therapy' framework, allowing critically ill patients access to cutting-edge treatments before formal product authorization. The approved therapy, an autologous cell treatment administering patient-specific EBV antigen-specific immune T-cells, demonstrated confirmed efficacy and safety in clinical data. This landmark decision dramatically expands patient access to advanced therapies and is poised to accelerate R&D and deployment within South Korea's biotech industry, potentially serving as an international model for expedited patient access.

IN DEPTH

Background and Challenges in Advanced Regenerative Medicine

Advanced regenerative medicine, leveraging cells and tissues to restore function, offers transformative potential for diseases resistant to conventional treatments. However, the path from research and development to clinical application and market approval for these highly complex and often personalized therapies is typically long and arduous. This protracted timeline severely limits early patient access, particularly for those suffering from severe or life-threatening conditions where time is of the essence.

Recognizing this critical unmet medical need, governments and regulatory bodies worldwide are exploring and implementing novel regulatory frameworks designed to facilitate earlier patient access to promising advanced therapies while maintaining rigorous safety and efficacy standards.

South Korea's Approval of 'Pre-Approval Therapy' Plan

In alignment with this global trend, the South Korean government has officially approved its first advanced regenerative medical treatment plan under an innovative regulatory approach termed 'pre-approval therapy.' This groundbreaking framework allows patients with severe diseases to access cutting-edge treatments even before the formal product has received full market authorization. This represents a significant shift in Korea's medical paradigm, prioritizing immediate patient care for conditions with limited existing options.

The specific therapy approved is an autologous cell therapy, which involves administering the patient's own EBV (Epstein-Barr virus) antigen-specific immune T-cells. The efficacy and safety profile of this treatment have been robustly validated through stringent clinical data, forming the basis for its 'pre-approval therapy' designation. This personalized cellular immunotherapy aims to enhance the body's immune response against specific pathogens or diseased cells, offering a novel therapeutic option for conditions like certain cancers.

Industry Impact and Future Outlook

This decision by the South Korean government is expected to have a profound impact on the domestic regenerative medicine sector and the broader biotech industry. Key implications and prospects include:

- **Dramatic Expansion of Patient Access:** For patients with severe diseases where treatment options are scarce, access to innovative advanced therapies will be significantly improved. This directly translates to enhanced quality of life and offers new hope.
- **Accelerated Development and Approval Processes:** For companies, the opening of an early approval pathway provides a strong incentive for development programs. This is anticipated to accelerate the entire process from R&D to clinical trials and market introduction for advanced therapies.
- **Promotion of Biotech Industry Growth:** The new regulatory framework is expected to encourage both domestic and international biotech companies to intensify their R&D and manufacturing investments in South Korea, further solidifying the country's position as a hub for advanced regenerative medicine.
- **International Model:** South Korea's innovative approach to early access could serve as a valuable model for other nations contemplating similar expedited pathways, potentially fostering accelerated development in regenerative medicine across the Asia-Pacific region and beyond.

The 'pre-approval therapy' system is a crucial step towards balancing scientific progress with urgent patient needs, delivering advanced medical treatments to society more rapidly. It signifies a landmark change in South Korea's healthcare paradigm, emphasizing patient-centric innovation.

Source: https://troy-technical.jp/%E9%9F%93%E5%9B%BD%E3%80%81%E5%88%9D%E3%81%AE%E5%85%88%E9%80%B2%E5%86

Helios Advances ARDS Therapy Approval, Bolstering Regenerative Medicine CDMO with New Kobe Manufacturing Hub

Published May 15, 2026 FISCO Japan

OVERVIEW

Helios is progressing towards regulatory approval for its Acute Respiratory Distress Syndrome (ARDS) therapeutic, HLCM051, while simultaneously enhancing its Contract Development and Manufacturing Organization (CDMO) business for regenerative medicine products. The company is leveraging government subsidies to build essential CDMO infrastructure, including process development, manufacturing, and quality control capabilities. With a new commercial-scale manufacturing facility in Kobe slated for completion by January 2028, Helios aims to significantly accelerate the commercialization of regenerative medicine products, positioning itself as a key manufacturing partner in Japan's advanced therapy ecosystem.

IN DEPTH

Background and the Evolving Regenerative Medicine Industry

The field of regenerative medicine, while promising groundbreaking therapies, faces inherent challenges in its manufacturing processes. Advanced medical products, particularly cell and gene therapies, demand sophisticated manufacturing technologies and stringent quality control systems due to their complexity. In Japan, the government is actively promoting the industrialization of regenerative medicine, leading companies to focus not only on R&D but also on establishing robust manufacturing infrastructure for commercialization.

Within this dynamic environment, Helios K.K. is strategically expanding its Contract Development and Manufacturing Organization (CDMO) business for regenerative medicine products, concurrently with its own product development pipeline.

Helios's Key Strategic Initiatives

Helios is advancing several critical strategic initiatives:

- **ARDS Therapeutic HLCM051 Approval Preparations:** The company continues its preparations for obtaining regulatory approval for HLCM051, a therapeutic candidate for Acute Respiratory Distress Syndrome (ARDS), acute cerebral infarction, and trauma. This represents a core product in Helios's pipeline, with anticipation for early market entry.
- **Strengthening Regenerative Medicine CDMO Business:** Alongside its proprietary product development, Helios is significantly investing in bolstering its CDMO business for regenerative medicine products. This involves offering its manufacturing capabilities and expertise to external clients, thereby contributing to the overall development of the regenerative medicine industry. This CDMO initiative includes:
    - **Infrastructure Development:** Building core functionalities in process development, manufacturing, and quality control to establish a comprehensive contract manufacturing service platform.

- **Leveraging Government Subsidies:** Helios is utilizing subsidies from the Ministry of Economy, Trade and Industry's FY22024 supplementary budget for the "Regenerative, Cell, and Gene Therapy Manufacturing Equipment Investment Support Project." This support helps mitigate capital expenditure and facilitates rapid infrastructure development.
- **Kobe Manufacturing Facility:** A new manufacturing facility in Kobe, specifically designed for the commercialization of regenerative medicine products, is projected for completion by January 2028. This facility aims for large-scale production and compliance with GMP standards, targeting both domestic and international contract manufacturing needs.

