ProGen Search

CGT CDMO Report:

Market Outlook - Q3 2025

Navigating the Cell & Gene Therapy CDMO Landscape

Prepared by

Byron Fitzgerald

Founder, ProGen Search

www.progensearch.com

ProGen Search partners with investors and leadership teams across Biotech, Pharma, CDMO, and CRO sectors to solve their most critical executive hiring challenges and build leadership teams that scale innovation. We were founded on the belief that executive search should be transparent, research-led, and deeply aligned to the future ambitions of the companies we serve.

Our story began from first-hand frustration with the traditional search model - one that often relied on opacity rather than insight. After 14 years in executive search - including scaling a consultancy to 36 consultants and refining an industry-leading model as co-founder of a specialist firm - ProGen's founder launched the business in December 2024 to deliver a more rigorous, open-source approach to leadership hiring.

Today, our clients trust us globally to identify, engage, and secure transformative talent - supported by deep sector research, transparent processes, and clear deliverables. Whether supporting scale-up biotech, investor-backed CDMOs, or emerging therapeutic platforms, we partner with clients not just to fill roles, but to shape the leadership needed to create long-term value.

2025 Cell & Gene Therapy Manufacturing and CDMO Landscape

Chapter 1: Executive Summary: A Market of Paradox and Opportunity

The global Cell and Gene Therapy (CGT) sector stands at a pivotal and paradoxical juncture in mid-2025. It is a market defined by unprecedented, explosive growth, with valuations projected to surge from approximately $7 billion in 2024 toward an astonishing $78 billion by 2033, fueled by a torrent of investment and a robust pipeline of potentially curative therapies. Yet, this hyper-growth is occurring in parallel with a period of intense consolidation, high-profile strategic failures, and a fundamental crisis in manufacturing that threatens to capsize the field's potential.
This report argues that success in the contemporary CGT market is no longer a simple function of scientific innovation or adding physical capacity. Instead, it is a complex equation of strategic positioning, technological differentiation, operational excellence, and financial resilience.

The analysis of the landscape as of Q3 2025 reveals several defining themes:

(1) **Manufacturing has become the central strategic battleground.** The industry is grappling with a profound and persistent "great bottleneck" that spans the entire value chain. From the complex, inconsistent production of viral vectors to the logistical nightmare of patient-specific autologous therapies and the high-risk final steps of fill/finish, the struggle to transition from bespoke, laboratory-scale processes to robust, industrialized manufacturing is the single greatest threat to the sector's momentum.

(2) **A "flight to quality and capability" is driving consolidation and reshaping the competitive landscape.** The period from 2024-2025 has been marked by transformative M&A activity. However, the focus has irrevocably shifted from acquiring mere capacity to securing specialized technologies, proven regulatory track records, and resilient supply chains. Landmark events like Novo Holdings' $16.5 billion acquisition of Catalent, the geopolitically-driven creation of a new global CDMO leader in Minaris Regenerative Medicine, and the strategic restructuring of Resilience highlight a market in flux, where only the most capable and well-capitalized players can thrive.

(3) **The talent crisis has surpassed capital as the most significant constraint on growth.** The CGT industry's growth is dramatically outpacing its ability to cultivate the skilled workforce required to sustain it. A critical shortage of specialized talent—from process development scientists and QA/QC analysts to hybrid "biomanufacturing executives" who can bridge the gap between science and industrial operations—is leading to idle, high-cost facilities, delayed clinical programs, and a crisis of capital efficiency across the sector.

(4) **Automation and strategic partnerships are the primary pathways forward.** The industry's response to these bottlenecks is coalescing around a single imperative: automation. A new generation of technology providers is emerging with end-to-end automated platforms designed to solve the core challenges of manual labor, scalability, and cost. This is forcing a shift in the traditional CDMO relationship, from tactical outsourcing to deep, strategic alliances where the choice of manufacturing partner and technology platform has become a cornerstone of a therapy developer's corporate strategy.

For C-level leaders, the implications are stark and immediate. The findings of this report demand a fundamental re-evaluation of how manufacturing is perceived and managed. It can no longer be a siloed operational function; it must be elevated to a core pillar of corporate strategy, on par with R&D and clinical development. The imperative is to move beyond tactical outsourcing and forge a resilient, forward-looking manufacturing and supply chain strategy. This requires stress-testing supply chain vulnerabilities, actively investing in the automation and technology platforms that will define the next generation of production, and treating the acquisition and retention of specialized talent as the critical, rate-limiting factor for growth that it has become. The companies that act on these imperatives now will be the ones that lead the market tomorrow.

Chapter 2: Global Market Dynamics: The Forces Shaping the New Competitive Battleground

A confluence of powerful forces is shaping the CGT CDMO industry. Unrelenting demand from a burgeoning therapeutic pipeline creates a foundation of growth, while technological innovation redefines the terms of competition. Simultaneously, market consolidation and geopolitical pressures are fundamentally redrawing the map of global leadership, creating both immense opportunities and significant risks.

2.1 The Engine of Growth: Pipeline Demand and the Outsourcing Imperative

The primary driver of the CGT CDMO market's extraordinary growth is the sheer volume and momentum of the global therapeutic pipeline. With over 2,500 active INDs on file with the FDA and a significant portion of the global pipeline (approx. 67%) in the preclinical stage, a deep and sustained demand funnel for development and manufacturing services is assured for years to come. This is compounded by the fact that a majority of biotechnology companies—particularly small and emerging firms—lack the capital, infrastructure, and specialized expertise to build their own cGMP-compliant facilities. Consequently, more than 53% of these companies now strategically outsource their development and manufacturing activities to CDMOs.

This outsourcing model is no longer a matter of convenience but a strategic necessity. The manufacturing processes for cell and gene therapies are notoriously complex and resource-intensive. By partnering with a CDMO, therapeutic developers can mitigate significant investment risks, gain access to cutting-edge technology, and leverage the regulatory experience of an established manufacturer. This outsourcing imperative is the central challenge for emerging therapy developers, with companies like Syntax Bio actively navigating this complex landscape to find the right CDMO partners to accelerate their programs. This dynamic has created a pronounced "capacity crunch," granting significant pricing power to established CDMOs but posing a critical risk of clinical delays for therapy developers, thereby fueling the emergence of disruptive new players aiming to solve these very bottlenecks.

2.2 Market Sizing by Segment: A Quantitative Outlook (2025–2030)

While the overall CGT CDMO market is projected to grow at a CAGR of approximately 27-30%, this growth is not uniform. The market can be broken down into several key service segments, each with distinct dynamics. Note: All figures are based on aggregated estimates from third-party industry reports.

Market Segment	Est. 2025 Market Size (USD)	Projected 2030 Market Size (USD)	Est. CAGR (2025-2030)	Key Drivers & Geographic Focus
Viral Vector Manufacturing	~$4.0 Billion	~$10.5 Billion	~21%	Pipeline demand for AAV/LVV; shift to in-vivo therapies. Dominated by North America, with strong growth in Europe.
Cell Therapy Services	~$3.5 Billion	~$9.5 Billion	~22%	Commercial autologous demand (CAR-T); strong investment in allogeneic/iPSC platforms. North America leads, APAC fastest growing.
Ancillary Services (Pimriarly QC & Release Testing)	~$2.8 Billion	~$7.5 Billion	~22%	Complexity of final product handling; need for robust potency assays and release testing. Growth mirrors the overall market.
Enabling Tech & Platforms	(Not specified)	(Not specified)	High Growth	Automation imperative; need to reduce COGS and process variability. Primarily driven by US/EU innovation hubs.

(1) **Viral Vector Manufacturing:** This is one of the largest and most critical segments. Driven by the vast number of gene therapies and gene-modified cell therapies in development, the demand for high-quality AAV and lentiviral vectors is intense. Industry reports estimate this sub-market will grow from approximately $4.0 billion in 2025 to over $10.5 billion by 2030. North America remains the dominant market for these services, but capacity is expanding rapidly in Europe to meet regional demand.

(2) **Cell Therapy CDMO Services:** This segment, encompassing both autologous and allogeneic therapy manufacturing, is the other core pillar of the market. Its growth is fueled by the commercial success of CAR-T therapies and massive investment in next-generation platforms like iPSCs. Valued at an estimated $3.5 billion in 2025, it is projected to expand to approximately $9.5 billion by 2030. While North America holds the largest share, the Asia-Pacific region, particularly Japan and South Korea, is expected to see the fastest growth as regional players build sovereign manufacturing capabilities.

(3) **Ancillary Services (Fill/Finish & QC):** This crucial support segment, which includes aseptic fill/finish, cryopreservation, and the full suite of quality control (QC) and release testing, is growing in lockstep with the broader market. The QC market alone is estimated at $2.82 billion in 2025 and is forecast to reach nearly $7.5 billion by 2030. The complexity and high value of the final product make these services a non-negotiable and high-growth area.

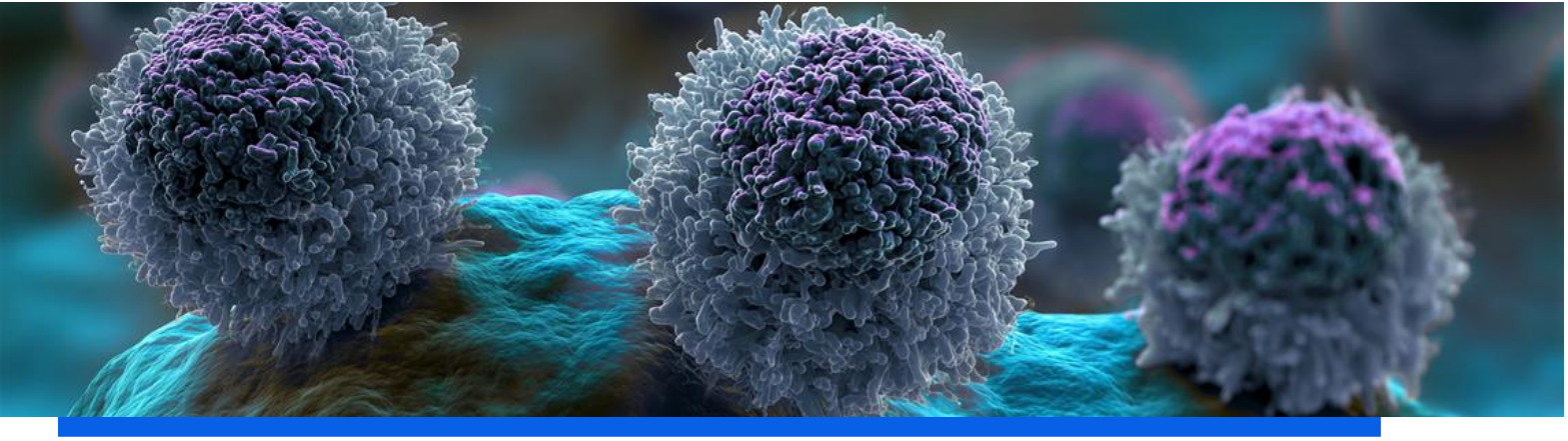
(4) **Enabling Technologies & Platforms:** While a specific market value is difficult to isolate as it is often embedded in service fees or capital equipment sales, this is a strategically vital, high-growth segment. The drive to automate processes and reduce the high cost of goods is fueling significant investment in the platforms developed by companies like **Cellares, Ori Biotech, and Miltenyi Biotec.** This segment's growth is a direct reflection of the industry's imperative to industrialize.

