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A That's Nice Brand

2026 EDITION

Our Update on, and Opinion of, the CDMO Landscape.

A Nice Insight Review 2026 Edition

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About Nice Insight

Nice Insight delivers specialized market research for scientists, conducted by scientists. Always on the cutting edge of the technical foundations of the industry, our expertise spans diverse scientific modalities. Whether you're exploring new technologies, assessing competitive landscapes, or identifying growth opportunities, our team can combine rigorous scientific methodology with market intelligence to offer actionable data and analysis that drive informed decision-making. Our pricing reports provide customers with the latest trends in the market, hard-to-find pricing, and analysis of important scientific innovation and challenges. These reports help innovators understand the price they'll pay for a contractor and what challenges they should anticipate, and allow CDMOs to evaluate their position in the market.

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Pharma's Almanac is the content community of Nice Insight, consisting of over 1,600 contributors, and the premier platform for thought leadership in life sciences. We use this platform to elevate brands' intellectual capital through content ghostwritten by our Ph.D. writing team. We have collaborated with hundreds of companies and thousands of SMEs to build a content presence that contributes to their brand recognition and perception in conjunction with other strategic efforts.

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30 years of experience and our depth of market research support effective consultancy for your business. Experienced consultants with real-world sector knowledge will work with your team on a project or ongoing basis to help you define and achieve key business goals. We also offer sector-specific analysis to position your company for investment, identify acquisition targets, or assist with divestments. We can support you with analysis of market conditions, company landscapes, and existing capacity to support your growth goals.

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About That's Nice

That's Nice works with both established and emerging Life Sciences brands to help their teams navigate the increasing market pressures associated with business transformations. We help shift business focus in response to the rapidly evolving Life Sciences market across all modalities and services. As expedited go-to-market strategies become the industry's new normal, our team supports clients in their efforts to optimize and streamline their communications. Launched in 1995, That's Nice is headquartered in NYC with 8 regional staff bases, exclusively serving the life science industry.

www.thatsnice.com

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For more information, please visit
www.pharmasalmanac.com/market-research/soti

Introduction

The tough economic and geopolitical landscape put pressure on innovator funding in 2023–2024, and the aftershocks still reverberated through 2025. The hoped-for investment rebound did not materialize; instead, venture capital investment into biotech fell again in early 2025, and throughout the year public markets remained selective and risk-averse. However, the new reality is that innovation cannot afford to wait for macro conditions to improve. Across a series of panel discussions with subject matter experts (SMEs) from contract development and manufacturing organizations (CDMOs), investors and innovator companies held to inform this report, there was consensus that companies must move forward within today's constraints rather than postponing development in anticipation of a more forgiving capital cycle.

This pragmatic shift is reshaping sponsor–CDMO relationships. Developers are adapting their outsourcing strategies to stretch limited budgets and mitigate uncertainty: breaking traditional end-to-end programs into milestone-based work packages, consolidating suppliers around trusted technical experts, and demanding clearer return on investment (ROI) visibility from each engagement. CDMOs, in turn, are adapting pricing models and commercial structures to sustain throughput — introducing milestone-triggered fees, success-based incentives, or shared-risk frameworks that align both sides under tighter financial control.

Yet the competitive landscape has also evolved. After a period of overexpansion during the post-pandemic boom, the sector has entered a more disciplined phase, focused less on capacity and more on capabilities.

In this report generated by Nice Insight, we review the global CDMO sector across 2025–2026, examining global outsourced manufacturing trends and charting the ebbs and flows of different therapeutic modalities. We comment on trends in the global CDMO landscape with respect to market dynamics and consolidation, global capacity changes, CDMO pricing trends, talent recruitment trends, and the ongoing innovation of manufacturing tools and technologies, identifying early signs of stabilization through adaptation rather than recovery, enabling strategic resilience and selective growth.

David Alvaro, Ph.D.
Editor-in-Chief,
Pharma's Almanac

"When the Biosecure Act was first proposed in December 2023, it signalled either immediate concern or opportunity for CDMOs, depending on their location. However, for many innovators, the concrete reality of significantly lower price points for services in China still outweighed the shadowy threat of geopolitical consequences. Now that the Senate has passed the Biosecure Act, notably included within the National Defense Authorization Act (and after our SME panels were held), it remains to be seen whether this will change in 2026."

The Ups and Downs of the Global Therapeutic Pipeline

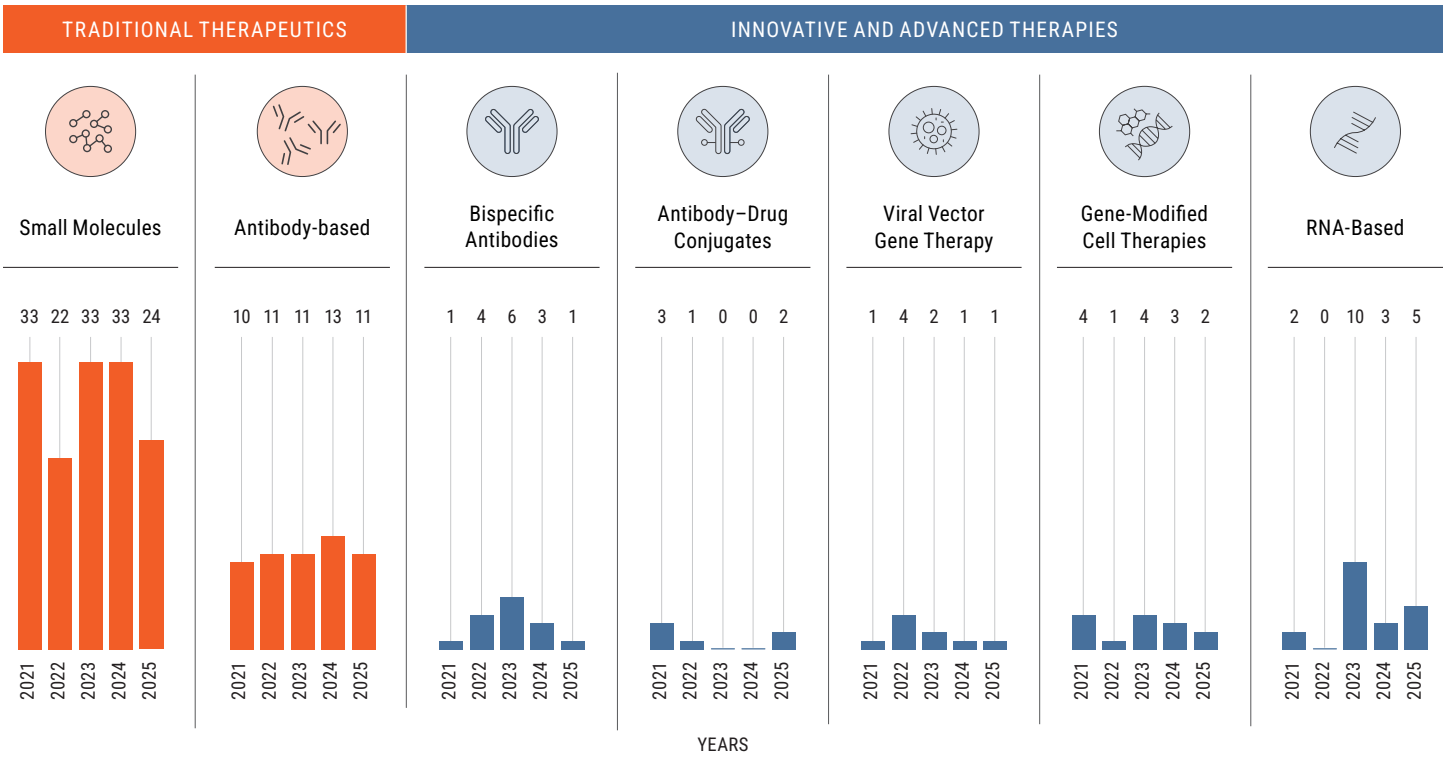
Overall, the global therapeutic pipeline remained strong during 2025. The U.S. Food and Drug Administration (FDA) had approved 43 new drugs (chemical and biologic) by the end of October, in line to match the average number of new approvals in recent years (2018–2024). As with the previous year, the economic pressures facing the industry during 2025 did not affect all drug modalities equally.

