BroadBranch Advisors

AN ASGCT 2026 SUMMARY

Key Trends Defining the Cell and Gene Therapy Market

The 29th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT) convened May 11-15, 2026 and drew more than 7,000 attendees from across the global cell and gene therapy (CGT) ecosystem. The roughly 320 exhibiting companies demonstrated robust commercial interest in the event's role as a market bellwether.

A conglomeration of themes emerged from this year's event that, when woven together, creates the backbone of commercially viable medicine. CGT has evolved beyond speculative therapeutic efficacy and is transitioning toward a market foothold. The conference painted a picture of an industry that is simultaneously pushing at the frontier of molecular engineering and grappling with the infrastructure, economics, and organizational models required to translate that science into accessible medicine. Here are some of the highlights from this year's convening that illustrate how advances are manifesting.

Reactivating Shelved Programs

KPerhaps the most organizationally significant announcement from ASGCT 2026 was the public debut of CGTxchange. This AI-enhanced marketplace, jointly launched by ASGCT and Orphan Therapeutics Accelerator (OTXL) to rescue deprioritized cell and gene therapy programs, directly addresses programs that have been abandoned due to lack of commercial attractiveness, but not due to scientific failure.

"It was market failure. Some investors who had moved into gene therapy had unrealistic expectations about the pace of returns. Most of these programs were not encountering true clinical failures. The science was there," stated Dr. Terry Flotte, ASGCT President.

Dr. Flotte noted that by the time ASGCT began systematically cataloging the problem, there were

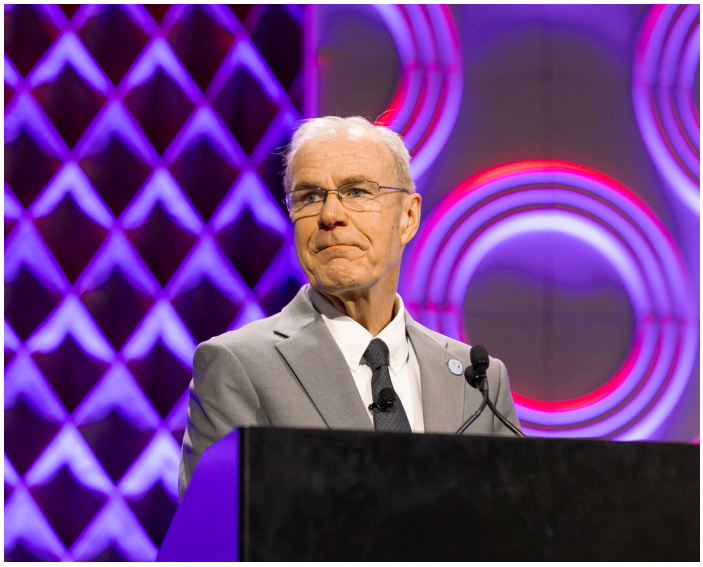
at least 50 technologies whose sponsors had halted development, liquidated assets, and walked away from clinical-stage therapies. This behaviour was seen across the development spectrum, including programs that had already dosed patients and demonstrated meaningful clinical signals. CGTxchange's solution to this problem is to connect assets with new sponsors, investors, and development partners.

On the operational side of CGTxchange, Beth White, Chief Operating Officer of OTXL, provided important context on the mechanics of the model, and on the strategic logic for CDMOs in particular. OTXL's structure as a nonprofit accelerator allows it to license shelved programs at low upfront cost, de-risk them through its evaluation process, network with affiliated CDMOs, CROs, and clinical development partners, and route revenue from successful approvals back into sustaining new programs.

"When you think about the current environment, a lot of CDMOs have excess capacity. So we wanted to find a business model that worked, because the science really wasn't an issue. A model that linked the program to a developer. These programs had data, they were IND ready or beyond," explained Dr. White.

WASKYRA (approved gene therapy for Wiskott-Aldrich syndrome) followed the OTXL model; it was licensed by Fondazion Telethon and manufactured by AGC Biologics. Additionally, AGC Biologics announced its formal induction into OTXL's Clinical Development Network, demonstrating the consortium's momentum.

The near-term goals of CGTxchange are clear: generate licenses transferring intellectual property from current holders to development-ready partners, re-initiate clinical programs, and pursue FDA approval. For CDMOs sitting on underutilized capacity, a reality driven by investment contraction in CGT since 2022, CGTxchange represents