Industry Impact and Future Outlook

Helios's strategic initiatives are poised to have several significant impacts on Japan's regenerative medicine industry. Firstly, the potential approval of its ARDS therapeutic, HLCM051, would offer a new treatment option for an unmet medical need, improving patient quality of life.

Secondly, the strengthening of its CDMO business is critically important for the entire Japanese regenerative medicine ecosystem. Many regenerative medicine startups and research institutions lack proprietary manufacturing facilities or specialized know-how, making reliable CDMO partners indispensable for accelerating development and achieving commercial success. Helios's comprehensive CDMO services will provide significant impetus for domestic regenerative medicine product developers.

Furthermore, the utilization of government subsidies and the construction of the new Kobe facility symbolize a broader strengthening of Japan's regenerative medicine manufacturing base. This is a crucial step in establishing Japan as a leading hub for regenerative medicine in the Asia-Pacific region and enhancing its international competitiveness. The operational launch of the Kobe facility in 2028 is expected to substantially increase domestic commercial production capacity for regenerative medicine products, forming a foundational pillar for the sector's sustained growth.

Source: #

Ajinomoto Develops Novel Culture Medium Supplement to Boost Gene Therapy Drug Productivity, Accelerating Biomanufacturing Efficiency

Published May 14, 2026　味の素株式会社 IRニュース　Japan

OVERVIEW

Ajinomoto Group, in collaboration with its U.S. subsidiary Forge Biologics (acquired in 2023 for ~¥82.8 billion), has developed a novel culture medium supplement designed to significantly enhance gene therapy drug productivity. This innovation primarily targets improving viral vector yields—critical carriers for therapeutic genes—by optimizing cell culture conditions. Ajinomoto plans to leverage this supplement in its own contract development and manufacturing (CDMO) operations and is exploring its sale to other pharmaceutical companies, aiming to accelerate efficiency and cost reduction across the broader gene therapy manufacturing sector.

IN DEPTH

Background and Challenges in Gene Therapy Drug Manufacturing

Gene therapy, a cutting-edge approach that aims to cure diseases by introducing therapeutic genes directly into cells, holds immense promise for conditions previously considered intractable. However, the commercialization and widespread adoption of gene therapy drugs are contingent upon the efficient and large-scale manufacturing of high-quality viral vectors, which serve as crucial carriers for delivering therapeutic genes into target cells. Viral vector production involves complex cell culture processes, and key challenges include enhancing productivity, reducing costs, and ensuring consistent product quality.

Cell culture media, in particular, directly influences the production efficiency of viral vectors, making its optimization a critical area of focus. The Ajinomoto Group has been actively engaged in developing advanced culture medium supplements to address these manufacturing bottlenecks.

Ajinomoto's Development of a Novel Culture Medium Supplement

The Ajinomoto Group has announced the successful development of a new culture medium supplement specifically designed to significantly enhance the productivity of gene therapy drugs. This breakthrough was achieved through close collaboration with its U.S. consolidated subsidiary, Forge Biologics, which Ajinomoto acquired in 2023 for approximately 82.8 billion yen (around $530 million).

Forge Biologics specializes in the contract development and manufacturing (CDMO) of adeno-associated virus (AAV) vectors, and their deep expertise played a crucial role in the development of this novel supplement. The newly developed culture medium supplement is designed to boost the proliferation capacity of vector-producing cells and their vector-generating efficiency, offering several key benefits:

- **Increased Productivity:** It significantly improves the efficiency of the culture process, leading to a substantial increase in viral vector yield per unit of culture volume.
- **Cost Reduction:** Higher productivity directly translates to reduced manufacturing costs, potentially contributing to lower pricing for gene therapy drugs, making them more accessible.

- **Quality Stabilization:** An optimized culture medium environment is also critical for ensuring the consistent quality of viral vectors, a paramount factor for clinical success and regulatory approval.

Industry Impact and Future Outlook

The development of this culture medium supplement is expected to have a substantial impact on the gene therapy drug manufacturing industry. Firstly, within the Ajinomoto Group's own CDMO business, the ability to produce high-quality and high-efficiency viral vectors will significantly strengthen its service offerings to clients. This will enhance the competitiveness of Forge Biologics' AAV vector manufacturing services and contribute to its market share expansion.

Furthermore, Ajinomoto is considering selling this new supplement not only for its internal use but also to other pharmaceutical and biotechnology companies. This initiative would provide a new tool for numerous companies developing and manufacturing gene therapy drugs to enhance productivity and reduce costs, potentially accelerating innovation and commercialization across the entire gene therapy sector.

Leveraging its extensive knowledge and technology in amino acids, accumulated over many years, the Ajinomoto Group is positioned to provide foundational technologies indispensable for the advancement of cutting-edge gene therapy. This effort underscores Japan's crucial role in contributing to global healthcare improvements within the life sciences sector, setting a new benchmark for biomanufacturing efficiency and quality.

Source: https://www.ajinomoto.co.jp/company/jp/ir/news.html

Terumo BCT and Steminent Partner to Automate Mesenchymal Stem Cell Manufacturing for Late-Stage Clinical Commercialization

Published May 13, 2026 Terumo Blood and Cell Technologies Taiwan

OVERVIEW

Terumo Blood and Cell Technologies (Terumo BCT) and Taipei-based Steminent Biotherapeutics Inc. have announced a strategic collaboration to accelerate late-stage manufacturing readiness for mesenchymal stem cell (MSC) therapies. This partnership addresses the critical challenge of transitioning from manual to automated manufacturing, a key barrier to broad commercialization. Utilizing Terumo BCT's Quantum Flex™ Automated Cell Expansion System, the collaboration will optimize automated cell expansion for Steminent's MSC-based therapy, ensuring scalable production workflows with consistent batch-to-batch quality and process robustness for global commercialization.

IN DEPTH

Background and Challenges in MSC Therapeutic Manufacturing

Mesenchymal Stem Cell (MSC) therapies hold immense promise in regenerative medicine due to their potent immunomodulatory and tissue repair capabilities. However, the successful commercialization and widespread patient access to MSC therapeutics are critically dependent on establishing large-scale, cost-effective manufacturing processes. Traditional MSC production often involves extensive manual steps, which contribute to quality variability, high contamination risks, and inherent limitations in scalability.