Small molecule drugs accounted for over 50% of all new drugs approved by the end of the third quarter of 2025. This was also a strong year for monoclonal antibody (mAb)-based drug approvals; the FDA approved 11 mAbs as of October 2025, one of which was for a bispecific antibody, continuing the emergence of this modality class.

Two new antibody–drug conjugates (ADCs) were approved in 2025; the first ADCs approved since 2022. Indeed, a recent article published by BCG reported that new modalities are experiencing accelerated growth, evidenced by the fact that 8 of the 10 best-selling biopharma products in 2025 are new-modality drugs. This was driven primarily by antibodies, proteins and peptides (specifically GLP-1 therapies), and nucleic acids.

The picture is less positive for advanced therapies, which had only eight new approvals so far in 2025; one viral vector–based gene therapy, two gene-modified cell therapies, and five RNA-based therapies. This represents a 50% drop from the approval high reached in 2023.

NUMBER OF THERAPIES APPROVED BY THE FDA IN EACH MODALITY BETWEEN 2021 AND 2025*



*YTD, as of October 31, 2025

PIPELINE SNAPSHOT OF SELECTED INNOVATIVE AND ADVANCED THERAPIES

Preclinical Clinical Marketed

ANTIBODY-BASED

mAbs

3% CAGR

2,487 2,700 2,625

2023 2024 2025

CAGR
-3%
7%
11%

bsAb

20% CAGR

231 299 333

2023 2024 2025

CAGR
22%
17%
29%

ADC

26% CAGR

582 678 920

2023 2024 2025

CAGR
31%
22%
9%

NUCLEIC ACID

DNA & RNA

15% CAGR

442 499 588

2023 2024 2025

CAGR
16%
13%
22%

RNAi

-6% CAGR

236 231 210

2023 2024 2025

CAGR
-12%
7%
7%

mRNA

15% CAGR

129 177 170

2023 2024 2025

CAGR
12%
15%
63%

CELL THERAPIES

Cell Therapy others

5% CAGR

1,030 1,082 1,142

2023 2024 2025

CAGR
11%
-2%
4%

CAR-T

2% CAGR

659 748 692

2023 2024 2025

CAGR
1%
3%
24%

Stem Cell

0% CAGR

542 568 541

2023 2024 2025

CAGR
4%
-4%
-2%

TIL

36% CAGR

21 33 39

2023 2024 2025

CAGR
55%
25%
-

GENE THERAPIES

Gene Augmentation

5% CAGR

766 832 837

2023 2024 2025

CAGR
5%
5%
0%

Gene Editing

14% CAGR

136 145 178

2023 2024 2025

CAGR
13%
22%
41%

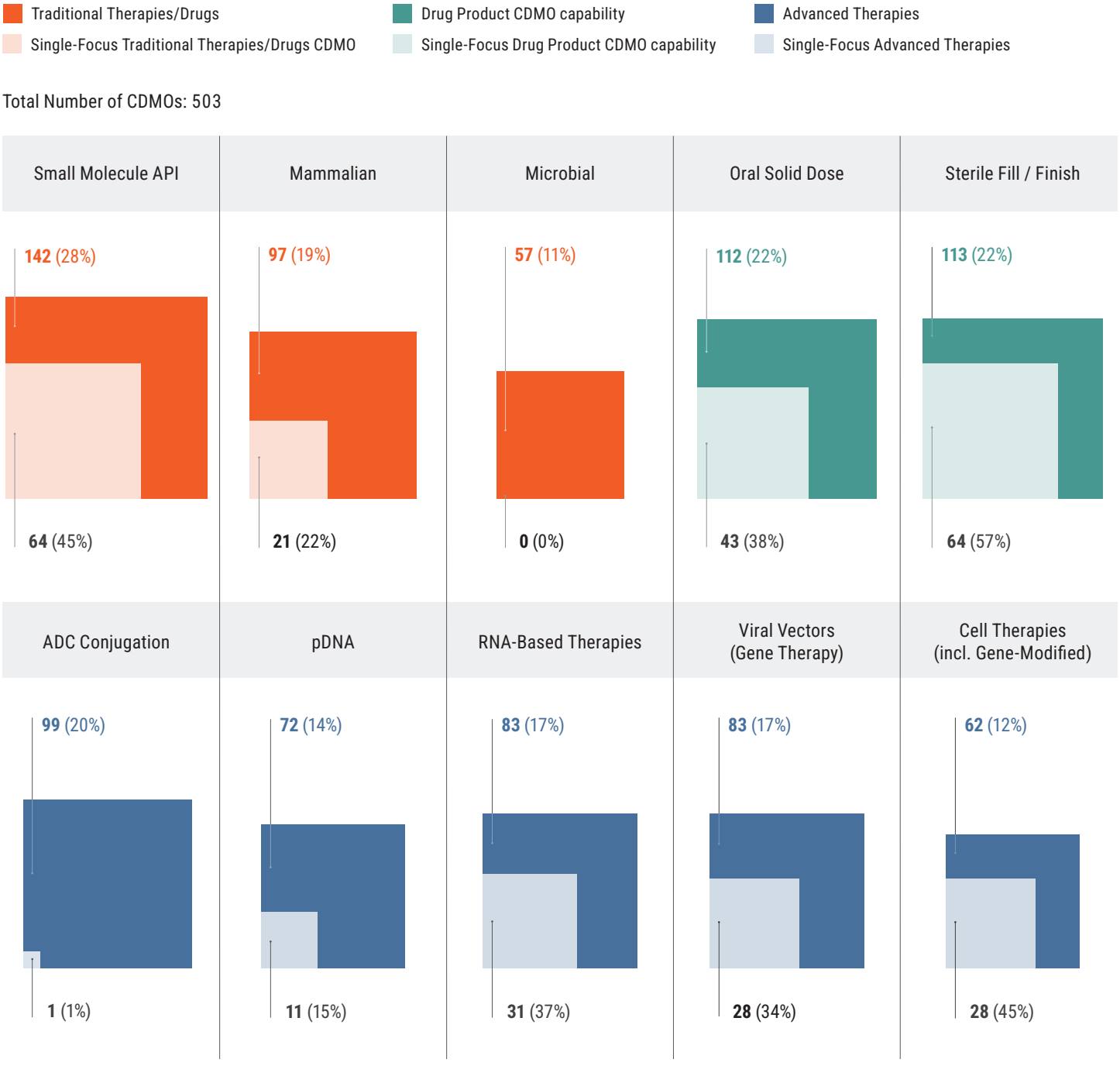
*Data taken and adapted from BCG New Drug Modalities 2025, Exhibit 3. Pipeline numbers include preclinical, clinical and marketed products.

The Global CDMO Landscape

During 2025, Nice Insight actively tracked over 500 CDMOs globally, an increase from the 400 CDMOs tracked in 2024. These CDMOs support development and manufacture across the spectrum of therapeutic modalities, from small molecule and traditional biologics to newer advanced therapies. This increased CDMO coverage is the result of a focused landscape analysis to better map the small molecule active pharmaceutical ingredient (API), oral solid dose (OSD), and sterile fill/finish CDMO sectors. This accounts for approximately 75% of the increased coverage, with the remaining 25% covering the other CDMO modalities.

THE GLOBAL CDMO "METAVERSE"

Total number and percentage of CDMOs per modality, and number and percentage of which focus on a single modality.