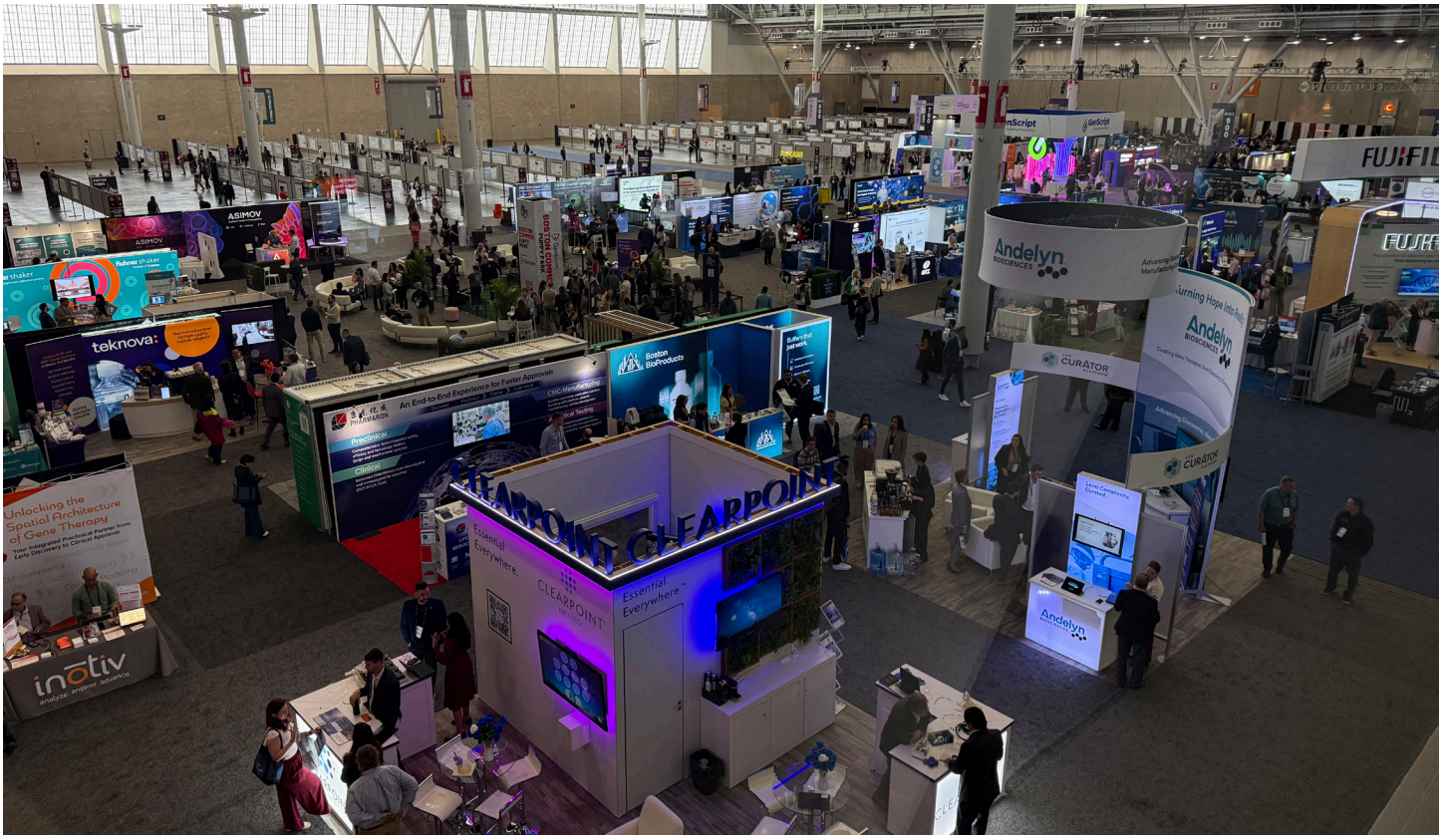


a genuinely novel business model. Rather than waiting for the next large biotech to fill a manufacturing suite, CDMOs can participate in a consortium that de-risks their investment through success-based agreements and, in doing so, help them establish a track record in modalities they have yet to prove commercially. The "IND-ready or beyond" qualifier of these programs means the risk profile is meaningfully lower than typical early-stage work.

Advanced AAV Capsid Engineering

The field has long understood that the tissue tropism of natural AAV serotypes is both its greatest asset and most significant liability. AAV9 can reach cardiac and skeletal muscle systemically, but it also floods the liver, raising toxicity concerns that have been a prominent issue for systemic AAV gene therapy programs. Multiple presentations highlighted a new generation of AAV capsid variants engineered for precise tissue targeting and dramatic de-targeting of off-target organs.

GenAssist's announcement of LD-8S09 is a compelling illustration of capsid engineering progress. In non-human primate studies, it demonstrated over 10x higher functional transduction in cardiac and skeletal muscle compared to standard AAV9, while reducing



vector DNA distribution in the liver to just 3% of AAV9 levels. Meanwhile, Genethon's ATA-200 program for LGMD-R5 showed that more than 90% of muscle fibers expressed the therapeutic SGCG protein in the first two patients treated, demonstrating a remarkable transduction efficiency.

AI-Driven Biologics Analytics

The exhibit floor featured a relatively high density of companies deploying artificial intelligence for construct optimization, manufacturing quality control, capsid quantification, and general data analytics. The industry would benefit from pushing AI vendors for clearer evidence of biological impact, not just computational performance.