2.3 The Technology Arms Race: From Contract Hands to Platform Partners

What's the risk? The competitive landscape for CGT CDMOs has evolved far beyond a simple contest of capacity. Today, the primary battleground is technology. CDMOs are no longer just "contract hands" but are increasingly positioned as technology providers, with differentiation hinging on their ability to solve the core challenges of CGT manufacturing: high costs, process variability, and scalability. Key market trends reflect this shift, with **35% of the industry moving toward automation and 29% leveraging artificial intelligence (AI)** for process optimization and quality control.
This technological arms race is most evident in the development and deployment of proprietary manufacturing platforms. These integrated systems are designed to standardize and streamline production, offering clients a faster, more reliable path to market.

- **Lonza's Cocoon® Platform:** An automated, closed-system for manufacturing autologous cell therapies.
- **Cellares' Cell Shuttle™:** A revolutionary "factory-in-a-box" aiming to industrialize cell therapy production.
- **Forge Biologics' (Ajinomoto) FUEL™ Platform:** A system designed for high-yield AAV production.
- **Univercells' Technology Ecosystem:** A unique combination of intensified, chained bioprocessing units designed for viral and cell production through its subsidiaries **Quantoom Biosciences** and **Exothera.**

The proliferation of these platforms is causing the market to bifurcate into two competing philosophies: an "Integrated Bespoke Scale" model championed by established giants like Lonza, and a "Standardized Automated Disruption" model pioneered by new entrants like Cellares and Univercells. This forces a critical strategic choice upon developers: partner with a high-touch expert for a novel process, or adapt their process to fit a high-efficiency standardized platform.



2.4 Reshaping the Landscape: Consolidation, Geopolitics, and the Push for Sovereign Capacity

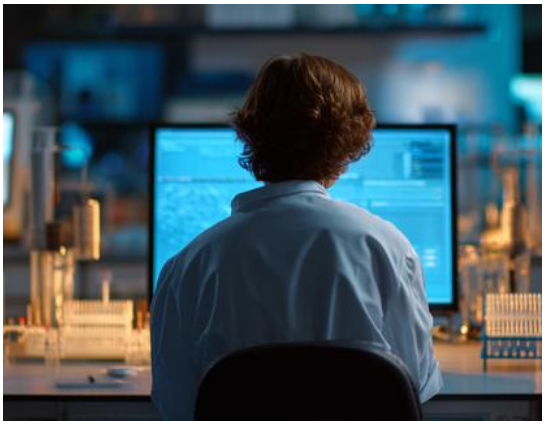
The CGT CDMO market is in a period of intense and transformative corporate activity, driven by both market pressures and powerful geopolitical currents. The landscape is being continuously reshaped by a wave of mergers, acquisitions, and strategic restructuring that are redefining the competitive hierarchy.

(1) **Market-Driven Consolidation:** Landmark transactions have underscored a "flight to quality." **The acquisition of Catalent by Novo Holdings for $16.5 billion in 2024**, which included key CGT assets from its earlier acquisition of **MaSTherCell**, sent shockwaves through the industry. While driven by the GLP-1 market, it created profound uncertainty for Catalent's CGT clients and a major business development opportunity for its rivals. In stark contrast, the **dramatic consolidation of National Resilience, Inc. in mid-2025**, which saw the closure of six of its ten manufacturing sites, serves as a critical cautionary tale about the risks of rapid expansion that outpaces sustained commercial demand. Similarly, the acquisition of **Novasep** by **Sartorius** has significantly strengthened the latter's capabilities in viral vector manufacturing.

(2) **Geopolitical Headwinds: The BIOSECURE Act and the Great Realignment:** Perhaps the most significant market-shaping force has been geopolitical. The proposed **U.S. BIOSECURE Act,** aimed at preventing U.S. federally-funded entities from contracting with certain Chinese "biotechnology companies of concern," directly targeted the parent company of **WuXi Advanced Therapies (ATU)**, a dominant player in the CGT CDMO space. This pressure was a direct catalyst for a fundamental market restructuring. In response, WuXi AppTec agreed in late 2024 to sell its U.S. and U.K.-based ATU operations to the private equity firm Altaris. Altaris then merged these assets with its existing portfolio company, **Minaris Regenerative Medicine**, to launch a new, single global CDMO in May 2025: **Minaris Advanced Therapies**. The consequence is profound: rather than simply removing a competitor, the BIOSECURE Act has unintentionally catalyzed the creation of a new, formidable, Western-owned global leader that instantly inherits a state-of-the-art infrastructure, deep expertise, and a proven commercial manufacturing track record.

(3) **The Push for Sovereign Capacity and "Friend-Shoring":** The BIOSECURE Act has massively accelerated a trend that began during the COVID-19 pandemic: the strategic imperative to build secure, domestic, and politically aligned ("friend-shored") supply chains. National governments have evolved from passive regulators into active ecosystem builders. This is evident in direct government funding and incentives designed to foster onshore manufacturing. For example, **AGC Biologics' new ¥50 billion facility in Yokohama, Japan**, is supported by a grant from the Japanese Ministry of Economy, Trade and Industry (METI) as part of a national strategy to bolster domestic biomanufacturing. This push for sovereign capability fundamentally alters the competitive landscape, placing a premium on CDMOs with secure, multi-regional footprints in politically stable jurisdictions and forcing all developers to add geopolitical risk assessment to their core partnership criteria.

Geopolitics, consolidation, and the race for sovereign capacity are no longer background forces - they are actively reshaping the CGT CDMO landscape, redrawing competitive lines and redefining what it means to be a strategic partner.



2.5 A Tale of Three Regions: North America, Europe, and Asia-Pacific

The global CGT CDMO market exhibits distinct regional characteristics:

- **North America** stands as the undisputed leader, commanding approximately **41% of the global market share.** This dominance is underpinned by a vibrant biotech ecosystem, substantial venture capital, and the presence of most leading CDMOs.
- **Europe** follows as the second-largest market, accounting for nearly **29% of the global share**. It is characterized by strong regulatory support from the EMA and a mature network of established pharmaceutical companies and CDMOs like **Cellex Cell Professionals** in Germany, **SyVento BioTech** in Poland, and analytical specialists like **Solvias** in Switzerland.
- **The Asia-Pacific (APAC) region** is projected to be the fastest-growing market. This growth is driven by increasing government investment, improving healthcare infrastructure, and a rising number of clinical trials in countries like China, Japan, and South Korea. Global CDMOs are strategically expanding their presence to capitalize on this growth, exemplified by **AGC Biologics'** major new facility in Yokohama, Japan, and Cellares' planned "Smart Factory" in the region.

North America leads, Europe stabilizes, and Asia-Pacific accelerates - each region shaping the future of CGT manufacturing through distinct strengths and strategic shifts.

Chapter 3: Directory of Global CGT CDMOs & Enablers: A Competitive Assessment (Q3 2025)

The cell and gene therapy manufacturing ecosystem is dominated by a handful of integrated life science giants—Thermo Fisher Scientific, Danaher, and Sartorius—that provide a vast portfolio of instruments, consumables, and services. Beneath this tier, a dynamic and diverse landscape of Contract Development and Manufacturing Organizations (CDMOs) and technology enablers compete and collaborate to serve the needs of therapy developers. The following section provides a detailed directory and competitive assessment of these players.

3.1 At a Glance: Global CGT CDMO Competitive Landscape
(Note: This is a representative, not exhaustive, list)

Category	Company Name	Headquarters	Key CGT Hubs	Primary Modality Focus	Key Capabilities	Service Phase	Notable 2024-2025 Strategic Move
The Integrated Global Leaders	**Lonza**	Basel, CH	Houston, TX; Geleen, NL	Cell Therapy, Viral Vectors	CAR-T, iPSC, AAV, LVV, Cocoon® Platform	Clinical & Commercial	Continued expansion of global biologics facilities.
	Catalent (Novo Holdings)	Somerset, NJ, USA	Baltimore, MD; Gosselies, BE	Cell Therapy, Viral Vectors, Plasmids	CAR-T, AAV, LVV, pDNA, Cold Chain Logistics	Clinical & Commercial	Acquired by Novo Holdings ($16.5B); reports of scaling back CGT focus.
	Thermo Fisher Scientific	Waltham, MA, USA	San Francisco, CA; Global VVS Network	Cell Therapy, Viral Vectors	Autologous/Allogeneic, AAV, LVV, Rotea/Xenon closed systems	Clinical & Commercial	Closed Plainville, MA, CGT site as part of strategic consolidation.
	Minaris Advanced Therapies	Philadelphia, PA, USA	Philadelphia, PA; UK; DE; JP	Cell Therapy, Viral Vectors	CAR-T, TIL, AAV, LVV, CTDMO, TESSA® Platform	Clinical & Commercial	New Entity (May 2025) formed from merger of Minaris RM and WuXi ATU (US/UK).
The Ascendant Challengers	**FUJIFILM Diosynth**	Tokyo, JP	Thousand Oaks, CA; College Station, TX	Cell Therapy, Viral Vectors	Autologous/Allogeneic, iPSC, AAV, LVV	Clinical & Commercial	Major expansion of California cell therapy facility operational in early 2025.
	AGC Biologics	Seattle, WA, USA	Milan, IT; Longmont, CO; Yokohama, JP	Cell Therapy, Viral Vectors, pDNA	Autologous/Allogeneic, AAV, LVV, pDNA, BravoAAV™/ProntoLVV™	Clinical & Commercial	Major expansion into Asia with new Yokohama site (operational July 2025).
	Charles River Labs	Wilmington, MA, USA	Memphis, TN; Global Network	Cell Therapy, Viral Vectors, Plasmids	Autologous/Allogeneic, AAV, LVV, pDNA, End-to-End Services	Clinical & Commercial	First NA CDMO with EMA approval for commercial allogeneic cell therapy.
	Samsung Biologics	Incheon, KR	Songdo, Incheon, KR	Biologics; Expanding into Advanced Modalities	Large-Scale Cell Culture, mRNA; moving into AOCs (gene delivery)	Clinical & Commercial	Plant 5 operational (Apr 2025); announced strategic move into AOCs (Jun 2025).
	Sartorius	Göttingen, DE	Global Network	Viral Vectors, Bioprocessing	End-to-end bioprocess solutions, viral vector services	Clinical & Commercial	Strengthened viral vector offering via acquisition of Novasep.
The Disruptors & Niche Champions	**Cellares**	S. San Francisco, CA, USA	Bridgewater, NJ; Planned EU/Asia sites	Cell Therapy (IDMO Model)	Automated, closed-loop manufacturing via Cell Shuttle™	Preclinical, Clinical & Commercial	Received FDA AMT Designation; partnership for Japan Smart Factory (May 2025).
	Resilience	San Diego, CA, USA	Philadelphia, PA; RTP, NC; Toronto, ON	Cell Therapy, Viral Vectors	Autologous/Allogeneic Cell Therapy, AAV/LVV Vectors	Clinical & Commercial	Major Restructuring (June 2025); closed 6 facilities to consolidate operations.
	RoslinCT	Edinburgh, UK	Edinburgh, UK; Hopkinton, MA, USA	Cell Therapy (iPSC Specialist)	cGMP iPSC Development & Manufacturing, CAR-T	Clinical & Commercial	Fully integrated post-merger with Lykan Bioscience; expanded US facility now operational.
	Ajinomoto (Forge Bio)	Tokyo, JP	Columbus, OH, USA	Gene Therapy (AAV Specialist), Plasmids	End-to-End AAV Services, pDNA, FUEL™ AAV Platform	Preclinical, Clinical & Commercial	Acquired by Ajinomoto; launched FUEL™ platform (Oct 2024).
	Univercells Group	Brussels, BE	Gosselies & Nivelles, BE	Technology, Viral Vectors, Cell Therapy	Integrated technology platforms for cost-effective manufacturing	Preclinical, Clinical & Commercial	Expanding global footprint through integrated subsidiaries (Exothera, Quantoom).