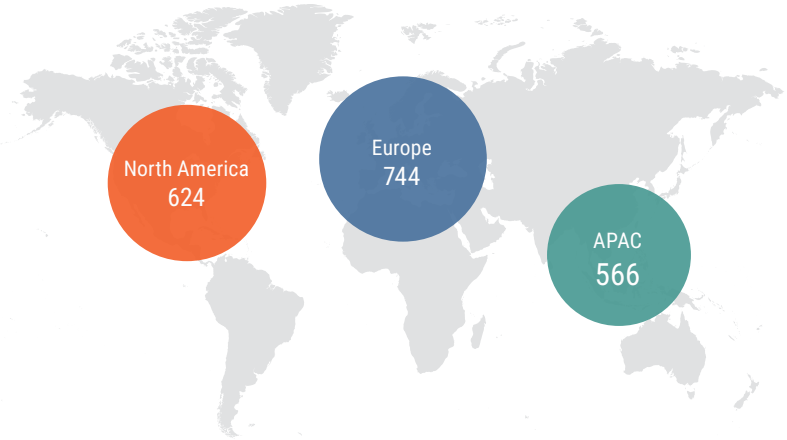
Overall, these CDMOs collectively operate 1,934 manufacturing sites globally (Americas, 32%; Europe, 39%; Asia-Pacific (APAC), 27%; Rest of World, 2%). Throughout 2025 and into 2026, CDMOs, innovators, and investors in the biopharma sector continue to navigate a landscape defined by funding constraints, capacity overages in certain modalities and scarcity in others, evolving regulatory pressures, and a somewhat staggered shift toward advanced therapies. Overall, the CDMO capability landscape closely follows the trends and challenges seen in the wider biopharma sector.

GEOGRAPHIC DISTRIBUTION OF CDMO MANUFACTURING SITES

GLOBAL

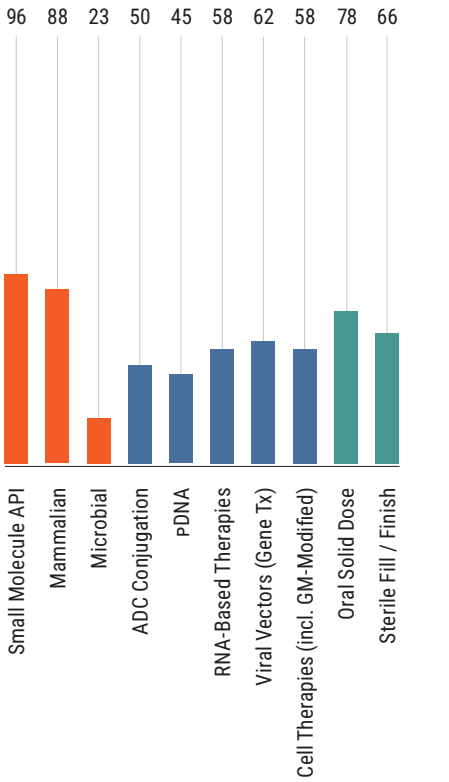
CDMO Manufacturing Sites: **1,934**

32% North America
39% Europe
27% APAC
2% Rest of World



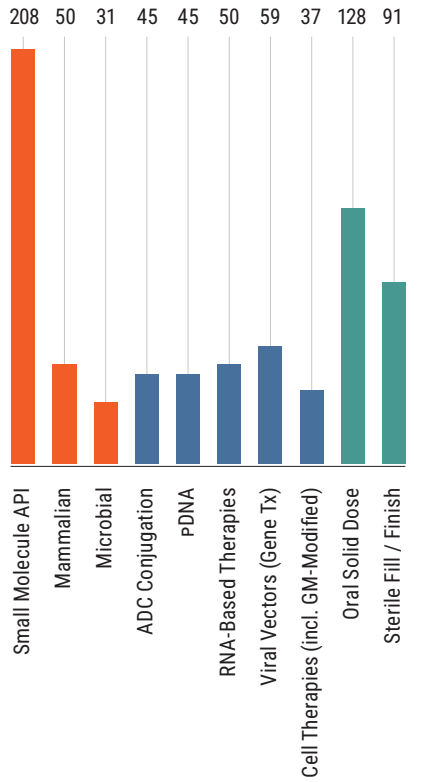
NORTH AMERICA

CDMO Manufacturing Sites: **624**



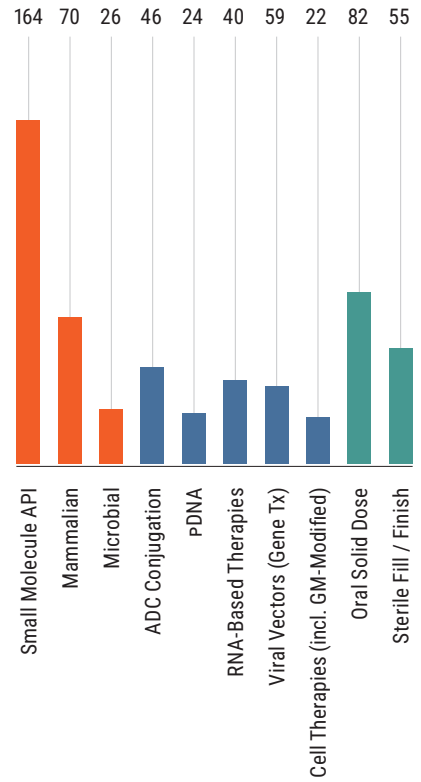
EUROPE

CDMO Manufacturing Sites: **744**



APAC

CDMO Manufacturing Sites: **566**



Traditional Therapies/Drugs Advanced Therapies Drug Product

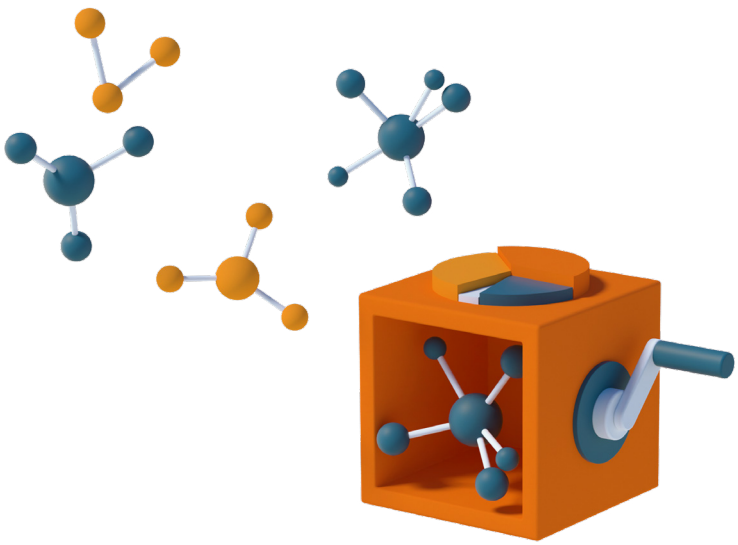
Small Molecule APIs

2025 was another strong year for small molecule APIs, with continued outsourcing of both early- and late-stage small molecule API projects to CDMOs to shorten timelines and share technical risk for complex/high-potency chemistries. Demand outpaced the available capacity for highly potent APIs (HPAPIs) and those with complex specialized chemistry requirements. Reshoring and onshoring for API continued to gain traction throughout 2025 with momentum from both major governments and industry alike, resulting in large capital expenditure (CapEx) announcements in 2025 for multi-billion-dollar API plants and new CDMO capacity.

Globally, nearly 30% of the 503 CDMOs tracked by Nice Insight have the capability to manufacture small molecules, directly following the trend within the drug development space, dominated by this mature modality type. Of these small molecule CDMOs, 45% are solely focused on this single modality. Regionally, Europe and APAC dominate the manufacturing facility landscape for API CDMOs, with less than 20% of sites located in North America. Within the 35% of global API facilities located in APAC, they are heavily concentrated in India and China. This geographic manufacturing facility distribution reflects the historical dominance of the European pharmaceutical sector and the presence of large-scale commercial API plants.

> "The political agenda in the U.S. for reshoring of API manufacturing presents both significant opportunities and challenges for U.S. based CDMOs. The various capital investments promised in 2025 by large pharma will take several years to be fully realized, so in the short-term the reshoring policy is likely to drive demand for domestic manufacturing services to already established and operational CDMOs. Conversely, for CDMOs to maintain position longer term, they must navigate the complexities of rapid infrastructure development and supply chain adjustments. Strategic investments in technology and infrastructure, along with flexible supply chain strategies, will be crucial for CDMOs to capitalize on this evolving landscape in 2026 and beyond."

April Stanley, MS, MBA
Senior Scientific Research Director, That's Nice



Sterile Manufacturing and Oral Solid Dose

During 2025, sterile fill-finish CDMOs have been navigating a re-calibration in outsourcing dynamics. Demand for injectable and biologics products remains high, driven by GLP-1–type products, advanced biologics, and increased outsourcing requirements from pharma and biotech clients. However, capacity constraints have persisted throughout 2025 due to long lead times for new sterile lines and the complexities of format, geography, and regulatory compliance.