The transition from manual to automated manufacturing systems, particularly for late-stage clinical development and commercial production, represents a significant hurdle in terms of cost, time, and regulatory approval. To overcome these challenges, strategic collaborations between companies possessing specialized technologies and expertise are becoming increasingly crucial.

Terumo BCT and Steminent's Strategic Collaboration

Terumo Blood and Cell Technologies (Terumo BCT) and Steminent Biotherapeutics Inc., a Taipei-based stem cell biopharmaceutical company, have announced a strategic collaboration aimed at accelerating the manufacturing readiness for late-stage mesenchymal stem cell (MSC) therapies. This partnership focuses on key objectives and approaches:

- **Optimizing Automated Cell Expansion:** Central to the collaboration is the optimization of automated cell expansion for Steminent's late-stage MSC-based therapy, targeting both clinical development and future commercial production. This will leverage Terumo BCT's Quantum Flex™ Automated Cell Expansion System to build efficient and scalable automated culture systems.
- **Developing Scalable Production Workflows:** Terumo BCT will lead the development of scalable production workflows designed to ensure batch-to-batch consistency and process robustness. This is expected to stabilize quality and improve cost-efficiency in large-scale manufacturing.

- **Supporting Commercialization Goals:** The collaboration is designed to help Steminent achieve its commercialization goals across key markets including Taiwan, Japan, Korea, and the United States. Automated manufacturing processes are essential for securing regulatory approvals and enabling rapid market entry in these regions.

Industry Impact and Future Outlook

This partnership between Terumo BCT and Steminent represents a significant milestone for the commercialization of MSC therapeutics. The automation of the manufacturing process is expected to have several profound impacts on the industry:

- **Reduced Manufacturing Costs:** By minimizing manual labor and improving efficiency, the manufacturing costs of MSC therapies can be reduced, potentially leading to lower treatment costs and broader accessibility.
- **Enhanced Quality Consistency and Reliability:** Automated and closed systems significantly reduce the risk of human error and contamination, leading to a substantial improvement in product quality consistency and reproducibility. This is vital for meeting stringent regulatory quality standards.
- **Expanded Patient Access:** The establishment of large-scale, stable manufacturing capabilities will enable the supply of MSC therapies to a greater number of patients, addressing critical unmet medical needs globally.
- **Driving Innovation in Asia-Pacific:** The collaboration between a Taiwan-based company and a global technology provider will accelerate regenerative medicine innovation in the Asia-Pacific region, further solidifying the region's position as a key hub for regenerative medicine.

Moving forward, this automated manufacturing platform is expected to be applied not only to MSC therapies but also to other cell therapy products, powerfully supporting the overall growth of the regenerative medicine sector. This showcases how targeted automation can overcome traditional biological manufacturing hurdles.

Source: https://www.terumobct.com/en/gl/our-company/news-and-events/news-releases/2026/terumo-

blood-and-cell-technologies-and-steminent-collaborate-to-.html

Collected: May 15, 2026 | Automated Research System (Gemini API)

AIST Develops Novel Culture Media Analysis Technology Using Multifluorescent Polymers and AI, Revolutionizing Biomanufacturing Quality Control

Published May 13, 2026 AFPBB News Japan

OVERVIEW

Japan's National Institute of Advanced Industrial Science and Technology (AIST) has developed a novel analytical technology to assess the quality of cell culture media and supplements, critical for biomanufacturing. This system employs a sensor with multiple fluorescent polymers to detect the overall characteristics of media as unique fluorescent patterns, which machine learning then uses to identify subtle differences and changes. Unlike conventional component-by-component analysis, this innovation simplifies pre-culture quality checks, prevents costly culture failures, and enhances overall biomanufacturing product quality. The research team from the Health and Medical Engineering Research Institute pioneered this advancement.

IN DEPTH

Background and Challenges in Cell Culture Media Quality Assessment

Cell and microbial culture forms the foundational technology for modern biomanufacturing industries, including biopharmaceuticals, regenerative medicine products, and cultivated meat. The success of these endeavors is highly dependent on the quality of the culture media and supplements used. However, culture media, composed of diverse ingredients, can exhibit subtle variations in quality between batches or due to storage conditions. Traditional quality assessment methods necessitate detailed, component-by-component analysis, which is laborious, time-consuming, and often fails to capture holistic changes in the media's overall characteristics.

Consequently, there has been a strong demand for new technologies that can rapidly and accurately evaluate media quality before cultivation, thereby mitigating the risk of culture failures.

AIST's Novel Analytical Technology Using Multifluorescent Polymers

To address these challenges, a research team at Japan's National Institute of Advanced Industrial Science and Technology (AIST) has developed a groundbreaking analytical technology for evaluating the quality of cell culture media and supplements.

- **Multifluorescent Polymer Sensor:** At the core of this technology is a sensor that combines multiple fluorescent polymers, each possessing distinct fluorescent properties. These polymers interact with various components within the culture medium, emitting unique fluorescent patterns.
- **Holistic Characteristic Detection:** Instead of isolating and analyzing individual components, the sensor detects a comprehensive "fingerprint" of the entire culture medium's fluorescent pattern. This enables a holistic capture of subtle chemical compositions and structural changes that are often undetectable by conventional methods.

- **Machine Learning for Identification:** The complex fluorescent patterns detected are then analyzed using machine learning algorithms. Machine learning is trained to identify minute differences in fluorescent patterns that distinguish between media of varying quality, automatically classifying and assessing the media's state. This eliminates human variability in judgment, ensuring objective and highly reproducible evaluations.

This research was conducted by Shunsuke Tomita, Kumi Morikawa, Nao Kojima, Sayaka Ishihara, Ryoji Kurita from the Health and Medical Engineering Research Institute, and Hiroyuki Kusada and Hideki Tamaki from the Biomanufacturing Research Center.