3.2 The Integrated Global Leaders

This tier comprises the largest, most diversified CDMOs offering end-to-end services across multiple advanced therapy modalities with a significant global manufacturing footprint.

- **Lonza:** A global giant with a formidable network (Houston, Geleen, Singapore). Lonza's expertise is exceptionally broad, covering CAR-T, TCR, iPSCs, AAV, LVV, and exosomes. Its key technological differentiator is the proprietary Cocoon® Platform, a closed, automated system designed to industrialize autologous cell therapy production. With a track record of supporting over 15 Phase III or commercial projects, it is a proven top-tier commercial manufacturer.
- **Catalent** (A Novo Holdings Company): Operating key hubs in Baltimore, MD, and Gosselies, Belgium (the former MaSTherCell facility), Catalent offers a comprehensive portfolio including CAR-T, TILs, iPSCs, viral vectors, and pDNA. The landmark $16.5 billion acquisition by Novo Holdings in 2024 provides immense financial stability but has created strategic uncertainty for its non-Novo client base, with industry reports suggesting a scaling back of CGT operations to prioritize the massive GLP-1 business. This has fundamentally altered its competitive position.
- **Thermo Fisher Scientific (Patheon):** Thermo Fisher's strategy is unique in its deep integration of CDMO services (under the Patheon brand) with its market-leading portfolio of products and technologies (Gibco media, single-use technologies from former ATMI life sciences). It offers proprietary closed-system hardware like the Rotea Counterflow Centrifugation System and the Xenon Electroporation System, creating a highly integrated "one-stop-shop" ecosystem for its partners. As part of its strategic operations, the company recently closed its CGT CDMO site in Plainville, Massachusetts, a notable consolidation move in the US market.
- **Minaris Advanced Therapies:** The newest global leader, launched in May 2025. Forged from the merger of Minaris Regenerative Medicine and the divested US/UK operations of WuXi ATU by private equity firm Altaris, it launched as an "instant heavyweight." It operates one of the world's premier CGT campuses in Philadelphia, PA, and inherits a proven track record, including the commercial manufacturing of the FDA-approved TIL therapy, lovance's AMTAGVI™. Its formation is a direct result of the geopolitical pressures of the U.S. BIOSECURE Act.

3.3 The Ascendant Challengers and Large-Scale Specialists

This tier includes major CDMOs with significant global scale and deep expertise, but which may have a more focused scope compared to the top-tier leaders.

- **FUJIFILM Diosynth Biotechnologies (FDB)**: With key sites in California and Texas, FDB has a strong focus on both cell and gene therapies, with a particular specialization in iPSCs. The company has been in a phase of aggressive expansion, completing a major upgrade to its California facility (operational early 2025) and announcing a massive $1.2 billion investment to expand its large-scale cell culture capabilities in North Carolina.
- **AGC Biologics:** AGC operates a global network with dedicated Cell and Gene Technology Centers in Milan, Italy; Longmont, CO; and a new site in Yokohama, Japan. Its Milan facility has a distinguished 30-year track record, securing nine commercial approvals from the EMA and FDA. The company's most significant recent move is its major expansion into the Asia-Pacific market with the Yokohama site, solidifying its global, three-continent manufacturing strategy.
- **Charles River Laboratories (CRL):** CRL's key strength lies in its fully integrated portfolio, combining cGMP manufacturing with its world-leading preclinical and testing services. This allows the company to support a program from the earliest stages of discovery through to commercial manufacturing. In a significant milestone, its Memphis facility became the first North American CDMO to receive EMA approval for the commercial production of an allogeneic cell therapy.
- **Samsung Biologics:** A "sleeping giant" in the CGT space. Historically a world leader in traditional biologics, Samsung is aggressively expanding into next-generation modalities. With the world's largest biomanufacturing capacity and its new Plant 5 operational as of April 2025, its strategic declaration to pursue Antibody-Oligonucleotide Conjugates (AOCs) in June 2025 is its most direct move into the gene therapy field to date. Its financial power and manufacturing prowess signal a long-term ambition to dominate the space.
- **Sartorius:** Through its Sartorius Stedim Biotech division, the company is a powerhouse in bioprocessing. The acquisition of Novasep significantly bolstered its capabilities in viral vector process development and manufacturing, complementing its extensive portfolio of equipment, consumables, and software used across the CGT value chain.
- **SK pharmteco:** The consolidated brand for SK's global CDMO operations, including the Center for Breakthrough Medicines in Philadelphia and Yposkesi in Europe. It offers end-to-end services with a significant focus on viral vectors and cell therapies, positioning itself as a major integrated player with a transatlantic footprint.
- **Curia:** A major global CDMO providing a broad suite of services. In the CGT space, it is notable for its strategic partnerships to enhance its offerings, such as its collaboration with Touchlight to access novel enzymatic DNA vector technology (dbDNA) for genetic medicine manufacturing.

3.4 The Disruptors and Niche Champions

This tier consists of companies changing the market through innovative business models, groundbreaking technology, or a deep, specialized focus.

- **Cellares:** A dedicated cell therapy specialist that has pioneered the "Integrated Development and Manufacturing Organization" (IDMO) model. Its proprietary Cell Shuttle™ platform—a modular, automated, "factory-in-a-box"—aims to solve the key bottlenecks of cell therapy production by dramatically increasing productivity and reducing costs. Its credibility was significantly bolstered in April 2025 when it received an FDA Advanced Manufacturing Technology (AMT) Designation, providing a streamlined regulatory path for its partners.
- **Resilience (National Resilience, Inc.)**: Following a major strategic restructuring in June 2025, Resilience has consolidated its operations into four core North American sites, closing six underutilized facilities. The company has streamlined its focus, with Philadelphia now serving as its Center of Excellence for cell therapies and its RTP, NC, facility dedicated to viral vectors. The move highlights the immense financial pressures of running a large CDMO network.
- **RoslinCT:** A dedicated, high-end specialist in cell therapy with a world-class reputation for its pioneering work in induced Pluripotent Stem Cells (iPSCs). Now fully integrated after its 2022 merger with Lykan Bioscience, it operates as a transatlantic CDMO with hubs in Edinburgh, UK, and Hopkinton, MA, and recently completed a significant expansion of its U.S. facility.
- **Ajinomoto Bio-Pharma Services (via Forge Biologics):** Through the $620 million acquisition of Forge Biologics, Ajinomoto is now a leading specialist in AAV-based gene therapy. Its core asset is the 200,000 sq. ft. "The Hearth" facility in Columbus, OH, and its proprietary FUEL™ AAV manufacturing platform, designed to accelerate timelines and significantly increase manufacturing yields.
- **Univercells Group:** A Belgian ecosystem of companies built to make biologics more affordable and accessible. It includes Quantoom Biosciences (developing novel mRNA production platforms), Exothera (a viral vector and cell therapy CDMO), Cellistic (an iPSC-focused development and manufacturing partner), and Unizima (focused on facility bioproduction services). This integrated structure provides a unique, technology-forward approach to the market.
- **Orgenesis Inc:** A pioneer of the decentralized, point-of-care (POC) manufacturing model. Through its Orgenesis Mobile Processing Units and Labs (OMPULs), the company aims to move therapy production closer to the patient, reducing logistical complexity and costs for a network of healthcare partners.

While global giants dominate the headlines, it’s the focused specialists and bold disruptors - from automated platform pioneers to niche modality experts - who are quietly solving the problems that others overlook, and in doing so, redefining what’s possible in CGT manufacturing.

3.5 Specialized Players & Regional Champions

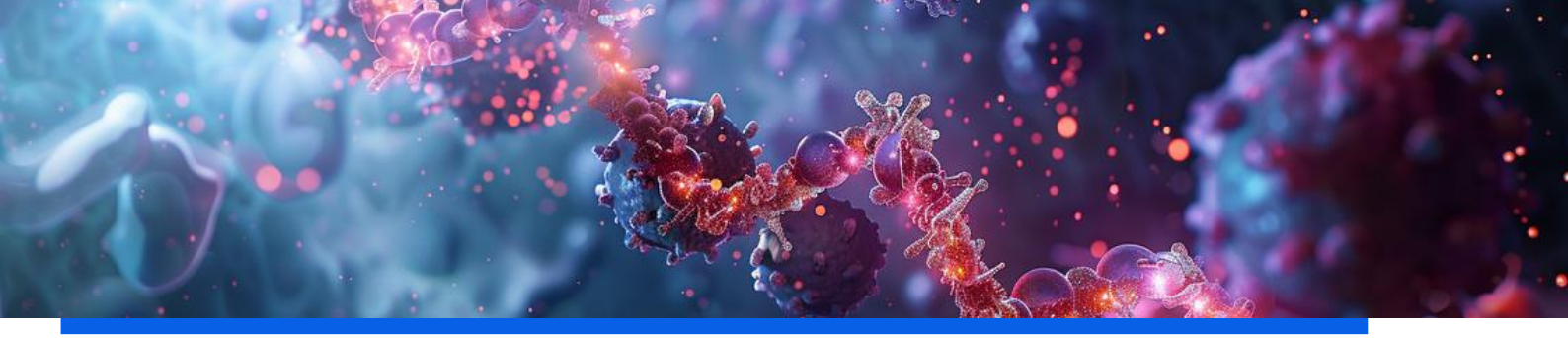
This tier represents a growing and critically important segment of the market, comprising CDMOs with deep focus in specific modalities, technologies, or geographic regions. They often compete by offering greater agility, specialized expertise, and more focused partnership models than the global giants.