There are 113 CDMOs offering dedicated sterile fill/finish capabilities, operating across 212 sites globally, with 74% of these dedicated aseptic manufacturing sites located in North America (31%) or Europe (43%). Towards the end of 2024 and into 2025, around 12% of these CDMOs reported the initiation of major capital projects, with investments totalling up to $1.5 billion USD, with 30% aiming to be online in 2025. The investments are focused on bringing new isolator-based, multiproduct, and flexible capacity online, while at the same time enhancing CDMOs' agility to realize small-batch biologics fills, modular facility design, automation, and closed systems to help reduce changeover times and contamination risk. In 2026, the sterile fill market will continue to shift from "capacity scarcity" toward "right-capacity at the right format, in the right place," with the winners being those CDMOs that can match evolving client needs with precision, regulatory strength, and flexibility.

Continuing from 2024, the demand for OSD, especially modified-release and high-potency oral drugs, remained steady in 2025, with pipelines containing more oncology and specialty small molecules requiring high-potency (HP) containment, testing and specialized packaging. CDMOs with HP capabilities can command premium pricing.

> "The huge growth in the steriles market is driven predominantly by the rising demand for self-administered and ready-to-use formats (autoinjectors/pens and prefilled syringes (PFS)). The demand for vial filling has held relatively steady. However, cartridge filling (for assembly into autoinjectors) is still a relatively niche capability, and many CDMOs who offer this service do so from multi-use lines that can be adjusted to fill cartridges, syringes or vials. Therefore, although the demand is rising for cartridges, capacity is being crunched for vials and syringes too."

Nigel Walker
Founder, That's Nice

> "While GLP-1s have driven demand for cartridge fill into autoinjectors, it's worth noting that the trend toward higher-concentration mAb formulations for subcutaneous (rather than IV) administration will also fuel demand for cartridge and PFS capacity. Beyond the fill itself, these presentations also have more complex formulation and delivery requirements, so it's likely that fill/finish CDMOs that can provide value from formulation development through to sourcing, testing, and assembling specialized components will be most highly sought after."

April Stanley
Senior Scientific Research Director, That's Nice

As we predicted last year, CDMOs with OEB (Occupational Exposure Band) 3-5 capabilities that can handle cytotoxic formulations continued to provide high margins on smaller volumes. Our analysis shows that 56% of API and 32% of OSD American or European CDMOs have HPAPI capabilities. This geographical distribution aligns with the regulatory requirements for defining manufacturing country of origin and the respective value associated with this important step in the manufacturing life cycle of a drug. In fact, the West dominates final dosage form (FDF) manufacturing, both in sterile and OSD. Europe is home to more API and FDF facilities than either the United States or APAC. However, while Asia, China, and other APAC countries feature some of the largest API facilities in the world and over 40% more API facilities than the United States, there are 27 fewer FDF CDMO sites in APAC than the U.S. This suggests that developers still prefer to reshore their bulk API before manufacturing the final dosage form, presumably to ease the launch onto the U.S. market.

mAbs and ADCs

As in previous years, mAbs remain the backbone of most therapeutic portfolios. Antibody demand continues to expand and diversify (mAbs, biosimilars, bispecifics, ADCs, multispecifics, and fragments), while manufacturing is moving toward higher-titers, process intensification (perfusion/continuous), multiplexed single-use, and geographically driven capacity shifts.

ANTIBODY MANUFACTURING TRENDS (2025)

Emerging Technology & Process Trends

- Process intensification / perfusion & continuous upstream processing
- Single-use and modular facilities
- Higher cell-line productivity / titers
- Multiplexed fill/finish and sterile supply-chain complexity

Product & Format Trends

- Classic full-length IgG monoclonals (mAbs)
- Biosimilars
- ADCs (antibody-drug conjugates)
- Bispecifics & multispecific antibodies
- Bispecific ADCs (emerging)
- Fragments / single-domain (Fab, scFv, nanobodies)

Market Dynamics & Commercial Forces

- Strong market growth & outsourcing
- Capacity bottlenecks for advanced formats
- Price pressure in commoditized biosimilar mAbs
- Supply-chain geopolitics & regional incentives

Impacts on Mammalian Antibody CDMOs by Region

United States: Premium market for advanced & secure supply
European Union: Technical depth, regulation & biosimilar demand
India: Scale, cost advantage and moving up the value chain
China: Scale, fast capacity build & integrated API ecosystems

Practical Implications for CDMO Strategy

- Segment capability & pricing
- Build ADC / cytotoxin containment & conjugation suites
- Invest intelligently in downstream capacity
- Offer hybrid geographies

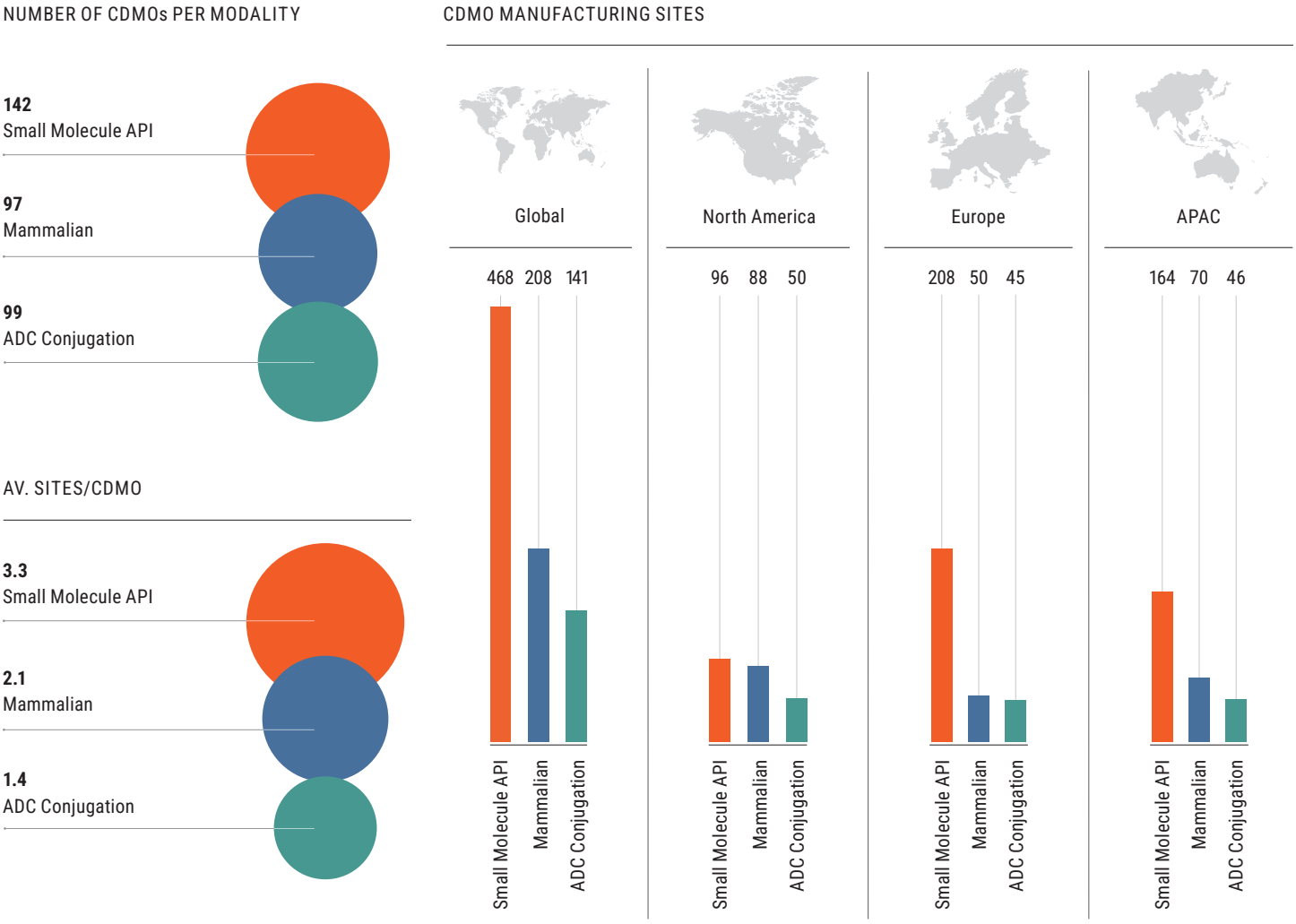
Globally, around 19% (97) of the 500+ CDMOs tracked in 2025 by Nice Insight have the capability to manufacture mAbs, with only 22% of these focused solely on mammalian-based biologics. ADCs continue to experience high demand, emerging as an attractive investment due to a growing clinical pipeline and a slowly expanding roster of qualified manufacturers. Early in 2025, the FDA approved two new ADC therapies, the first since 2022.