Form Bio launched FormManufacturing, a platform combining AI-driven construct design optimization (FormSightAI) with genomic quality and comparability analytics (FormBatchQC). The platform addresses well-documented problems: a vast majority of FDA rejections for cell and gene therapies are triggered by quality or manufacturing issues, and minor genomic changes during cell line expansion, viral integration, and scale-up that can alter product potency and safety without detection until late-stage development or regulatory review. However, the open question remains: how much of this improves biological outcomes versus optimizing informatics pipelines? Form Bio reports an 8x improvement in genome integrity, a 2-3x increase in manufacturing yield, and a 5x improvement in controllable expression — metrics that, if reproducible across a diverse set of programs, could equate to genuine biological impact.

CRISPR + PiggyBac Gene Writing (FiCAT)

Integra Therapeutics presented preclinical data from their FiCAT (Find-Cut-and-Transfer) platform, demonstrating the simultaneous insertion of four therapeutic genes and the deletion of one

unwanted gene in a single intervention. FiCAT combines two distinct molecular mechanisms: the precision DNA targeting of CRISPR-Cas9, which directs the system to a specific genomic locus, and a proprietary PiggyBac transposase, which executes the controlled insertion of genetic payloads into that predetermined safe site. In a head-to-head comparison with LVVs (currently approved for CAR-T cell therapies) T cells modified with FiCAT matched or outperformed LVVs across key performance indicators including cell viability, tumor-killing ability, and genotoxicity associated with integration.

Particle Quantification

The accurate characterization of capsid populations to determine what fraction of particles carry a complete, functional genomic payload remained an active concern with exhibitors highlighting their solutions. Accurate characterization and quantification is a regulatory expectation that has become increasingly scrutinized as programs advance toward commercialization. Cryogenic transmission electron microscopy (cryo-TEM) has been the standard for capsid characterization, particularly for AAVs. Delong Instruments' LVEM 25E adds a new tool to the proverbial toolbox with a much lower barrier to entry: it can be installed in a standard laboratory space using a single power outlet and requires no cooling water, vibration isolation, or dedicated room. Forge Biologics approached the same challenge from an analytical chemistry angle, presenting an Analytical Ultracentrifugation (AUC) assay to characterize the AAV empty-to-full capsid ratio by their sedimentation coefficient, which varies between empty, partial, and full capsids. On the LVV front, Progen debuted the GENSPEED R2 Analyzer which allows users to leverage automation to provide rapid and consistent quantification.

Market Implications and Future Outlook

Stepping back from ASGCT 2026, a broader story emerges about where the cell and gene therapy market is heading. Understanding this narrative is essential for the scientists, manufacturers, investors, and regulators who will shape the next phase of this field; patients are waiting for these therapies and need it to be shaped correctly.

Orphan Therapeutics as a New Asset Class

The launch of CGTxchange is an assertion that clinically validated, scientifically rigorous gene therapies that have been deprioritized represent an undervalued asset class. CGTxchange could establish a new market for shelved programs that creates liquidity for IP holders, puts excess CDMO capacity to productive use, and offers renewed hope for the patient populations left waiting. CGTxchange transactions and CDMO consortium agreements announced in late 2026 will be an indicator of the program's success.

CDMO Consolidation Around Integrated Capabilities

The capacity surplus that exists today in AAV and viral vector manufacturing will not be absorbed by conventional pharmaceutical demand alone. CDMOs that participate in novel development models such as orphan therapeutics consortia, platform-authorized gene therapy programs, and autologous cell therapy automation will occupy a structurally differentiated position. The CDMO

that can only do one thing well is becoming less competitive than the one that bridges design, manufacturing, analytics, and regulatory intelligence.

AAV Engineering Creates IP Opportunities.
As the field moves from natural serotypes to engineered variants with defined tissue targeting profiles, the capsid itself becomes a proprietary asset distinct from the therapeutic gene cargo. This creates a two-layered IP structure, vector and payload, with significant implications for licensing, partnership formation, and competitive moat. Similar to how linker IP became increasingly significant in ADC production, engineered capsid libraries may grow to become valuable market assets.

Regulatory Approvals Will Determine the Pace of AI Adoption.
The abundance of AI tools displayed raises a question the FDA will ultimately answer: what constitutes sufficient evidence of AI-informed quality improvement for regulatory purposes? The FDA's attention to Novel Assessment Methodologies (NAMs) and its ongoing engagement with computational approaches suggest an openness to AI-driven evidence, but the specific standards for defensible, reproducible AI-generated evidence in submissions are still taking shape. Companies investing now in building that regulatory evidence base will be positioned to lead when those standards are more established.

Grammar Changes in Gene Editing
Whether CRISPR + PiggyBac platforms like FiCAT become the primary manufacturing modality for next-generation CAR-T therapies will depend on clinical validation results still years away. But if FiCAT or a similar platform demonstrates equivalent or superior clinical outcomes to LVV-manufactured CAR-T cells in phase 1 studies, the manufacturing implications are potentially market disruptive and worth monitoring.

The BroadBranch Advisors Impact

BroadBranch helps clients better understand their markets and identify opportunities through:

- Voice-of-customer and end-user research
- Competitive landscape and positioning analysis
- Technology adoption and disruption assessments
- Commercial diligence and growth strategy development

In an environment defined by complexity, integration, and rapid innovation, independent market intelligence has never been more critical.

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