- **Viral Vector Specialists:** Pure-play vector CDMOs like **Genezen**, **Andelyn Biosciences**, **Advent Bioservices**, **uBriGene Biosciences**, and **Pharmaron Biologics** (with a key site in Liverpool, UK) provide focused expertise. **Ascend Advanced Therapies**, following its merger with **ABL Inc.**, has expanded its capabilities beyond AAV to include oncolytic viruses and viral vaccines, strengthening its position.
- **Cell Therapy Specialists:** The market is seeing a rise of agile, cell-therapy-focused CDMOs. **Cellipont Bioservices** and **Kincell Bio** represent new, purpose-built US facilities, while **Artis BioSolutions** recently launched via the acquisition of a manufacturing site from **Landmark Bio**. In Europe, key specialists include **Cellex Cell Professionals** (Germany), **CELLforCURE** (France), **Cell-Easy** (adipose-derived stem cells, France), **eXmoor Pharma** (UK), **3P Biovian**, and **Cellin Technologies**. **SCTbio** and **Matica Biotechnology** (noted for its partnership with Texas A&M) are other key players in this segment.
- **Component & Raw Material Specialists:** This critical sub-segment includes providers of essential materials. **Life Science Group Ltd.** offers cGMP contract manufacturing of custom cell culture media. **EXO Biologics** is a specialist CDMO focused on the emerging field of exosomes. **VGXI**, **Aldevron** (a Danaher company), **Wacker**, and **GenScript ProBio** are leaders in GMP-grade plasmid DNA. **Nitto Denko Avecia Inc.** and **TriLink BioTechnologies** are key suppliers for oligonucleotides and mRNA components.
- **Analytical Service Specialists:** Companies like **Solvias** provide highly specialized analytical testing, quality control, and characterization services that are essential for regulatory submissions and product release, forming a critical pillar of the manufacturing ecosystem.
- **National Innovation Hubs:** Organizations like **the Cell and Gene Therapy Catapult** in the UK and **CCRM** in Canada are vital ecosystem builders. They provide infrastructure, process development expertise, and collaborative networks to help bridge the gap between academic research and industrial-scale manufacturing.
- **Hybrid & Venture-Backed Models: ElevateBio** operates a unique hybrid model as a technology-driven company that is part CDMO, part platform developer, and part venture creator. **Made Scientific** (formerly BioCentriq) provides development and manufacturing services in New Jersey. **GeneFab** offers a unique model integrating synthetic biology and gene circuit design with GMP manufacturing. **CTMC** is a unique joint venture between **Resilience** and **MD Anderson Cancer Center** focused on rapid clinical translation.

3.6 Key Enabling Technology Providers

Distinct from CDMOs, these companies provide the critical "picks and shovels"—the automated platforms, robotics, and tools—that are essential for industrializing CGT manufacturing.

- **Automation & Closed-System Hardware: Miltenyi Biotec** (CliniMACS Prodigy®), **Ori Biotech** (IRO Platform), and **Cellular Origins** (Constellation robotics) are leaders in automating cell therapy workflows. **Optima's** "ProCell" isolator is another key piece of hardware enabling closed-system processing.
- **Non-Viral Engineering Technology: Kytopen** is a key innovator with its "Flowfect" technology, a high-throughput, non-viral method for cell engineering that is being adopted through partnerships with players like **Aldevron**.
- **Cryopreservation & Logistics: BioLife Solutions, Inc.** is a market leader in the tools for cryopreservation and logistics, providing GMP-grade cryopreservation media and advanced shipping containers that are critical for the CGT cold chain.
- **A New Wave of Innovators:** The technology landscape is vibrant with companies developing novel solutions. This includes a new wave of next-generation automation and technology companies like **Astraveus**, **Limula**, **Lupagen**, **Cellino**, **CellQuest**, and **MFX**, who are developing innovative tools to further improve efficiency and reduce costs in CGT manufacturing.



Chapter 4: Strategic Archetypes: The Business Models Shaping CGT Manufacturing

The Cell and Gene Therapy ecosystem is not monolithic. To navigate its complexities and capture value, companies have adopted distinct strategic postures. Understanding these archetypes is essential for developers seeking partners, for investors assessing risk, and for service providers positioning themselves in a competitive market. Four primary models have emerged, each with a unique approach to value creation, risk management, and its role in the supply chain.

4.1 Archetype 1: The Fully Integrated Developer

Description: This archetype consists of therapeutic developers who make the strategic and capital-intensive decision to build, own, and operate their own end-to-end manufacturing infrastructure. Rather than outsourcing, they internalize the entire production process, from process development and raw material sourcing to final product manufacturing and release.

How They Create Value: The primary value driver is control. By owning the entire manufacturing process, these companies gain maximum control over quality, production timelines, supply chain security, and, critically, their proprietary intellectual property and trade secrets related to their unique manufacturing processes.

Position in Supply Chain: They effectively are their own supply chain. This model represents the ultimate form of vertical integration in the biopharmaceutical industry.

Advantages:

- **IP Security:** Eliminates the risk of sensitive process knowledge being exposed to third parties.
- **Seamless Tech Transfer:** Avoids the costly, time-consuming, and risky process of transferring a complex biological process from a developer's lab to a CDMO.
- **Supply Chain Control:** Insulates the company from CDMO capacity shortages and allows for direct management of production priorities, which is crucial for commercial launch.

Risks and Challenges:

- **Massive Capital Expenditure:** Building and validating a GMP-compliant CGT facility requires hundreds of millions of dollars, a significant financial burden.
- **High Fixed Costs:** These facilities carry high operational and maintenance costs, regardless of production volume.
- **Asset Risk:** If the lead therapeutic program fails in late-stage clinical trials, the company is left with a highly specialized, expensive, and potentially idle asset, as seen with BioNTech's Gaithersburg facility shutdown.
- **Representative Examples:** Legend Biotech/J&J (with their network for Carvykti), Iovance Biotherapeutics (with their dedicated TIL facility in Philadelphia), Cellectis (with in-house facilities in Paris and Raleigh, NC).

In cell and gene therapy, how you manufacture is as strategic as what you develop - from full vertical integration to lean outsourcing, your business model defines your competitive edge.

4.2 Archetype 2: The Pure-Play CDMO

Description: These are service providers whose business is exclusively focused on offering contract development and manufacturing services to third-party clients. They do not develop their own competing therapeutic pipelines.

How They Create Value: They create value by providing on-demand access to specialized expertise, flexible cGMP capacity, and deep regulatory experience. Their "complete, not compete" model is a powerful value proposition, as it eliminates the conflict of interest that can arise when a CDMO also has its own pipeline, assuring clients that their projects and IP are the sole focus.

Position in Supply Chain: They are the manufacturing backbone for the majority of the CGT industry, particularly for small- to mid-sized biotech companies that lack in-house capabilities.

Advantages:

- **Diversified Risk:** A broad client base mitigates the financial impact of any single client's program failing.
- **Operational Focus:** All resources and talent are dedicated to manufacturing excellence and customer service.
- **Experience Across Modalities:** Working with multiple clients provides broad experience across different therapeutic approaches and technologies.

Risks and Challenges:

- **Intense Competition:** The space is becoming increasingly crowded, putting pressure on pricing and margins.
- **Market Volatility:** They are highly exposed to the overall financial health of the biotech sector. A downturn in venture funding, as seen in 2024, can lead to client project delays or cancellations, directly impacting revenue.
- **Talent Wars:** They are on the front lines of the human capital crisis, constantly competing to attract and retain the scarce talent needed to run their facilities.

Representative Examples: **Minaris Advanced Therapies**, **Genezen**, **Kincell Bio**, **Andelyn Biosciences**.

Pure-play CDMOs win by focus - no pipelines, no conflicts, just execution. In a market built on trust, being a specialist manufacturer is not a limitation, it’s a strategic advantage.

4.3 Archetype 3: The Hybrid Innovator

Description: This archetype operates a dual business model, simultaneously developing a proprietary pipeline of therapies while also offering CDMO services to external clients. Often, the CDMO services are built around the company's unique, proprietary technology platform, which it also uses for its internal programs.

How They Create Value: This model creates a powerful, virtuous cycle. The internal therapeutic pipeline serves to de-risk and validate the company's technology platform, making it more attractive to potential CDMO clients. In turn, the revenue generated from the CDMO business is non-dilutive and can be used to fund the capital-intensive development of the internal pipeline.

Position in Supply Chain: They occupy a unique space, acting as both a therapy developer and a key service provider to other developers.

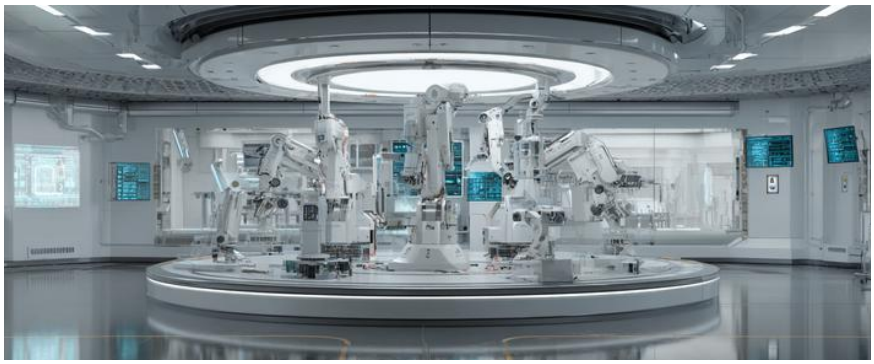
Advantages:

- **Diversified Revenue Streams:** Reduces reliance on volatile venture capital or public markets.
- **Technology Showcase:** The internal pipeline acts as a real-world proof-of-concept for their manufacturing platform and expertise.
- **Deep Process Understanding:** Having to solve their own manufacturing challenges provides them with invaluable insights that benefit their CDMO clients.

Risks and Challenges:

- **Channel Conflict:** There is an inherent risk of competing directly with their own clients, which can create trust issues.
- **Resource Allocation:** Management must carefully balance the allocation of capital, capacity, and talent between internal programs and external client projects.
- **Strategic Complexity:** Operating two distinct business models requires a sophisticated and experienced leadership team to manage effectively.

Representative Examples: **ElevateBio**, **Pluri** (with its PluriCDMO division), **GeneFab**.