In line with increased demand for ADCs, CDMOs are expanding their capabilities to include ADC conjugation—we identified 99 CDMOs with this capability in 2025, over double from last year. This confirms our 2024 prediction that adding ADC conjugation to an existing API or mAb supply chain would provide a differentiating market opportunity for CDMOs in 2025 and provide a degree of resilience and robustness that will hold true for 2026 and beyond.

April Stanley
Senior Scientific Research Director, That's Nice

> "The fortuitously timed opening of Fujifilm Biotechnologies' $3.2 billion Holly Springs site in North Carolina and subsequent commercial manufacturing deal with Regeneron earlier this year demonstrates two things. First, that the reshoring agenda is influencing biologics outsourcing strategies as well as API, and secondly, that while the industry is somewhat trending toward smaller commercial volumes (rare diseases and other niche indications), there is still space in the market for mega-capacity facilities for blockbuster mAbs."

GEOGRAPHIC DISTRIBUTION OF ADC CDMO MANUFACTURING SITES



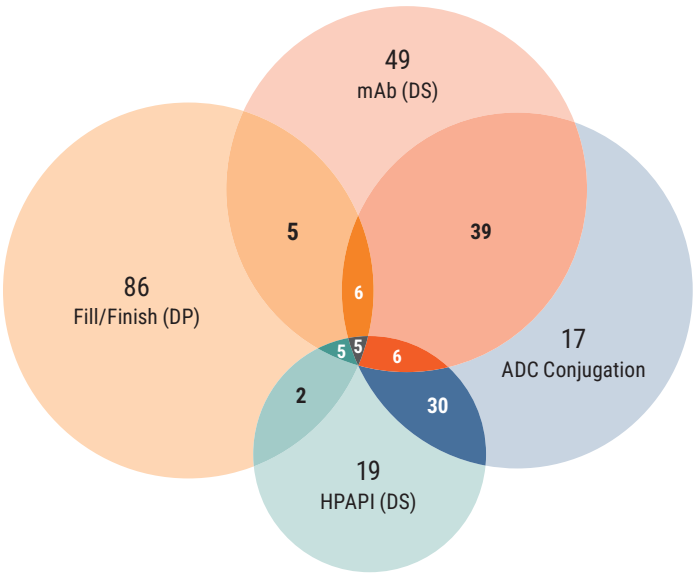
There are six CDMOs globally that can offer mammalian production, API synthesis and conjugation capabilities. However, even within those CDMOs that can produce all the elements of an ADC, HPAPI filling can be a missing link in the value chain, especially considering the additional burden of shipping toxic compounds. In fact, only five CDMOs worldwide can support the full suite of ADC outsourcing needs, which includes antibody production, API synthesis, conjugation and HPAPI fill. However, none of these 5 CDMOs offer all of those capabilities within the same country / location.

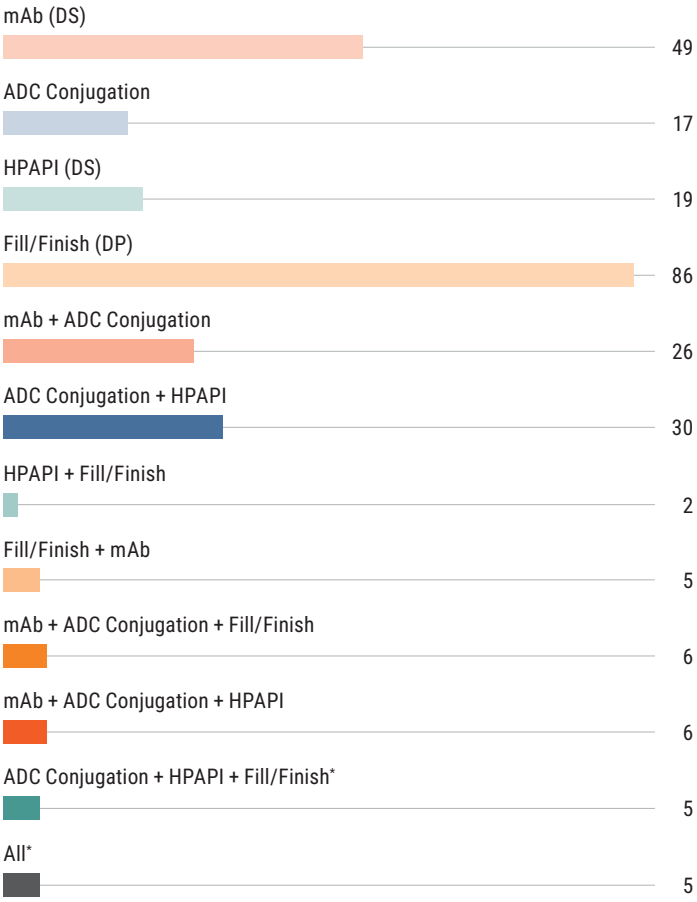
Looking ahead, the development of bispecific ADCs and those targeting novel antigens is anticipated to gain momentum, potentially leading to an increase in approvals, with the first commercial launch of a bispecific ADC predicted by 2029. These emerging formats will mean that CDMOs face an elevated bar for quality attributes, such as drug-to-antibody ratio (DAR) distribution, site-specific conjugation fidelity, and impurity control, as bispecific architectures magnify variability.

David Alvaro, Ph.D.
Editor-in-Chief,
Pharma's Almanac

> "While the idea of bringing all the elements of the ADC value chain together within a single company is appealing—and highly differentiating—it would also be very challenging. To really solve challenges for developers, these capabilities must not only exist within the same company, but within the same country, and would require the CDMO to have deep—and equal—expertise in every aspect of the value chain."

SUPPLY CHAIN FOR ADC MANUFACTURING





*Same 5 CDMOs.

CDMO Pricing Dynamics in 2025

As budgets became tighter and the economy less certain over the last two years, it has been increasingly important that CDMOs step up to become true strategic partners to their customers rather than third-party vendors, fundamentally reshaping how new therapies are brought to market. The role of CDMOs as strategic partners will continue to evolve in 2026 and beyond, as they function as extensions of their clients' internal R&D and manufacturing departments. This will necessitate tighter integration, mutual trust, and a shared vision for product success.

The continued shift from pure fee-for-service to strategic partnership for CDMOs has resulted in a shift in pricing strategy and dynamics in the outsourcing market. Understanding the nuances of how CDMOs price their services should be central to strategy for their clients, investors, and competitors truly seeking competitive advantage in 2026 and beyond. Done well, it enables faster market entry, fewer regulatory headaches, and better alignment of risk and reward. Done poorly, it can lead to cost overruns, delayed launches, or even outright failure.

Nice Insight's recent analysis of pricing trends, combined with discussions with industry leaders across a range of modalities and CDMO offerings, show that for more mature modalities the market is moving toward value, not cost-based pricing. Whereas, for the new more innovative advanced therapies, pricing dynamics during 2025 were heavily dependent on modality, development phase and creative deal-making reflecting the buyers power in the marketplace. Overall, clients have become more sophisticated, expecting transparency and demanding pricing that reflects risk, complexity, regulatory burden and speed. Consequently, they're moving away from the traditional low-bid model that has proven to be so risky.

2025 has marked the end of the CDMO sector being a complacent cost center and the start of it behaving like a proper commodity market: volatile in nature, segmented by modality, clinical phase and commercial production, and painfully responsive to capacity and pipeline signals.