Industry Impact and Future Outlook

This novel culture media analysis technology is expected to have widespread implications for the biomanufacturing industry:

- **Simplified and Expedited Quality Control:** By replacing complex, component-specific analyses with rapid, straightforward fluorescent pattern detection and machine learning-based evaluation, the process of media incoming inspection and pre-culture quality checks will be significantly streamlined.
- **Reduced Risk of Culture Failure:** The ability to accurately detect abnormalities in media quality before cultivation can prevent costly issues such such as culture failures or compromised product quality. This contributes to manufacturing process stability and cost reduction.
- **Enhanced Overall Biomanufacturing Quality:** Stable supply and utilization of high-quality media ensure consistency in the final bioproducts, contributing to improved safety and efficacy of regenerative medicine and biopharmaceuticals.
- **Expanded Technological Applications:** Beyond cell culture media, this technology shows promise for quality evaluation of various biological samples and environmental samples, and even for real-time monitoring in specific bioprocesses.

AIST's innovative media analysis technology is poised to become a critical foundational technology for Japan's biomanufacturing sector, enhancing its international competitiveness. It exemplifies how the convergence of advanced analytical science and AI can open new avenues for solving complex manufacturing challenges in the life sciences, providing more reliable and efficient bioproduction worldwide.

Source: https://www.afpbb.com/articles/-/3635001

Collected: May 15, 2026 | Automated Research System (Gemini API)

ProBio and Curocell Achieve BLA Approval for Next-Gen CD19-Targeted CAR-T Therapy, Initiating Commercial Production in South Korea

Published May 11, 2026 ProBio CDMO South Korea

OVERVIEW

ProBio CDMO and Curocell have secured Biologics License Application (BLA) approval for anbalcabtagene autoleucel (Anbal-cel; CRC01), their next-generation CD19-targeted CAR-T cell therapy for relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Clinical trials demonstrated an 82% overall and complete response rate, supported by Curocell's proprietary OVIS™ platform, which enhances efficacy by suppressing immune checkpoints. ProBio provided end-to-end CDMO support, securing Korea's first GMP certification for a lentiviral vector facility, enabling seamless transition to commercial manufacturing and underscoring South Korea's innovation in advanced therapies.

IN DEPTH

Background and Advancements in CAR-T Cell Therapy

CAR-T (Chimeric Antigen Receptor T-cell) cell therapy represents a revolutionary advancement in immunotherapy, demonstrating profound clinical success, particularly in specific blood cancers. This innovative approach involves genetically modifying a patient's own T-cells to equip them with the ability to recognize and attack cancer cells expressing specific antigens, such as CD19. While CAR-T therapies have achieved high response rates, their development and commercialization are challenged by complex manufacturing processes, stringent quality control requirements, and the demanding regulatory approval pathways.

In this context, Contract Development and Manufacturing Organizations (CDMOs) play an indispensable role. By providing specialized manufacturing capabilities and regulatory expertise, CDMOs help developers overcome these hurdles and accelerate the delivery of innovative therapies to patients.

ProBio and Curocell's Collaboration and BLA Approval

ProBio, a CDMO, and Curocell, a South Korean biotechnology company, have jointly announced a significant milestone: the Biologics License Application (BLA) approval for their next-generation CD19-targeted CAR-T cell therapy, anbalcabtagene autoleucel (Anbal-cel; CRC01). This therapy is indicated for patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

This approval is a landmark achievement, symbolizing South Korea's growing innovation in the field of advanced therapies. Clinical data from Phase 1/2 studies for CRC01 demonstrated compelling efficacy, with an 82% overall response rate and an 82% complete response rate, alongside a manageable safety profile. A key feature enhancing CRC01's therapeutic potential is Curocell's proprietary OVIS™ platform, which is designed to suppress immune checkpoint receptors, thereby augmenting the anti-tumor effect of the CAR-T cells.

ProBio provided comprehensive support to Curocell throughout the development journey, spanning from post-Investigational New Drug (IND) supplier changes and Phase 2 clinical manufacturing to BLA application and commercial production. ProBio leveraged its global CDMO quality system and facility to facilitate this process. Notably, ProBio successfully passed the GMP inspection by the Ministry of Food and Drug Safety (MFDS), becoming the first entity in Korea to receive GMP certification for a lentiviral vector (LVV) manufacturing facility. The program has now transitioned into the commercial manufacturing phase.

Industry Impact and Future Outlook

The BLA approval and commercial readiness of this CAR-T cell therapy by ProBio and Curocell will have several critical impacts on the South Korean and global cell therapy industries:

- **Addressing Unmet Medical Needs:** This therapy offers a new treatment option for patients with relapsed or refractory DLBCL, potentially improving their prognosis and quality of life.
- **Driving Korean Innovation:** The approval highlights South Korea's established capabilities in R&D and manufacturing for cell and gene therapies, reinforcing its position as a global leader in this advanced field.
- **Reaffirmation of CDMO Importance:** ProBio's extensive support and its achievement of GMP certification for LVV manufacturing underscore the indispensable role of specialized CDMO partners in the commercialization of complex cell and gene therapy products. CDMOs significantly reduce the manufacturing, quality control, and regulatory hurdles faced by developers, accelerating market entry.
- **Advancement of Next-Gen CAR-T Technology:** The incorporation of proprietary technologies like the OVIS™ platform suggests a trajectory toward overcoming limitations of existing CAR-T therapies (e.g., persistence and toxicity), potentially accelerating the development of more effective and safer next-generation CAR-T cell therapies.

This success story is poised to drive the growth of the cell therapy industry in the Asia-Pacific region and set a new benchmark for delivering innovative therapies to patients globally.

Source: https://www.probiocdmo.com/probio-and-curocell-achieve-key-car-t-milestone-with-bla-regulatory-approval-and-commercial-readiness.html

Collected: May 15, 2026 | Automated Research System (Gemini API)

SuperMeat Secures $6M in Funding, Accelerating Commercialization of Cultivated Chicken for Swiss Market Entry

Published May 13, 2026 PPTI News - Protein Production Technology International UK

OVERVIEW

SuperMeat has raised $6 million in Series A-4 funding, part of a targeted $10 million round, to accelerate the commercialization of its cultivated chicken technology and planned market entry in Switzerland. The company is prioritizing commercial-scale process verification, regulatory preparation, and consumer validation studies. SuperMeat has also forged an R&D and technology development agreement with Ajinomoto and expanded its collaboration with Micarna (a Migros subsidiary) to support product development and consumer studies. Furthermore, the company integrated continuous bioprocessing technology with Stämm in February 2025, signaling a clear path towards industrial-scale production.