The hybrid innovator walks a tightrope - building therapies and platforms in parallel. When done right, it creates a virtuous cycle where internal success fuels external trust, and every client project sharpens the edge of their own pipeline.

4.4 Archetype 4: The Platform Enabler

Description: These are technology-centric companies that do not manufacture therapies themselves, but instead design, build, and sell the foundational "picks and shovels" of the industry. Their products are the automated systems, robotics, software, and integrated platforms that are used by both therapy developers and CDMOs to enable and industrialize their manufacturing workflows.

How They Create Value: Their core value proposition is solving the industry's most fundamental problems: high costs, lack of scalability, and process variability. By providing standardized, automated, and high-tech solutions, they enable the entire ecosystem to produce therapies more efficiently and reliably.

Position in Supply Chain: They are critical upstream technology suppliers that sit at the intersection of hardware, software, and biology.

Advantages:

- **Highly Scalable Model:** Unlike service-based businesses, their model is product-based, allowing them to sell multiple units globally.
- **Industry-Wide Impact:** Their success is tied to the growth of the entire CGT market, not the binary outcome of a single clinical trial.
- **High-Margin Potential:** Proprietary, patented technology platforms can command significant pricing power.

Risks and Challenges:

- **Long Adoption Cycles:** Convincing a developer or CDMO to adopt a new manufacturing platform and adapt their validated processes is a long and complex sales process.
- **High R&D Investment:** Developing and validating these complex systems requires significant upfront R&D investment.
- **Technological Obsolescence:** They face the constant threat of being leapfrogged by a newer, more efficient technology.

Representative Examples: **Cellares**, **Ori Biotech**, **Miltenyi Biotec**, **Cellular Origins**.

They don’t make therapies - they make therapy possible. Platform enablers are the silent architects of CGT’s future, building the tools that transform science into scalable, industrial reality.

Chapter 5: The CGT Manufacturing Value Chain: A Segment-by-Segment Analysis

The journey of a cell or gene therapy from concept to patient is not a single process but a complex, interconnected value chain. Each link represents a specialized set of activities, technologies, and expertise. Understanding these distinct segments is crucial to appreciating the operational challenges and strategic dependencies that define the industry.

5.1 Segment 1: Starting Materials & Cell Sourcing

Core Function: This foundational segment involves the acquisition and processing of the primary biological components. For autologous therapies, this is the highly personal and logistically complex process of collecting a patient's cells via apheresis. For allogeneic therapies, it involves sourcing cells from qualified, healthy donors to create master cell banks. For most gene therapies, the critical starting material is high-purity, GMP-grade plasmid DNA (pDNA), which serves as the template for viral vector production or mRNA synthesis.

Role in the Process: This is the absolute first step and a frequent bottleneck. The quality, consistency, and timely availability of starting materials directly impact every subsequent manufacturing step and the quality of the final therapeutic product.

Representative Players: Aldevron, **ProBio**, **Charles River Laboratories** (pDNA); **Excellos**, **BBG Advanced Therapies** (donor cell sourcing); **ANEMOCYTE** (starting materials for immuno-oncology).

While global giants dominate the headlines, it's the focused specialists and bold disruptors - from automated platform pioneers to niche modality experts - who are quietly solving the problems that others overlook, and in doing so, redefining what's possible in CGT manufacturing.

5.2 Segment 2: Viral Vector Production

Core Function: This segment focuses on the design, large-scale production (upstream), and purification (downstream) of viral vectors—primarily Adeno-Associated Virus (AAV) and Lentivirus (LVV). These vectors act as the delivery vehicles that carry the therapeutic genetic payload into the patient's cells.

Role in the Process: For in vivo gene therapies, the viral vector is the drug product. For ex vivo cell therapies, it is a critical raw material used to genetically modify the cells. This segment is widely considered one of the most technically challenging and capacity-constrained parts of the entire value chain.

Representative Players: **Genezen**, **Andelyn Biosciences**, **FUJIFILM Diosynth**, **SK pharmteco (CBM)**, **Ascend Advanced Therapies**, **ReciBioPharm (Vibalogics).**

5.3 Segment 3: Cell Processing & Gene Editing

Core Function: This involves the core 'manufacturing' steps for cell therapies. It includes isolating the target cells from the starting material, activating them, using a vector or non-viral method (like CRISPR) to introduce the new genetic material, and then expanding the newly engineered cells to a therapeutically relevant dose.

Role in the Process: This is the central value-creation step where the raw biological material is transformed into a living drug. The efficiency, consistency, and sterility of these steps are paramount to the product's safety and efficacy.

Representative Players: This is a core competency of nearly all cell therapy CDMOs, including **Minaris Advanced Therapies**, **RoslinCT**, **Cellipont Bioservices**, **Kincell Bio**, and **Cellex Cell Professionals**.

5.4 Segment 4: Enabling Platforms & Automation

Core Function: This segment comprises the "picks and shovels" innovators who develop the hardware, software, and robotics that automate and standardize the manufacturing process. Their goal is to replace manual, open processes with closed, automated, and digitally integrated workflows.

Role in the Process: These platforms are critical for solving the industry's core challenges of scalability, cost, and process variability. They are the key to transitioning CGT manufacturing from a bespoke craft to a robust industrial process.

Representative Players: Cellares, **Ori Biotech**, **Miltenyi Biotec**, **Cellular Origins**, **Cytiva**, **Astraveus**, **Multiply Labs**.

5.5 Segment 5: Full-Service CDMO Manufacturing

Core Function: This segment represents the fully integrated service providers who combine many of the above functions into a seamless, end-to-end offering. They provide process development, analytical services, clinical and commercial GMP manufacturing, quality control, and regulatory support under a single organizational umbrella.

Role in the Process: These organizations serve as the strategic manufacturing backbone for the majority of the industry. They allow therapy developers to outsource the immense complexity and capital cost of manufacturing, enabling them to focus on R&D and clinical execution.

Representative Players: Lonza, **Thermo Fisher Scientific**, **Minaris Advanced Therapies**, **AGC Biologics**, **Charles River Laboratories**, **Resilience**.

5.6 Segment 6: The Analytical Testing Imperative

Core Function: This segment provides the essential research, development, and testing support that underpins a therapy's journey to the clinic. This includes early-stage process and analytical development, creation of robust potency assays, product characterization, stability studies, and GMP quality control (QC) release testing. For CGTs, where the "product is the process," analytical testing is not an afterthought; it is a core part of defining the therapy itself.

Role in the Process: Robust analytical methods and a deep understanding of a product's critical quality attributes (CQAs) are prerequisites for a successful regulatory submission (IND/BLA). This segment provides the data and scientific rationale to prove a manufacturing process is controlled and the resulting product is safe, pure, and potent.

The Growing Analytical Bottleneck & Strategic Investment: As the CGT pipeline matures, the demand for specialized, high-quality analytical services is outstripping supply, creating a significant bottleneck. Recognizing this, savvy investors and service providers are making major strategic moves. A prime example is the recent expansion by **Solvias AG**. In early 2025, the company opened a major new laboratory center focused explicitly on the analytical needs of biologics and cell & gene therapies. This investment, and others like it, signals a critical maturation of the CGT ecosystem. It demonstrates a market shift beyond simply building more bioreactors towards reinforcing the foundational pillars of quality and regulatory compliance. For therapy developers, this trend means that specialized analytical partners are becoming as strategically important as manufacturing partners, offering a way to de-risk development and accelerate timelines to regulatory approval.

Representative Players: Charles River Laboratories (as a major CRO), **Solvias**, and this is a key integrated service offered by all major CDMOs.

The future of CGT manufacturing won't be built on capacity alone - it will be defined by automation, integration, and the precision of the data behind every dose.

5.7 Segment 7: Logistics & Cryopreservation

Core Function: This specialized segment manages the immensely complex "cold chain" required for CGT products. This involves the cryopreservation (freezing) of living cells to ensure stability, the use of specialized cryogenic shippers, and the time-critical, temperature-controlled transportation of both starting materials and the final drug product.

Role in the Process: This is the final, critical link connecting the manufacturing facility to the patient. A failure in this "last mile"—a temperature deviation, a customs delay, a handling error—can result in the complete loss of an irreplaceable, high-value therapy.

Representative Players: This is a core integrated capability of the largest CDMOs like **Catalent** and **Lonza**, who leverage their global clinical supply networks, as well as specialists like **BioLife Solutions, Inc.**

From donor cell to final dose, CGT manufacturing is a chain of high-stakes precision - every link, from sourcing and vectors to automation, analytics, and cryo-logistics, must hold. It’s not just a process - it’s an ecosystem of interdependent breakthroughs.

Chapter 6: The Great Bottleneck: Deconstructing the Barriers to Scale

The CGT sector stands at a paradoxical juncture. The industry is witnessing unprecedented clinical momentum, yet beneath this veneer of success lies a fundamental crisis rooted in profound and persistent manufacturing bottlenecks that threaten to capsize the field's potential. Patient access remains severely limited; despite eight approved CAR-T products being available for seven years, only 30,000 to 40,000 patients have been treated, a fraction of the eligible population.

6.1 The Facility Engineering Gauntlet: Building for Living Medicines

Beyond the process science, the physical infrastructure itself represents a formidable barrier to entry and a major driver of cost. A CGT facility is one of the most complex and expensive types of pharmaceutical plant to design, build, and operate, requiring a synthesis of cleanroom technology, biological containment, and logistical planning.

Cleanroom Classifications and HVAC Complexity: CGT manufacturing requires strictly controlled environments to prevent microbial contamination. Facilities are designed with a cascade of cleanrooms of increasing air quality, classified by EU GMP standards as Grade D, C, B, and A.

- **Grade A:** The most critical zone, where the product is directly exposed (e.g., during filling). This is typically achieved within an isolator or a laminar air flow hood, providing sterile, particle-free air.
- **Grade B:** The background environment for Grade A zones. Personnel must be fully gowned.
- **Grade C/D:** Less critical areas for preparatory work.

This classification system necessitates a highly complex Heating, Ventilation, and Air Conditioning (HVAC) system. To protect the product from the environment, these cleanrooms must be kept under positive pressure, ensuring air flows out of the cleanest rooms. This creates an engineering paradox when handling viral vectors, which require negative pressure to contain the virus and protect the operator. Reconciling this requires sophisticated, multi-zoned HVAC systems with carefully controlled airlocks and pressure differentials, dramatically increasing design complexity and cost.

Open vs. Closed Systems: The choice between open and closed processing has massive implications for facility design and cost.

- **Open Systems:** Traditional processing involves manual manipulations in open-fronted Biological Safety Cabinets (BSCs). While offering flexibility, this approach carries a higher risk of contamination and requires the entire surrounding room to be a high-grade (e.g., Grade B) cleanroom, which is extremely expensive to build and maintain.
- **Closed Systems:** The industry is aggressively moving toward functionally closed systems, such as isolators or fully automated, end-to-end platforms like the Miltenyi CliniMACS Prodigy® or Cellares' Cell Shuttle. By isolating the product from the operator and the environment, these systems can be placed in a lower-grade (e.g., Grade C) background environment, significantly reducing the facility's capital and operational costs. This shift is a key enabler of scalable and decentralized manufacturing.