Across the sector, from HPAPIs through traditional biologics, to advanced therapies (cell, gene, and RNA) and sterile fill-finish, tight capacity for complex modalities, rising capital and regulatory costs, and client demand for both integrated services and dedicated expertise have pushed list and request for proposal (RFP) prices higher in some areas, while they have conversely flattened or grown more negotiable in others.

> For years, CDMOs have marketed themselves as "strategic partners" to their customers, but — if a strategic partnership can be equated to a marriage — it is of course easier to be a good partner "in health" within a favorable economy. In today's economic landscape, CDMOs have to prove their partnership potential "in sickness" too. This inevitably increases their own financial risk, but it also poses an opportunity to demonstrate that value means more than just price."

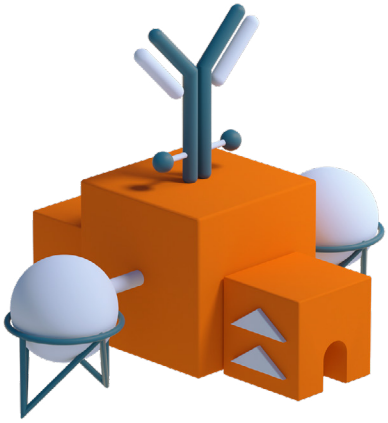
Nigel Walker
Founder, That's Nice

> We've seen large pharma in particular consolidate their outsourcing strategies, often trying to keep more of their supply in the U.S. They are increasingly open to strategic models: FTE arrangements, guaranteed minimums, and other structures designed to secure capacity. That said, once you're in the relationship, pharma can quickly revert to transactional behavior."

Rod Ketner, Ph.D.
Vice President Business Operations, Serán Bioscience

HPAPIs

HPAPIs experienced a distinct pricing surge in 2025, which is expected to remain in 2026. Demand for HPAPIs is growing quickly as the discovery and development of targeted therapies increases, but capacity remains constrained by the cost of containment infrastructure, operator safety protocols, and the technical expertise required. CDMOs with OEB 4/5 facilities are commanding significant premiums, with batch prices reflecting not only equipment and safety investments but also the scarcity of trained staff. In many cases, sponsors are willing to pay more for guaranteed occupational safety compliance and supply chain reliability than for sheer throughput.



> From the innovator side, the biggest factor is timelines. If a CDMO says they can't fit us in for nine months, that's a non-starter. Flexibility on scheduling, invoicing, or payment mapping can be a lifesaver for startups."

Michael Torres, Ph.D.
Chief Executive Officer, CrossBridgeBio

> The complexity involved in HPAPI manufacture, including staff training, occupational health compliance, and mitigation of environmental risk factors, has made HPAPI outsourcing one of the highest-margin small molecule niches, rivalling biologics in pricing power. It's also an area where continuous manufacturing processes may have the biggest impact over the next few years. Smaller volumes and automated processes improve manufacturing safety, while reduced waste and lower CO2 emissions reduce environmental impact. Not to mention reduced manufacturing footprints and lead times for fully continuous processes, too. Although there's a high initial CapEx barrier involved in switching to continuous systems, these have the potential to significantly impact HPAPI pricing in particular over the next few years."

David Alvaro, Ph.D.
Editor-in-Chief, *Pharma's Almanac*

Biologics

In general, biologics CDMOs rode the post-pandemic recovery with stronger pricing power than many expected. Demand for mAbs, biosimilars, and novel protein therapeutics pushed up facility utilization rates at top-tier CDMOs, allowing those companies to protect margins and selectively raise fees for tech transfers and scale-up work, with a willingness by sponsors to pay for speed, expertise and regulatory know-how.

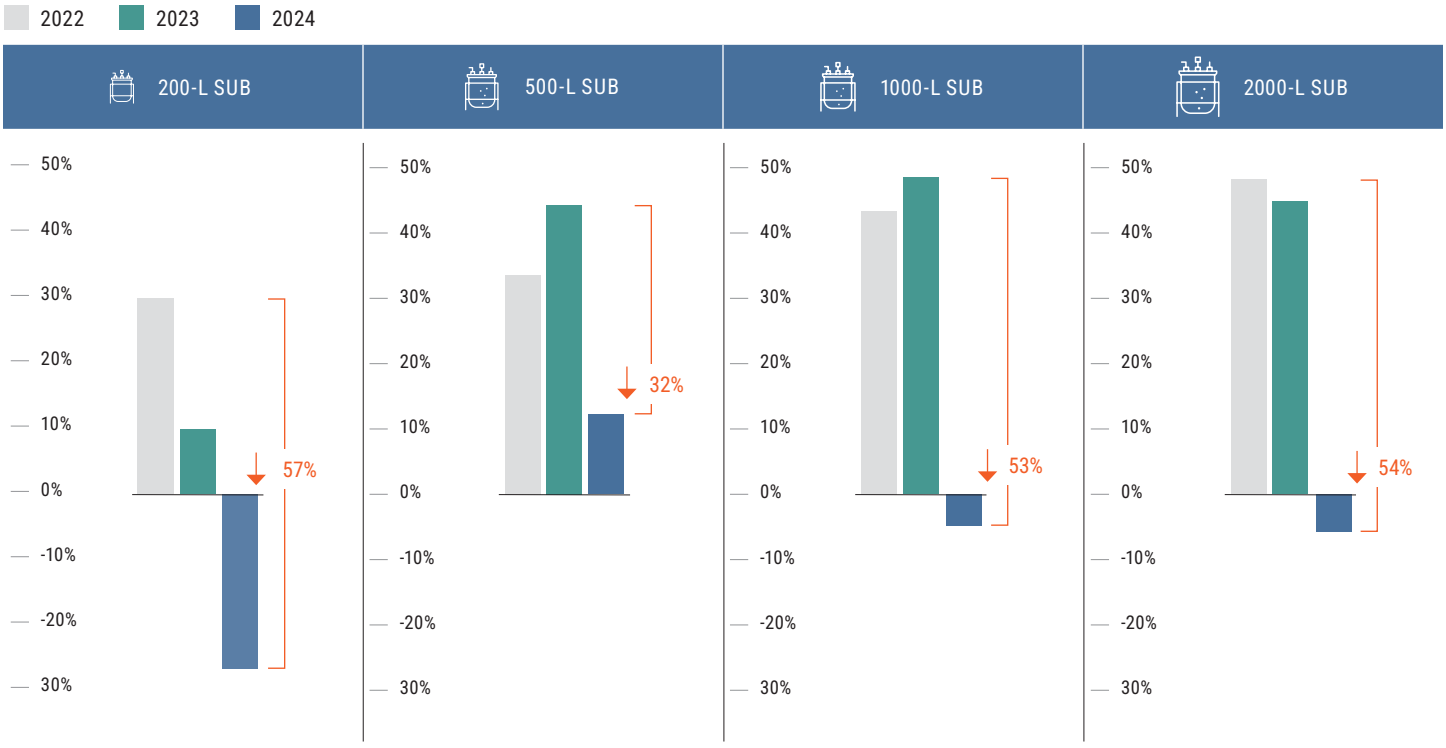
A new trend that emerged during 2024-25 was a bifurcation in the market with respect to scale. Small biotechs requiring clinical batch scales from 200-L to 2,000-L liters for mammalian protein production found themselves in a buyer's market. CDMOs were faced with increased pressure to lower prices for 2,000-L and smaller batches. Nice Insight's analysis has shown that, for clinical batch scales of 2,000-L and lower (e.g., 1,000-L, 500-L, 200-L), the average price across these scales has fallen to 6% lower than average pricing levels before COVID, and between 45% and 50% from the average peak price recorded in 2022–2023. Commercial projects, however, that are typically performed at larger scale and require multiple batches or multi-year contracts have not yet seen the same pricing fluctuations observed for clinical projects.

This reduction in clinical-scale pricing initiated in 2024 continued into 2025, with geographic location playing a pivotal role in CDMO pricing dynamics. This is influenced by variations in labour costs, utility rates, competitive landscape, and regulatory environments, all underpinned by cultural and societal differences and conventions.