IN DEPTH

Background and the Path to Commercialization in Cultivated Meat

The cultivated meat industry holds significant promise as a sustainable solution for food supply and ethical animal welfare. However, transitioning this innovative technology from laboratory research to a commercial market demands overcoming multiple challenges, including establishing large-scale production capabilities, significantly reducing manufacturing costs, and navigating complex regulatory approval processes in various countries.

SuperMeat, an Israel-based cultivated meat company specializing in cultivated chicken, is actively addressing these hurdles. Its strategic focus is on commercialization, particularly targeting the European market, with an initial emphasis on Switzerland.

SuperMeat's Funding and Commercialization Strategy

SuperMeat has successfully completed an initial closing of its Series A-4 financing round, securing US$6 million as part of a targeted US$10 million raise. This capital injection is primarily earmarked to accelerate the commercialization of its cultivated chicken technology and facilitate its planned market entry into Switzerland. The company's immediate priorities include a multi-pronged approach:

- **Process Verification at Commercial Scale:** Demonstrating the reproducibility, efficiency, and robustness of its production process at a commercial manufacturing scale. This is a crucial prerequisite for regulatory approval.
- **Regulatory Preparation:** Compiling the necessary documentation and data for submission to Swiss regulatory authorities for product approval. Adherence to national food safety regulations is a vital part of this process.
- **Consumer-Facing Validation Studies:** Conducting research to gauge consumer acceptance and gather feedback on the product. These studies are critical for market success post-launch.

Strategic Partnerships and Technological Advancements

To bolster its commercialization strategy, SuperMeat has forged several powerful partnerships:

- **Ajinomoto Collaboration:** A research and development and technology development framework agreement has been established with Ajinomoto, a major Japanese food and biotechnology company. This collaboration is expected to contribute to optimizing the flavor, texture, and nutritional profile of cultivated meat products.
- **Expanded Micarna Partnership:** SuperMeat has extended its collaboration with Micarna, a subsidiary of the Swiss retail giant Migros. This partnership is vital for consumer validation studies within the Swiss market and for ensuring market fit from the early stages of product development. Joint product development with Ajinomoto and Migros-led consumer validation studies in Switzerland are planned, preceding the regulatory submission.
- **Continuous Bioprocessing Integration:** In a significant technological advancement for industrial-scale production, SuperMeat integrated continuous bioprocessing technology with Stämm in February 2025. Continuous processes are more efficient and stable than traditional batch processes, contributing significantly to improved production efficiency and cost reduction, which are key for making cultivated meat price-competitive.

Industry Impact and Future Outlook

SuperMeat's recent developments are indicative of the broader progress in the cultivated meat industry, especially concerning commercialization in the European market. Switzerland, known for its stringent food regulations, could serve as a crucial gateway; a successful approval there could pave the way for expansion into other European countries. Partnerships with established corporations like Ajinomoto and Migros are instrumental in enhancing the credibility and market acceptance of cultivated meat products.

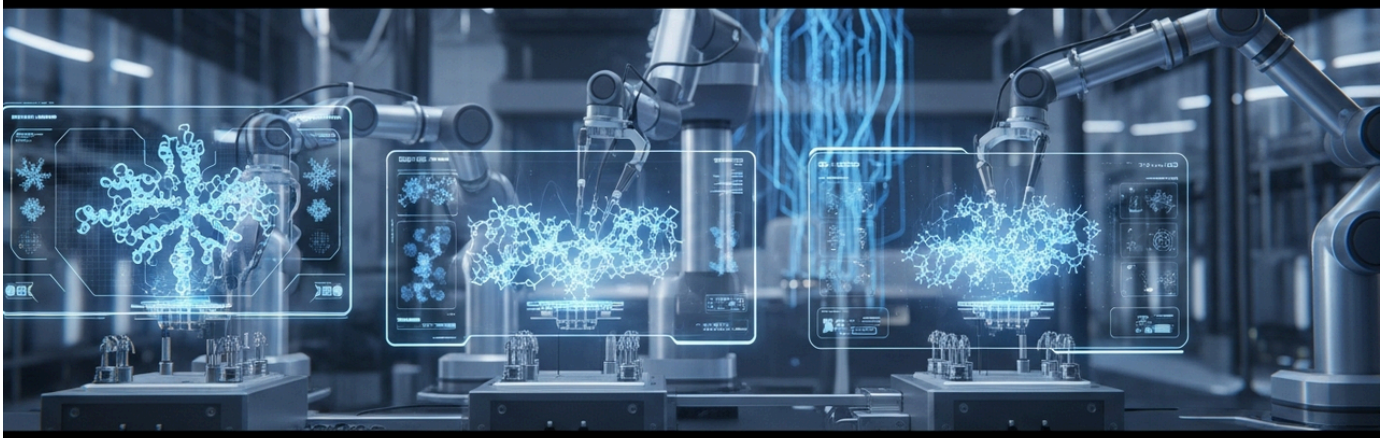
Technologically, the adoption of continuous bioprocessing is key to driving down the cost of cultivated meat, ultimately making products more affordable for consumers. SuperMeat's trajectory represents a significant step towards a future where cultivated meat is a more realistic and accessible component of sustainable food systems, showcasing how targeted innovation and strategic collaborations can accelerate the path to market for novel food technologies.

Source: https://www.proteinproductiontechnology.com/post/supermeat-secures-us-6-million-series-a-4-funding-to-advance-cultivated-chicken-launch-in-switzerland

Collected: May 15, 2026 | Automated Research System (Gemini API)

Form Bio Launches FormManufacturing: An AI-Driven End-to-End Platform for Genetic Medicine Design and Manufacturing Optimization

Published May 11, 2026 Morningstar USA



OVERVIEW

Form Bio has introduced FormManufacturing™, an AI-driven, end-to-end platform for predicting, optimizing, and monitoring manufacturability of genetic medicines, debuting with an AAV-focused offering. Integrating AI-driven design optimization with deep genomic characterization, this platform addresses a critical bottleneck in cell and gene therapy (CGT) manufacturing, where 74% of FDA rejections stem from quality or manufacturing issues. FormManufacturing aims to mitigate risks from subtle genomic changes during scale-up, provide molecular intelligence for high-quality CGT production, and accelerate the development of safer, more efficacious, and manufacturable therapeutics.