Cryogenic Storage Infrastructure: The long-term stability of most cell therapies depends on cryogenic storage (below -135°C). A commercial-scale facility requires a dedicated "cryo-farm" of large, validated liquid nitrogen freezers, each equipped with continuous monitoring systems. This necessitates significant investment in supporting infrastructure, including bulk liquid nitrogen storage tanks, vacuum-jacketed piping, robust backup power systems, and advanced monitoring and alarm systems to prevent catastrophic loss of irreplaceable patient material.

Multi-Modal Facility Challenges: Operating a facility that handles both cell therapies and live viral vectors is a major challenge due to the risk of cross-contamination. Regulatory agencies require strict segregation. This often means building entirely separate suites with independent HVAC systems, separate material and personnel flows, and dedicated equipment. This duplication of infrastructure substantially increases capital costs and operational complexity, forcing many CDMOs to specialize or invest in highly flexible, single-use technologies to manage campaign-based manufacturing. These engineering requirements directly impact cost (high capital and operational expense), scalability (design choices can lock-in or limit future expansion), and time-to-market (complex facility construction and validation can take years).

In CGT, the barrier isn't science - it's infrastructure. The complexity of building for living medicines is becoming the bottleneck that defines the pace of the entire industry.

6.2 Solving the Scale-Up Problem: A Deep Dive into Enabling Technologies

The immense manufacturing challenges detailed in this report are being met with a wave of technological innovation. The "Platform Enablers" are developing the tools and systems that form the foundation of modern, scalable CGT manufacturing. These technologies can be grouped into four critical categories.

Hardware Platforms and Bioreactors:

- **Purpose:** These are the integrated, often automated, "factory-in-a-box" systems designed to perform the entire end-to-end cell therapy manufacturing process within a single unit. They replace the need for multiple, disconnected pieces of equipment.
- **Adoption & Impact:** This is a rapidly emerging category with high strategic importance. Early adopters are partnering with developers of these platforms to de-risk their path to commercial scale. The impact is potentially transformative, promising to dramatically reduce cost by minimizing labor and expensive cleanroom requirements, increase consistency by eliminating manual variability, and improve speed by enabling parallel processing and faster tech transfer.
- **Examples: Cellares**' Cell Shuttle, **Lonza's** Cocoon® Platform, and **Miltenyi Biotec's** CliniMACS Prodigy® are leading examples of comprehensive, automated platforms aiming to industrialize cell therapy production.

Closed-System Bioprocessing Equipment:

- **Purpose:** This category includes specialized, single-function equipment designed to perform a specific step (e.g., cell separation, gene delivery, fill-finish) within a closed, sterile environment. This is a crucial step-change from traditional open processing in biosafety cabinets.
- **Adoption & Impact:** Adoption is becoming widespread as companies seek to "close" their processes to reduce contamination risk. These tools directly increase consistency and safety. By enabling operations in lower-grade cleanrooms, they also significantly reduce facility capital and operational costs.
- **Examples: Thermo Fisher**'s Gibco™ CTS™ Rotea™ for cell processing and Xenon™ Electroporation System for non-viral gene delivery; automated fill-finish lines from companies like **Vanrx Pharmasystems** (now part of **Cytiva**).

Data and Automation Software:

- **Purpose:** This includes the software layer that controls manufacturing hardware, monitors processes in real-time, and captures vast amounts of data for analysis and compliance. This is the "brain" of the modern CGT facility.
- **Adoption & Impact:** While still maturing, the adoption of sophisticated Manufacturing Execution Systems (MES) and cloud-native platforms is accelerating. The impact is a paradigm shift toward data-driven manufacturing. AI and machine learning algorithms can monitor processes to predict batch success, increasing consistency and reducing failure rates. Digital records improve speed by streamlining batch release and ensuring GMP compliance.
- **Examples: Ori Biotech's** cloud-native data platform, which captures process data every seven seconds; software suites from major automation providers like **Siemens** and **Rockwell Automation** are being adapted for CGT workflows.

Cryopreservation and Cold Chain Handling Tools:

- **Purpose:** These are the specialized tools required to manage the "cold chain" for living therapies. This includes controlled-rate freezers, cryogenic vials and bags designed to withstand ultra-low temperatures, and automated thawing systems for use at the clinical site.
- **Adoption & Impact:** These tools are essential and universally adopted for any therapy that is not administered immediately after manufacturing. Their primary impact is on product consistency and quality. A failure in cryopreservation can lead to a loss of cell viability and potency. Innovations in vial/bag technology and automated thawing systems are critical for ensuring that the therapy administered to the patient is the same as the one that left the factory, directly impacting speed-to-patient by enabling a robust ship-from-inventory model.
- **Examples:** Controlled-rate freezers from companies like **Thermo Fisher** and **Cytiva**; specialized cryogenic storage and transport solutions from **BioLife Solutions, Inc.**

Scaling CGT isn't just about doing more - it's about doing smarter. The rise of automated platforms, closed systems, and AI-driven software is transforming manufacturing from an artisanal process into a true industrial system.

6.3 The Viral Vector Conundrum: Quality, Scalability, and Safety

Viral vectors, particularly AAV, are the foundational delivery technology for most gene therapies, and their manufacturing remains a fundamental impediment.

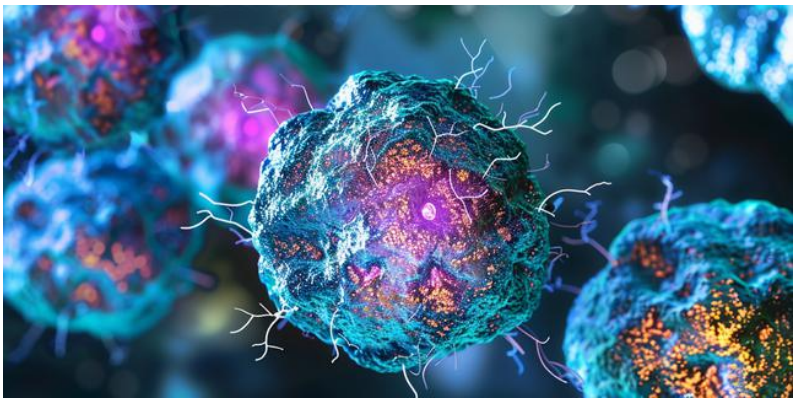
- **Scalability and Consistency:** Production remains more art than science, lacking the standardized platforms of traditional biologics. This leads to low yields, high costs, and significant batch-to-batch variability.
- **The Quality Control Crisis:** The most critical downstream bottleneck is the separation of therapeutically potent "full" viral capsids from inactive "empty" ones. These impurities can trigger a stronger immune response without providing any therapeutic benefit. The purification steps are technically challenging, expensive, and often lead to significant loss of the valuable final product.
- **The AAV Safety Imperative:** In 2025, direct, vector-associated toxicity has taken center stage. The most prominent example is Sarepta Therapeutics' gene therapy Elevidys, where two patient deaths from acute liver failure were reported. The fallout was swift: a pause in clinical trials, suspension of commercial shipments, and withdrawal of revenue guidance. This event has elevated vector safety from a clinical concern to a primary commercial and manufacturing risk, casting a long shadow over the entire AAV field.

6.4 The Great Divide: The Autologous "Scale-Out" vs. Allogeneic "Scale-Up" Gauntlet

Can we actually build all these therapies? The two dominant cell therapy paradigms face distinct but equally formidable scaling challenges.

- **The Autologous "Scale-Out" Nightmare:** The "n-of-1" nature of personalized therapies necessitates a circular, "vein-to-vein" supply chain that is a logistical nightmare. For Vertex's Casgevy, the process can take up to six months. For Iovance's Amtagvi, the average manufacturing time is 34 days, during which 17% of patients in clinical trials dropped out due to disease progression or manufacturing failure. The bottleneck is no longer just cell biology, but the management of thousands of individual, high-stakes supply chains. Innovators like Excellos (integrating donor sourcing with manufacturing) and BBG Advanced Therapies (launching mobile leukapheresis centers) are emerging to tackle these upstream starting material challenges.
- **The Allogeneic "Scale-Up" Peril:** "Off-the-shelf" allogeneic therapies promise a more traditional, scalable manufacturing model. However, the story of Allogene Therapeutics serves as a crucial case study. In 2025, the company was forced to delay key clinical trials and reduce manufacturing operations not due to production failures, but due to "site-level operational constraints, including staffing shortages" at clinical trial sites. This reveals a profound truth: for a clinical-stage allogeneic company, the true bottlenecks can be clinical execution and capital preservation.

In gene therapy, the vector is the vehicle - but right now, it’s stuck in traffic. High cost, low yield, and rising safety risks have turned AAV manufacturing into the sector’s most urgent and unforgiving bottleneck.



6.5 The Final, Frozen Mile: Mastering Cryopreservation and Logistics

If upstream manufacturing is a scientific challenge, the final stages of the CGT value chain—cryopreservation and logistics—are a high-stakes operational gauntlet. For living medicines, particularly patient-specific autologous therapies, a failure in this "last mile" is not a simple supply disruption; it is an irreversible loss of an irreplaceable therapeutic dose.

The Vein-to-Vein Logistics Gauntlet: Autologous therapies operate on a circular, "just-in-time" model that is unique in pharmaceuticals. The process requires flawless, clockwork coordination between the patient, the clinical apheresis center, the centralized manufacturing facility, and the final infusion site. A manufacturing slot cannot be booked until patient cells are collected; the patient's pre-conditioning chemotherapy cannot begin until the final, manufactured product has a confirmed delivery date. This creates a chain of dependencies where a single delay—in shipping, in manufacturing, or at the clinic—can cause the entire multi-week process to fail, forcing a critically ill patient to wait even longer.

The Perils of Cryopreservation: To provide shelf-life and enable global shipping, most CGT products are cryopreserved. However, the process of freezing and thawing living cells is inherently damaging. As water freezes, it forms ice crystals that can physically rupture cell membranes, while the increasing concentration of solutes can become toxic. To mitigate this, manufacturers use cryoprotectant agents (CPAs) like dimethyl sulfoxide (DMSO) and controlled-rate freezers that cool the product at a precise rate (e.g., -1°C per minute) to minimize ice crystal formation. Even with these measures, a loss of 20-40% cell viability post-thaw is not uncommon. This variability is a major CMC challenge and requires robust potency assays to ensure the final thawed product remains therapeutically effective.

Container Strategy: Vials vs. Bags: The choice of the final product container is a critical, early-stage decision with significant downstream implications.