Nowhere is this geographical difference more clearly exemplified than by the pricing analysis obtained and tracked by Nice Insight examining the clinical GMP production of mammalian-expressed proteins. In 2024, the consolidated average price for a 1,000-L single-use bioreactor batch for CDMOs located in North America was $0.9 million USD, compared with a price of $1.1 million USD for the same scale in Europe. However, the price for the same service in APAC (China) was pegged at $0.5 million USD. This difference is primarily attributed to significantly lower operational costs, with rates often 30–50% less than in Western geographies.

> "Historically, the question was always, 'How big can you make a batch?' … But increasingly, the question is, 'How small can you go?"
>
> **Timothy Compton**
> Chief Strategy Officer, Alcami

CLINICAL-SCALE GMP MAMMALIAN PROTEIN—PRICING TREND (2022-2024)



China has experienced a significant surge in the establishment of CDMOs specializing in mammalian cell culture over the past five years, driven by access to more affordable skilled labor and global demand linked to access to the internal Chinese market, as well as attractive governmental incentives, favorable policies, and the provision of substantial funding to bolster the biopharmaceutical industry, which encourages both domestic and international investments.

The regional cost disparities present a strategic dilemma for clients. While the allure of lower costs in certain geographies is strong, it necessitates a careful balancing act between immediate cost savings and potential additional and indirect costs related to project scope synergizing with regulatory alignment and consideration of supply chain logistics, project governance, and oversight. Indeed, one multinational CDMO told us that while some of their mammalian clients specifically request U.S.-based manufacturing, roughly the same number again will ask for their manufacturing to be offshored to take advantage of significant cost benefits. This decision depends largely on the financial situation of the company and the risk tolerance of their investors and leadership team. It will be interesting to see what, if any, impact the Biosecure Act has on the price differential between the United States and China now that it has passed the Senate.

> "While it is true that biopharma companies currently have the upper hand in a buyer's market, caution should be had in an approach to drive down prices too far. It is well recognized that a price race to the bottom can have many negative consequences for businesses, customers, and society as a whole. Indeed, to maintain low prices, companies may eventually cut corners and reduce the quality of their products. CDMOs may have less money to invest in innovation. Reduced margins for a CDMO can lead to financial instability for outsourcing providers. A race to the bottom can rapidly create an unbalanced industry that is unable to correctly serve the needs of customers, companies, shareholders, employees, or, in this sector, ultimately the patients."

David Alvaro, Ph.D.
Editor-in-Chief, *Pharma's Almanac*

> "The lowest option is not always the best option. It is important to fully understand what is included in the scope, and if the proposed program of work aligns with the compliance and regulatory requirements of the client. Transparency and line-item costing is essential in achieving this goal. Has the scope excluded or reduced critical analytical support services? Or conversely, does it include services that are not strictly needed? Sometimes the middle option delivers on quality, budget, timeline and flexibility."

James Grote
Research Director, That's Nice

Advanced Therapies

During 2024 and throughout 2025, owing in part to the funding environment and geo-political uncertainties, CDMOs offering services focused on advanced therapies, specifically gene therapy CDMO services, have reported that early clinical-phase projects have been few and far between. Early-stage clinical clients have been requesting smaller and more exploratory pieces of work, and CDMOs have responded with establishment of feasibility studies and manufacturability assessment-based service offerings. These feasibility studies are performed on a smaller budget, typically between $50,000 USD up to $190,000 USD, depending on scale, aligned purification assessment, and whether the budget includes materials. Our analysis showed little or no geographical variation in pricing, with price points driven solely by the need to attract new clients and win business for the CDMO and with the goal of generating data to support fundraising for the client.

Although the overall GMP batch list pricing for mid to late clinical stage has remained relatively stable over 2024–2025, increasing in line with or just above inflation, competition around pricing has been aggressive at the small feasibility and Phase I clinical scale. Some larger CDMOs that have commercial revenue streams and/or other profitable business units are performing IND-enabling development or manufacturing for free, for delayed payment, or even for equity. As a result, the CDMO gains a relationship with a potential client when funding picks back up. This offering, of course, is only possible for companies that have alternate sources of steady revenue, which most often is obtained through commercial contracts.

Sterile

The surge in demand for GLP-1 agonist drugs, driven by their clinical success in treating diabetes and obesity, is fundamentally reshaping the sterile injectable CDMO sector. These therapies, delivered primarily by pre-filled syringes (PFS) or auto-injectors, are driving unprecedented capacity requirements that permeate throughout the supply chain and the pricing that sterile injectable CDMOs can command.

As such, pricing dynamics have evolved rapidly throughout 2024 and 2025. Capacity constraints have created strong upward pressure on manufacturing service fees. CDMOs with established sterile injectable expertise are commanding premium rates, especially for clients racing to secure long-term supply agreements for GLP-1 franchises. Conversely, smaller biotech firms developing injectables in unrelated therapeutic areas face rising costs and longer timelines as CDMO slots are monopolized by GLP-1 innovators.

Nice Insight's analysis revealed that fill/finish prices have been increasing by more than 10% annually since the various GLP-1 agonist drugs entered the market, resulting in sterile pricing increasing at a far faster rate than any other aspect of the CDMO pricing market that we track. During the first half of 2025, clinical sterile prices had increased 20% over 2023 prices. Additionally, CDMOs are charging smaller developers price premiums of between 20% to 30% on top of the values listed in our pricing tables for services and consumables.

> "We heard from one industry source that value-based pricing is becoming increasingly common for commercial fill/finish projects; for example, manufacturers will charge more for a commercial GLP-1 fill than for an identical low-value product fill. This seems to be less true of clinical materials, however, where cost of goods is less relevant."

April Stanley
Senior Scientific Research Director, That's Nice

In the medium term, this demand surge may catalyze broader modernization of the sterile injectable landscape, with automation, modular cleanroom design, and advanced containment systems becoming the norm. However, the near-term reality going into 2026 is clear: GLP-1 agonists have tilted the balance of power toward CDMOs with scale and flexibility, reshaping both capacity allocation and pricing trends in favor of those best positioned to deliver at volume.

While the west is grappling with sterile shortage due to high demand of GLP-1 agonists, countries within the African Union are grappling with a vast shortage of local facilities at all — a situation made painfully clear during the COVID-19 pandemic. African states had to rely on importing vaccines, which led to a long delay in their distribution among the population. The African Union now has set a goal for providing universal access to healthcare by 2030, and a key first step is building sterile facilities to provide vaccines to the African population. They plan to bring on vaccine drug substance manufacturers after the fill/finish capabilities are enhanced. It's not yet clear how this will impact the rest of the global sterile supply chain, but given the current constraints, exacerbated shortages of suitable vials and syringes for filling may be expected.

Pricing Dynamics and Outlook for 2026

We believe that, for commoditized biologics and routine sterile fills, CDMO price growth will moderate as new capacity starts to absorb demand and sponsors push harder on long-term deals. For high-growth modalities, such as HPAPIs and bespoke commercial biologics, pricing power will remain with established and specialist CDMOs. Premiums for short lead times and complex modalities will persist and may even rise if pipeline progress and regulatory approvals accelerate.

Conversely, the advanced therapies sector will remain a buyer's market for early clinical sponsors until investment returns, thereby increasing the number of assets entering the clinical pipeline. Overall, for CDMOs, the winners in 2026 will be the ones investing smartly in specialized capacity, digital tightness on batch yields, and transparent pricing models that let sponsors trade certainty for speed.

As the CDMO market continues to evolve, the understanding that CDMO pricing should be treated as a strategic asset (not just a variable cost to be minimized) will enable biotech, investors, and CDMOs alike to be better positioned for competitive differentiation. Access to strategic pricing information, such as Nice Insight's range of CDMO pricing data, which includes price breakdowns at the service line level, should be viewed as a critical enabler to support business planning and growth.