IN DEPTH

Background and the Manufacturing Bottleneck in Genetic Medicines

Genetic medicines, particularly cell and gene therapies (CGTs), hold immense promise as transformative treatments for intractable diseases. However, the journey from initial construct design to commercial-scale manufacturing with consistent quality remains one of the industry's most significant challenges. Reports indicate that 74% of FDA rejections for CGT products are attributable to quality or manufacturing issues, underscoring manufacturability as a decisive factor in therapeutic success.

The manufacturing process is often unpredictable, with subtle genomic changes occurring during cell line expansion or scale-up leading to product quality variations and costly rework. To overcome these hurdles and accelerate the delivery of life-saving therapies, novel approaches combining artificial intelligence (AI) with advanced data analytics are critically needed.

Form Bio's "FormManufacturing™" Platform: An AI-Driven Solution

Form Bio, a leader in AI-powered genetic medicine development, has launched "FormManufacturing™," an innovative platform designed to predict, optimize, and monitor manufacturability for CGTs across the entire lifecycle, from initial construct design to commercial scale-up. Debuting with an AAV (adeno-associated virus)-focused offering, the platform provides key functionalities and benefits:

- **AI-Driven Design Optimization:** AI algorithms predict manufacturability at the genetic construct design stage and propose optimizations. This proactive approach helps to preempt manufacturing challenges early in development, significantly reducing later-stage failures.
- **Deep Genomic Characterization:** The platform integrates deep genomic characterization to monitor and assess subtle genomic changes that may occur during cell line expansion or vector production, providing real-time insights into their impact on product quality.
- **Manufacturing Process Monitoring and Optimization:** By analyzing data from actual manufacturing processes, AI monitors performance in real-time, supporting optimization to ensure process stability and product consistency.

- **Payload Characterization and Manufacturing Comparability Analytics:** It integrates characterization of the therapeutic gene (payload) with comparability analytics to evaluate how manufacturing process changes affect the final product, crucial for regulatory submissions and batch-to-batch consistency.

By integrating these capabilities, FormManufacturing™ provides comprehensive molecular intelligence for genetic medicine developers to manage quality and reduce manufacturing risks effectively.

Industry Impact and Future Outlook

Form Bio's FormManufacturing™ platform has the potential to revolutionize genetic medicine manufacturing. Its key impacts and outlook include:

- **Resolving Manufacturing Bottlenecks:** By leveraging AI and genomic data to predict and optimize manufacturability, the platform addresses one of the biggest barriers to CGT commercialization. This will reduce development delays and mitigate costly failures.
- **Enhancing Quality and Safety:** Real-time quality monitoring and AI-driven optimization will significantly improve product consistency and safety, directly leading to the provision of safer and more efficacious therapeutics for patients.
- **Accelerating Development and Reducing Costs:** By integrating manufacturability considerations from the design stage and optimizing processes, the platform can shorten development timelines and reduce both R&D and manufacturing costs for genetic medicines.
- **Accelerating CGT Sector Growth:** With reduced manufacturing risks, more companies may be encouraged to enter the CGT space, accelerating the overall pace of innovation and product development.

Through this platform, Form Bio aims to redefine how biopharma developers manage quality and mitigate risks throughout the genetic medicine lifecycle. This represents a crucial step toward a future where advanced therapies reach patients more rapidly and reliably, establishing new benchmarks for efficiency and quality in advanced biomanufacturing globally.

Source: https://www.morningstar.com/news/accesswire/1165508msn/form-bio-launches-formmanufacturing-an-end-to-end-platform-for-ai-driven-design-and-manufacturing-of-genetic-medicines

Collected: May 15, 2026 | Automated Research System (Gemini API)

Pharmaceutical Membrane Filtration Market: Size, Share, and Growth Forecast to 2034 – A Straits Research Overview

Published May 11, 2026 Straits Research Germany

OVERVIEW

This article provides an overview of a market research report published by Straits Research, detailing the pharmaceutical membrane filtration market's current status and projected growth to 2034. The report identifies the increasing adoption of continuous bioprocessing in biologics manufacturing and tightening regulatory controls as primary market drivers. The global market is anticipated to continue its robust growth trajectory, propelled by these trends.

IN DEPTH

This article provides an overview of a market research report published by Straits Research.

Report Overview

This report focuses on the global pharmaceutical membrane filtration market, providing a detailed analysis of its size, share, and growth projections through 2034. It highlights the expanding adoption of continuous bioprocessing in biopharmaceutical manufacturing and increasing regulatory stringency from global agencies (such as the FDA and EMA) concerning contamination control in sterile injectables as key market drivers.

Geographically, the Asia-Pacific region is projected to experience the fastest growth, driven by enhanced biopharmaceutical production capacities in countries like China, India, and Japan.

Key Research Findings

- **Accelerated Market Growth:** The pharmaceutical membrane filtration market is forecast for robust growth, propelled by rising demand for biologics and the integration of continuous manufacturing processes.
- **Prevalence of Continuous Bioprocessing:** Major players like WuXi Biologics and Samsung Biologics are expanding their perfusion-based upstream systems, integrating them with continuous downstream clarification trains to enhance biologics output efficiency. These continuous systems heavily rely on alternating tangential flow ultrafiltration for efficient cell retention, thereby sustaining and increasing demand for filtration membranes globally.
- **Regulatory Tightening and Membrane Demand:** Stricter regulations from agencies like the FDA and EMA regarding sterile injectable contamination control are compelling manufacturers to use validated, low-protein-binding PES (Polyethersulfone) and PVDF (Polyvinylidene Fluoride) membranes. This drives demand for high-quality, compliant membrane filtration solutions.

- **CDMO Facility Modernization:** FDA-aligned modernization of CDMO facilities towards continuous bioprocessing, facilitated by regulatory programs, boosts real-time membrane utilization and reduces downtime, further strengthening market demand for these filtration solutions.