- **Cryovials:** Offer robustness and are often more compatible with automated fill-finish systems, potentially reducing contamination risk and improving scalability. However, they typically hold smaller volumes, requiring multiple vials for a single patient dose, which can complicate final administration at the clinic.
- **Cryobags:** Can hold a full patient dose in a single container, simplifying administration. However, they are more susceptible to damage during handling and freezing, and their flexible nature makes them more challenging to integrate with high-throughput automated filling platforms. This choice impacts everything from capital equipment investment to the final protocol used at the patient's bedside.

Last-Mile Failure and Mitigation: The final shipment from the manufacturing site to the hospital is the point of maximum risk. Common causes of failure include temperature excursions in the cryogenic shipper, customs delays for international shipments, and simple courier error. To mitigate these risks, companies employ sophisticated strategies. Shipments are made in validated, liquid nitrogen "dry shippers" equipped with GPS trackers and continuous temperature monitoring. Specialized logistics partners are used to manage complex international routes and provide contingency plans. Some companies, particularly for commercial products, are building out networks of regional supply hubs to shorten shipping distances and provide redundant inventory, ensuring that a backup dose is available in case of a last-mile failure.

In cell and gene therapy, the last mile isn't just logistics - it's life-critical. One temperature spike, one delay, and years of science can vanish with a single irreplaceable dose.

6.6 Corporate Case Studies: Navigating Product Launches and Strategic Headwinds

The theoretical bottlenecks and strategic pressures facing the CGT industry are best understood through the real-world experiences of companies on the front lines. The period from 2024 into mid-2025 has been a crucible, revealing which manufacturing strategies are succeeding, which are faltering, and how quickly fortunes can change based on a company's ability to produce and deliver its therapy reliably and safely.

Product-Level Case Studies: The Gauntlet of Commercialization

- **Legend/J&J (Carvykti):** The partnership's aggressive, multi-pronged capacity expansion—combining new dedicated facilities with strategic CDMO partnerships—stands as the preeminent case study in successfully scaling an autologous cell therapy to meet massive commercial demand, on track to achieve blockbuster status in 2025. However, even this best-in-class effort is struggling to keep pace with clinical need, highlighting the sheer scale of the autologous challenge.
- **Iovance (Amtagvi):** Iovance's experience provides a sobering look at post-approval operational stumbles. The company's 2025 revenue was significantly impacted by manufacturing inefficiencies, including high patient drop-off and batch failure rates, leading to negative gross margins and a substantial downward revision of commercial forecasts. This demonstrates how quickly commercial success can unravel when manufacturing processes are not fully optimized.
- **Sarepta (Elevidys):** The Sarepta case is the ultimate cautionary tale of 2025. Two patient deaths linked to AAV vector-related liver toxicity led to clinical holds, a suspension of commercial supply, and a withdrawal of financial guidance. This event proves that a fundamental safety flaw in the core manufacturing "raw material"—the viral vector itself—can instantly negate years of clinical development and commercial progress, casting a long shadow over the entire AAV field.

Corporate-Level Case Studies: Strategic Responses to Market Pressures

- **Resilience:** The Great Consolidation: Faced with the immense operational costs of a sprawling 10-site network and a market that had shifted from speculative capacity-building to demanding proven execution, Resilience undertook a major strategic restructuring in June 2025. By closing six facilities and consolidating its focus on core strengths in cell therapy and viral vectors at its remaining sites, the company made a difficult but necessary pivot from a high-growth narrative to a more sustainable, focused operational model. This move serves as a critical cautionary tale for the industry about the dangers of over-leveraged expansion that outpaces secured commercial demand.
- **Catalent:** Reprioritization Under New Ownership: The acquisition of Catalent by Novo Holdings in 2024, driven primarily by the need for GLP-1 drug capacity, created a strategic crisis for its CGT business. Faced with immense internal pressure to prioritize the multi-billion-dollar GLP-1 franchise, Catalent's CGT clients were forced to confront the risk of de-prioritization and potential conflicts of interest. The market has responded with a widespread re-evaluation of CDMO counterparty risk, creating a significant business development opportunity for rival CDMOs who can guarantee their independence and focus on advanced therapies.
- **Cellares:** Doubling Down on Automation and Global Expansion: In response to the clear and persistent bottleneck in scaling autologous cell therapies, Cellares has aggressively pursued its technology-first strategy. After establishing its commercial-scale "Smart Factory" in Bridgewater, NJ, the company announced a strategic partnership in May 2025 to build its first international factory in Japan. This move, supported by its recent FDA AMT Designation, signals a clear strategy to create a global, standardized, and automated manufacturing network, positioning its IDMO model as a leading solution to the industry's scale-out crisis.

In CGT, the factory is the product. Clinical success can unravel overnight without manufacturing precision, and strategic missteps in operations now determine who leads - and who folds - in the race for commercialization.

Chapter 7: The Human Capital Crisis: Leadership and Hiring Trends in CGT

The CGT sector is propelled by staggering growth forecasts, but it is fundamentally constrained by a severe and widening talent deficit that threatens to undermine its trajectory. This is the great disconnect between market readiness and workforce readiness, which has evolved beyond a simple numbers game into a complex challenge of leadership, specialization, and talent migration.

7.1 The Skills Gap at the Bench: The War for Technical Talent

The most immediate constraint is the shortage of hands-on technical professionals. The scale of the deficit is daunting; in the United Kingdom, for example, the CGT workforce is forecast to fall short by nearly 4,000 roles by 2028. This is not a generalized labor shortage; it is an acute deficit in highly specific roles that are essential for day-to-day operations:

- **Process Development (PD) & Manufacturing Science and Technology (MSAT) Scientists:** These individuals are the bridge between R&D and manufacturing. They are responsible for developing scalable, robust, and reproducible manufacturing processes. A lack of experienced PD/MSAT talent is a primary cause of clinical delays and manufacturing failures.
- **Quality Control (QC) Analysts:** With the complexity of CGTs, QC is not a simple checklist. It requires deep expertise in sophisticated analytical techniques like flow cytometry, qPCR, and cell-based potency assays. The shortage of analysts who can develop, validate, and execute these assays under GMP conditions is a major bottleneck for product release.
- **GMP Manufacturing Associates:** These are the front-line operators who execute the complex, often manual, manufacturing processes in the cleanroom. The work requires meticulous attention to detail and an unwavering commitment to aseptic technique. More than 20% of CDMOs report that their operations are under moderate to significant capacity constraints due to the inability to hire and retain qualified manufacturing staff.

7.2 The Leadership Void: The Hunt for the Hybrid Biomanufacturing Executive

A more strategic and arguably more dangerous deficit exists at the leadership level. The industry's rapid maturation from R&D to commercial-scale biomanufacturing has created a "leadership valley of death." The archetypal "founding scientist" is often ill-equipped to navigate scalable production, while traditional pharma manufacturing executives frequently lack the deep scientific understanding of living cells. This has created an acute scarcity of hybrid "biomanufacturing executives" who possess a rare blend of skills:

- Deep scientific literacy in cell biology and virology.
- Proven expertise in industrial-scale GMP manufacturing operations.
- Strong financial acumen to manage multi-hundred-million-dollar budgets and COGS models.
- Regulatory savvy to navigate complex CMC discussions with the FDA and EMA.

The CGT revolution isn't short on capital or innovation - it's short on people. Without the scientists, operators, and hybrid leaders to build and scale these therapies, even the most promising pipelines will stall.

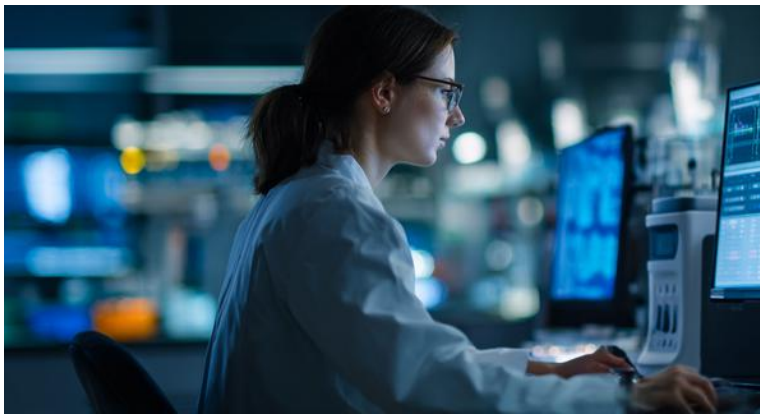
7.3 New Hiring Trends: Talent Migration and the Rise of the Specialist

The intense competition for this scarce talent has created new market dynamics. One of the most significant trends is talent migration. Experienced operators and mid-level managers are being actively recruited away from large, established CDMOs like Lonza and Thermo Fisher by smaller, more agile, and often better-funded startups and specialized CDMOs. Companies like Kincell Bio and ProBio have successfully built their leadership teams by offering significant equity and the opportunity to build something new, creating a leadership vacuum and operational risk at the larger organizations they leave behind. This "poaching" has become a key strategic risk for established players and a primary growth vector for challengers.

7.4 Case Studies in Consequence: When Talent Gaps Lead to Failure

The talent and leadership gaps are not theoretical risks; they are manifesting as high-profile corporate failures.

- **The CMC Delay & Valuation Hit:** A clinical-stage biotech, poised to initiate a pivotal trial for its lead gene therapy candidate, announced a six-month delay explicitly due to "challenges in scaling the manufacturing process." The root cause was an inability to hire experienced MSAT scientists to successfully transfer the process to their CDMO partner. The delay forced the company to seek emergency financing on unfavorable terms and triggered a 30% drop in its stock price over the following quarter.
- **The QC Bottleneck & Reputational Damage:** A commercial-stage CDMO, despite having state-of-the-art manufacturing suites, began experiencing consistent three-week delays in batch release for a major client's autologous therapy. An internal audit revealed the bottleneck was not in production, but in the QC lab, which lacked a sufficient number of qualified analysts to perform the complex, multi-day cell-based potency assays required for release. The delays led to financial penalties from the client and significant reputational damage in the market.
- **The Leadership Churn & Lost Business:** A mid-sized, PE-backed CDMO lost its Head of Operations and two senior site directors to a smaller, venture-backed competitor within a single quarter. The leadership vacuum created immediate operational instability. A key late-stage client, citing concerns over the site's ability to manage its upcoming BLA submission and commercial launch, pulled its program, resulting in a multi-million-dollar revenue loss and jeopardizing the CDMO's growth targets.



In CGT, talent doesn't just build companies - it can break them. As specialists migrate to challengers and leadership gaps widen, the real competitive advantage isn't technology - it's who you can retain.