About the Publisher

Straits Research is a global market research firm that provides detailed market intelligence reports across various industry sectors. Their reports offer in-depth insights into market trends, competitive landscapes, and growth opportunities, serving as a valuable resource for companies in their strategic decision-making processes.

Source: https://straitsresearch.com/report/pharmaceutical-membrane-filtration-market

Collected: May 15, 2026 | Automated Research System (Gemini API)

Advanced 3D Bioprinting Techniques Drive Progress in Organoid and Tissue Development for Regenerative Medicine and Drug Discovery

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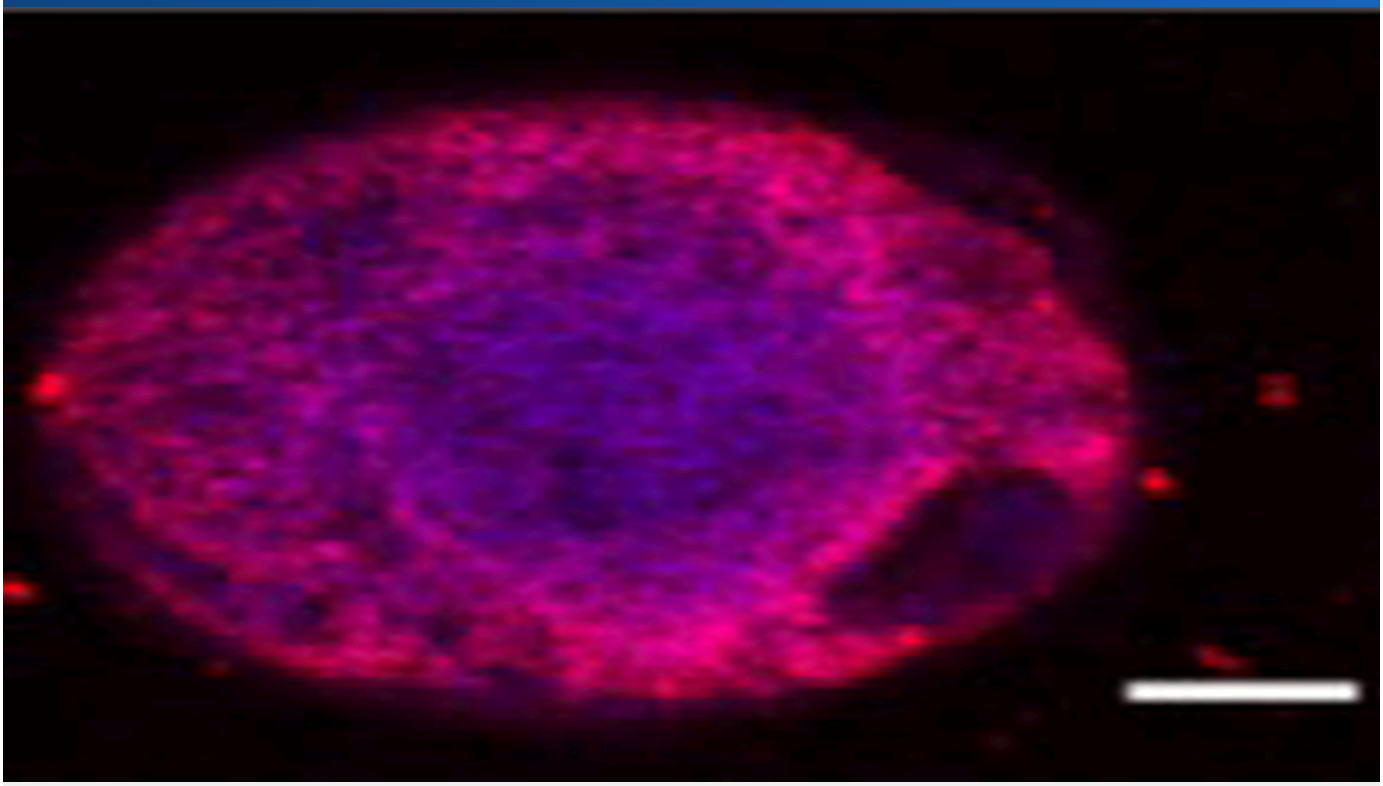

OVERVIEW

This technical article highlights advancements in 3D bioprinting for creating sophisticated organoid and tissue models, emphasizing their potential for cell therapy, personalized diagnostics, and drug discovery. Organoids, derived from stem cells, replicate in vivo organ structure and function, offering physiologically relevant in vitro models. The research underscores the need for automated biofabrication methods, like laser-assisted bioprinting, to overcome limitations of random spheroid self-assembly and enhance control over size and architecture. Poietis' NGB-R LAB system is presented as a multimodal 3D bioprinting platform combining extrusion and laser techniques with robotics for automated, precise tissue construction.

IN DEPTH

Background and the Importance of Organoid and Tissue Engineering

In fields such as regenerative medicine, drug discovery, and personalized medicine, the development of in vitro model systems that accurately replicate the complex structure and function of in vivo organs and tissues has been a long-standing goal. Traditional two-dimensional (2D) cell cultures often fail to provide sufficient information due to significant deviations from the in vivo microenvironment. Organoids, conversely, are three-dimensional (3D) tissue cultures derived from stem cells that differentiate and self-organize, offering a more physiologically relevant model.

However, organoid manufacturing has its own challenges, particularly in controlling size and architectural features. Three-dimensional (3D) bioprinting technology is emerging as a key solution to address these limitations.

Advances in Organoid and Tissue Development via 3D Bioprinting

3D bioprinting, a technology that constructs 3D structures by layering cells and biomaterials, enables precise control over the design and manufacturing of organoids and complex tissue models. This technical article highlights the following key advancements:

- **Necessity of Controlled Biofabrication:** The production of spheroids (spherical cell aggregates) traditionally relies on random self-assembly, resulting in limited control over size and internal architectural features. Automated and controllable biofabrication methods, such as laser-assisted bioprinting, are crucial for overcoming this limitation and constructing more uniform and functional tissue structures.
- **Research in Cartilaginous Tissue Models:** Studies have demonstrated that cartilaginous spheroids formed from human periosteum-derived cells maintain high cell viability and differentiation capacity even after bioprinting. This indicates the potential of 3D bioprinting to process living cells without damage and construct functional tissues.