Chapter 8: Strategic Outlook and Forward-Looking Analysis

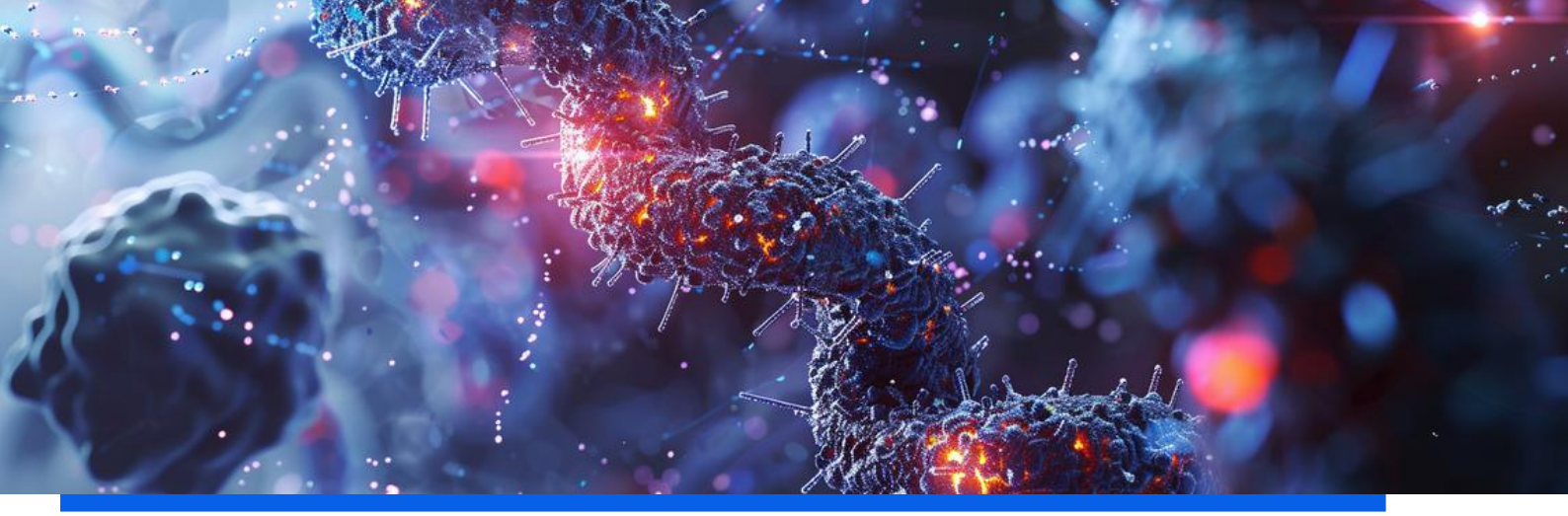
The CGT market is at a critical inflection point. The analysis of market dynamics, competitive positioning, and manufacturing realities reveals a clear trajectory defined by a relentless race for scale, technological mastery, and supply chain control.

8.1 Beyond the Waitlist: Vetting a True Manufacturing Partner in 2025

The persistent capacity crunch and market shocks have fundamentally altered the criteria for selecting a CDMO partner. A successful partnership in 2025 requires due diligence that probes the strategic and financial resilience of the manufacturer, not just its technical prowess.

- **Financial Stability & Corporate Backing:** The **Resilience** consolidation is a stark reminder that even well-funded CDMOs are not immune to market pressures. Assessing a CDMO's financial health and ownership structure (e.g., venture-backed vs. owned by a large corporate entity like **Ajinomoto** or **Sartorius**) is now a crucial risk mitigation step.
- **Geopolitical Risk Profile:** The creation of **Minaris Advanced Therapies** from the forced divestiture of **WuXi ATU** is the clearest possible illustration of how geopolitical tensions can reshape the supply chain. Developers must now assess the nationality of a potential partner's parent company and its exposure to legislation like the BIOSECURE Act.
- **Technological Fit and Process Flexibility:** Developers must determine if their therapeutic process is a good fit for a CDMO's standardized platform (e.g., **Cellares' Cell Shuttle™**) or if it requires a more customized, bespoke approach. This trade-off between process adaptation and platform efficiency is a central strategic decision.
- **Regulatory Track Record & Leadership Stability:** Amidst these new considerations, traditional gold standards remain paramount: a proven regulatory track record with agencies like the FDA and EMA is the most reliable indicator of competence. Furthermore, assessing the stability and tenure of a CDMO's site-level leadership team has become a critical, yet often overlooked, indicator of operational consistency and reliability.

In 2025, choosing a CDMO is no longer about availability - it's about resilience. Financial backing, geopolitical exposure, platform compatibility, and leadership stability have become the new pillars of partnership diligence.



8.2 The Next Frontier: Preparing for Allogeneic, In-Vivo, and Non-Viral Modalities

Even as the industry grapples with manufacturing the current generation of therapies from developers like **Atara Biotherapeutics**, **Cabaletta Bio**, **Sangamo Therapeutics**, **Genenta Science**, **INmune Bio**, and **Beacon Therapeutics**, the pipeline is advancing rapidly.

- The development of **allogeneic, or "off-the-shelf," cell therapies** requires a shift from a "scale-out" model to a "scale-up" model, necessitating expertise in large-scale bioreactor cell culture, a capability where established biologics manufacturers like **Samsung Biologics** have a distinct advantage.
- **The In-Vivo Revolution and the Non-Viral Frontier:** A groundswell of interest from major pharmaceutical players like **AbbVie**, **AstraZeneca**, **Novartis**, **Sanofi**, and **Takeda** highlights a strategic pivot towards **in-vivo CAR-T** technologies and direct gene delivery approaches. This next wave seeks to eliminate the complex and costly ex-vivo cell processing steps entirely by engineering cells directly inside the patient's body. This frontier is being pioneered by innovative biotechnology companies such as **Capstan Therapeutics** (a UPenn spin-out), **Umoja Biopharma**, and **Interius BioTherapeutics** (also from UPenn). This trend also encompasses novel non-viral delivery platforms from companies like **Kelonia Tx, Orna Therapeutics**, and **Sana Biotechnology**, challenging the long-held dominance of viral vectors and signaling a major future shift in manufacturing requirements towards technologies like lipid nanoparticles (LNPs). This push will require CDMOs to continually invest in new technologies and expertise to remain competitive.

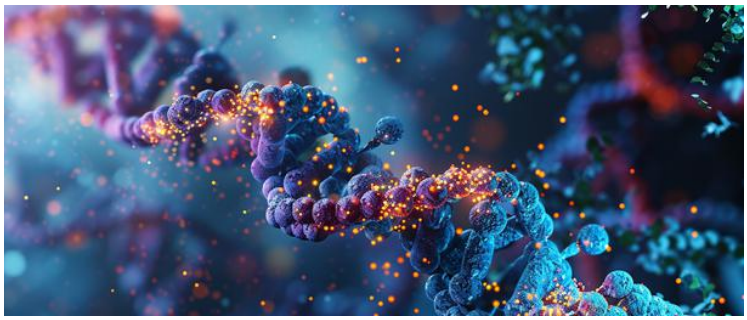
8.3 Concluding Analysis: Imperatives for Success in a Dynamic Market

The CGT CDMO market in Q3 2025 is defined by the powerful tension between explosive growth and intense competitive, financial, and geopolitical pressures. The analysis reveals three core imperatives for success:

(1) Achieve End-to-End Integration: The "one-stop-shop" concept has matured into the "CTDMO" model, where the seamless integration of development, manufacturing, comprehensive in-house testing, and regulatory support is the new standard.

(2) Win the Technology Race: Investment in technology is no longer optional. Automation, proprietary manufacturing platforms, and the application of AI are essential for reducing the prohibitively high cost of goods and improving process robustness.

(3) Secure a Global, Resilient Footprint: A successful CDMO must be both global and resilient. A manufacturing footprint spanning North America, Europe, and Asia is critical for market access and supply chain security. However, as the Resilience case demonstrates, this footprint must be built on a foundation of financial sustainability and, as the WuXi ATU divestiture highlights, it must also be geopolitically resilient.



"The future of CGT manufacturing won't look like its past. As the pipeline shifts to allogeneic, in-vivo, and non-viral platforms, success will belong to those who can scale new modalities, integrate end-to-end, and stay ahead of geopolitical and technological disruption.

8.4 - Five Strategic Questions Every CGT Leader Should Be Asking in 2025

The themes of this report translate into critical, actionable questions that every leadership team in the cell and gene therapy space must address to navigate the current landscape and position themselves for success.

(1) Is Our Manufacturing Strategy a Core Pillar of Our Corporate Strategy?

- **Why it matters:** Manufacturing is no longer a downstream, tactical consideration. It dictates timelines, cost of goods, and ultimate commercial viability.
- **Ask yourself:** Is our Head of Tech Ops a key voice in C-suite strategic planning? Are we prepared to pivot between in-house build, pure-play CDMO, and hybrid models as our pipeline matures and the market evolves?

(2) Have We Truly Stress-Tested Our Supply Chain?

- **Why it matters:** The era of stable, predictable supply chains is over. Geopolitical shocks, partner financial instability, and logistical failures are now predictable risks.
- **Ask yourself:** What is our contingency plan if our primary CDMO is acquired by a competitor or deprioritizes our program? How exposed are we to geopolitical tensions or single-source suppliers for critical raw materials?

(3) Are We Investing to Win the Technology Race, or Just Watching It?

- **Why it matters:** Automation and next-generation platforms are the only viable paths to reducing COGS and achieving industrial scale. Waiting on the sidelines is a losing strategy.
- **Ask yourself:** Is our process "automation-ready"? Are we actively partnering with platform enablers to de-risk our path to scale, or are we locking ourselves into outdated, manual processes?

(4) Is Talent Our #1 Strategic Constraint?

- **Why it matters:** The talent crisis is real and is actively delaying clinical trials and constraining growth. Capital can build a facility, but only people can run it.
- **Ask yourself:** What is our proactive plan to not just hire, but retain the critical technical and leadership talent needed to execute our goals? Are we treating talent acquisition with the same urgency as fundraising?

(5) Is Our Analytical Program Ready for Regulatory Prime Time?

- **Why it matters:** For complex living medicines, you cannot manufacture what you cannot measure. A weak analytical package is a leading cause of clinical holds and regulatory delays.
- **Ask yourself:** Are we treating our analytical development with the same rigor as our process development? Are we engaging with specialized analytical service providers early enough to de-risk our regulatory submissions?

ProGen Search

LET'S CONNECT

ProGen Search partners with leading Cell & Gene Therapy innovators to secure the leadership talent they need to scale.

If you're navigating growth, facing talent challenges, or planning your leadership roadmap in the CGT space, we would welcome the opportunity to connect and share insights.

Need to Hire Candidates?

Want to Discuss Hiring Plans?

Or just have questions to discuss?

Click **here** to book in a call today.

BOOK NOW

Byron Fitzgerald
Founder, ProGen Search
www.progensearch.com