- **Poietis' NGB-R LAB System:** Poietis's "Next Generation Bioprinting Systems (NGB-R) LAB" is introduced as an innovative multimodal 3D bioprinting platform. This system combines two advanced technologies: extrusion-based bioprinting (extruding bioinks containing cells) and laser-assisted bioprinting (precisely depositing cells with a laser). Furthermore, integrated robotics allow for the automated creation of various structures, from single cells to complex 3D spheroids.

Industry Impact and Future Outlook

The advancements in organoid and tissue development through 3D bioprinting are poised to bring revolutionary impacts across the life sciences sector:

- **Innovation in Drug Discovery:** By providing more realistic disease models, the efficiency and accuracy of drug screening will improve, leading to shorter development times and higher success rates. The ability to replicate complex tissue-tissue interactions is particularly advantageous for evaluating drug efficacy.
- **Advancement of Personalized Medicine:** Bioprinting patient-derived organoids enables personalized diagnostics and therapeutic development, allowing for predictions of individual patient responses to treatments.
- **Cell Therapies and Regenerative Medicine:** The capability to construct functional tissues and organs in vitro could lead to scaffold materials for cell therapies and, in the future, the development of transplantable artificial organs.
- **Standardization and Reproducibility in Research:** Automated and precise bioprinting promotes the standardization of research processes and enhances experimental reproducibility, thereby increasing the reliability of scientific discoveries.

This technology, born from the convergence of bioengineering, cell biology, and computational science, is expected to continue its rapid development, opening new frontiers in life science research and medical applications. The ability to engineer complex biological structures with unprecedented control is a key enabler for the next generation of advanced therapeutics and diagnostics globally.

Source: https://www.news-medical.net/whitepaper/20260513/3D-bioprinting-for-organoid-and-tissue-

development.aspx

Lonza Reports Strong Q1 2026 Performance, Driven by Robust CDMO Growth and Strategic Transformation into Pure-Play Biopharma Partner

Published May 08, 2026 Lonza Switzerland

OVERVIEW

Lonza delivered strong Q1 2026 performance across its Contract Development and Manufacturing Organization (CDMO) business, aligning with full-year expectations despite macroeconomic challenges. The company secured multiple integrated drug substance-drug product contracts and extended its commercial manufacturing agreement for Genetix's ZYNTEGLO™. Customer interest remains high for its large-scale mammalian capacity in Vacaville (US), with construction progressing well at its commercial-scale aseptic drug product facility in Stein (CH). Lonza has completed its transformation into a pure-play CDMO by divesting its Capsules & Health Ingredients (CHI) business, and is actively seeking M&A opportunities to expand capabilities, confirming its 2026 outlook for strong growth.

IN DEPTH

Background and Dynamics of the CDMO Market

The increasing complexity of drug development and manufacturing challenges within the pharmaceutical industry has fueled a global surge in demand for Contract Development and Manufacturing Organizations (CDMOs). CDMOs provide a comprehensive range of services, from early-stage development to commercial production, enabling pharmaceutical and biotechnology companies to focus on R&D and efficiently bring products to market. The emergence of complex modalities, particularly biologics and cell and gene therapies, further accentuates the importance of CDMOs with specialized expertise and state-of-the-art facilities.

Lonza, headquartered in Switzerland, has long established itself as a leading player in the CDMO industry, consistently adapting to evolving market demands.

Lonza's Q1 2026 Performance and Strategic Progress

Lonza reported a strong performance across its entire CDMO business in Q1 2026. This achievement came despite prevailing geopolitical and macroeconomic challenges, aligning with the company's full-year trajectory and demonstrating its robust business foundation.

Key highlights include:

- **Sustained Business Momentum:** Lonza experienced continued business momentum across its diverse technology platforms and global manufacturing sites. This reflects the broad appeal of Lonza's service offerings and its strong market reputation.
- **Secured and Extended Contracts:** The company successfully secured multiple new integrated drug substance-drug product contracts. Furthermore, it extended its commercial manufacturing agreement for Genetix's ZYNTEGLO™, signaling strong, long-term partnerships and client trust in Lonza's capabilities for advanced therapeutics.
- **High Demand for Large-Scale Mammalian Capacity:** Customer interest remains high for Lonza's large-scale mammalian cell culture capacity in Vacaville, USA, with peak sales anticipated in the early 2030s. This underscores the continued reliance on Lonza's capacity and technological prowess in biologics manufacturing.

- **Progress on New Facility Construction:** Construction of Lonza's commercial-scale aseptic drug product facility in Stein, Switzerland, is progressing well. This facility will address the rising demand for sterile drug products and further enhance Lonza's comprehensive CDMO capabilities.
- **Completion of Pure-Play CDMO Transformation:** Lonza finalized its strategic transformation into a pure-play CDMO by divesting its Capsules & Health Ingredients (CHI) business. This move allows the company to fully focus on its core business of pharmaceutical contract development and manufacturing, streamlining its strategic direction.
- **Active Exploration of M&A Opportunities:** Lonza is actively building a pipeline of M&A opportunities to further expand its capacities and technologies. This demonstrates a clear commitment to sustained growth in biologics and advanced synthesis sectors.

Industry Impact and Future Outlook

Lonza's strong Q1 2026 performance and strategic advancements reaffirm its leadership in the global CDMO market. The transformation into a pure-play CDMO enables specialization aligned with market needs, allowing for concentrated resources in high-growth areas.

The provision of integrated drug substance-drug product services and the maintenance of large-scale manufacturing capacities offer significant advantages to clients by simplifying the development process and accelerating time-to-market with a single, end-to-end partner. The extended manufacturing agreement for advanced therapies like ZYNTEGLO™ further highlights Lonza's reliability in complex biopharmaceutical production.

Moving forward, Lonza is expected to continue strengthening its capabilities in high-growth areas, such as cell and gene therapy, through strategic M&A activities. The company will remain an indispensable player in the global biopharmaceutical supply chain, contributing to the acceleration of pharmaceutical innovation and improved patient access to vital medicines worldwide.

Source: https://www.lonza.com/news/2026-05-08-06-30

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