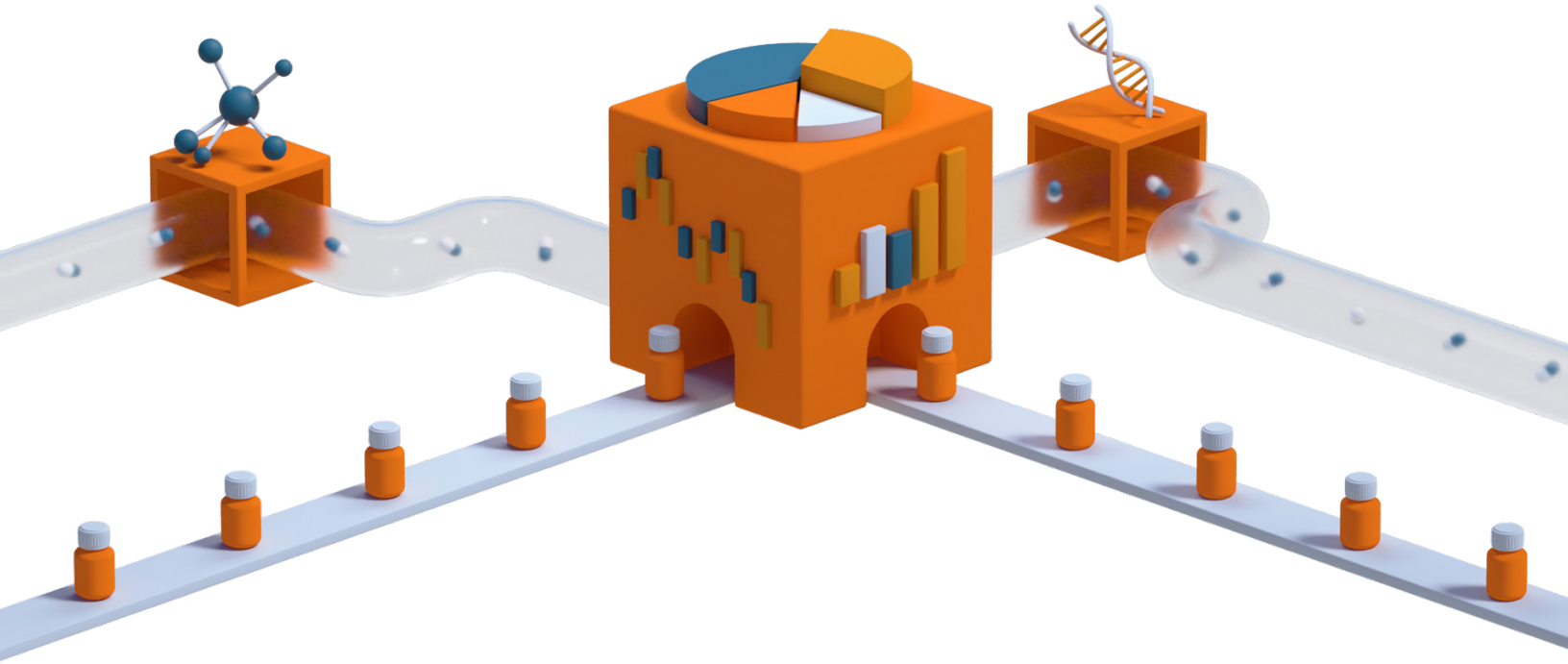
Overall, 2026 will continue to see asymmetric pricing for CDMO services, with stable or falling costs for high-volume, low-complexity work, and persistent premiums for anything novel, small-batch, hazardous, or speed-critical.

> It's unsurprising that our pricing data reflects the same trends that we've heard in discussion with industry experts; where therapeutics are becoming more complex, and adopting increasingly complex formats, innovators are starting to favor specialist CDMOs over "one stop shops", and are willing to pay a premium for technical expertise and regulatory confidence."

James Grote
Research Director, That's Nice

> The pricing dynamics of 2025 reveal a global recalibration: sponsors seek flexibility, CDMOs seek strategic partnerships, and patients wait for affordability to catch up with discovery. The tension between innovation and access sharpens, but it also inspires new models, shared risk, performance-based contracts, and global supply harmonization. As we enter 2026, pricing power now stems from scarcity of expertise, specialized infrastructure, and regulatory mastery, not from scale alone."

April Stanley, MS, MBA
Senior Scientific Research Director, That's Nice



Innovative Technology Trends, Challenges, and Opportunities in the CDMO Sector

If the past decade was defined by discussions about digital transformation, 2025 marks the year when digital tools, automation, and enabling manufacturing technologies quietly became the baseline for competitiveness. Across all of our expert panel discussions, the consensus was clear: technologies once described as differentiators — AI, modular facilities, continuous processes, and advanced expression systems — are now fundamental infrastructure.

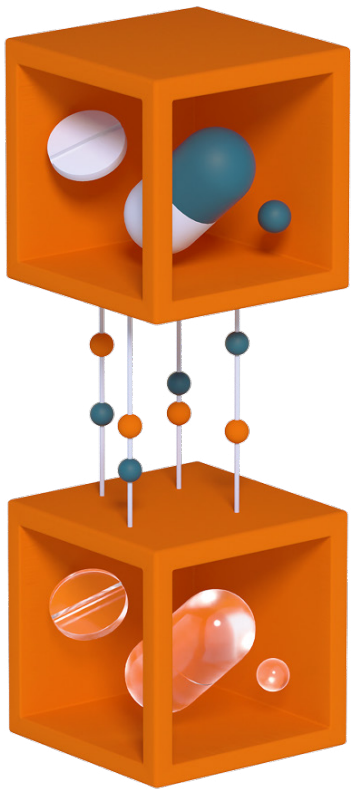
What distinguishes leaders in 2025 is not early adoption but depth of implementation and integration. The CDMOs that stand apart are those embedding these tools into quality systems, process design, and even the material biology of manufacturing itself — redefining how drugs are developed, scaled, and sustained.

Digital Twins and Process Optimization

The use of digital twins has matured from concept to execution. In both biologics and small molecule process development, these models are now being used to simulate bioreactor dynamics, predict yield responses, and guide scale-up before a single batch is run.

The most sophisticated adopters are coupling twins with advanced analytics and artificial intelligence (AI) to detect deviations earlier and simulate what-if scenarios during development runs. The result is not futuristic autonomy but fewer failed runs, faster process performance qualification (PPQ) readiness, and stronger regulatory packages.

> "Digital twins are "the new connective tissue" between development and GMP manufacturing. They offer continuity across tech-transfer boundaries that have historically introduced inefficiency and error. In biologics, for example, they are helping teams visualize and optimize cell culture kinetics, nutrient utilization, and perfusion parameters in silico. In small molecules, digital twins are integrated with flow chemistry systems to model thermal and mixing conditions in real time, accelerating optimization cycles."
>
> **Biologics Panel Opinion**



AI in Quality and Operations

Across all modalities, AI and machine learning are finally shedding their "moonshot" image. The conversation has shifted from discovery informatics to pragmatic deployment within validated systems: enterprise resource planning (ERP), manufacturing execution systems (MES), quality management systems (QMS), and laboratory information management systems (LIMS).

These are modest but measurable improvements that free human bandwidth for higher-value tasks. SMEs emphasized that validated AI — systems whose algorithms are explainable and locked within a GMP framework — is where the industry is finding its stride.

This pragmatic approach also reflects cultural maturity: a move away from proof-of-concept enthusiasm toward AI as invisible infrastructure that is embedded, trusted, and compliance-friendly.

> "The real ROI of AI today isn't in reinventing processes. It's in streamlining compliance and release around automating deviation trending and root-cause analysis, predictive maintenance and batch-yield forecasting, and smart scheduling and resource planning to reduce idle time between campaigns."
>
> **Small Molecules Panel Opinion**

> "On the manufacturing side, I think the potential is huge, but the reality is a bit overhyped right now. We're not yet at the stage where AI is delivering major operational impact."
>
> **Nick Hutchinson**
> Associate Vice President of Business Operations, Just-Evotec Biologics

> "We've focused on integrating our data through a new SAP system rolled out earlier this year. That gives us the ability to apply AI for smarter supply chain management: forecasting demand, optimizing ordering patterns, and improving both commercial and clinical manufacturing scheduling."
>
> **Timothy Compton**
> Chief Strategy Officer, Alcami

Continuous and Modular Manufacturing

Continuous manufacturing has long been heralded as the next leap in efficiency, but its real-world adoption has followed divergent paths.

The consensus across the biologics and advanced therapy panels was that continuous operations will expand incrementally through modular, closed-system design rather than wholesale plant conversions.

The rise of modular facilities—preassembled cleanroom pods, ready-to-use (RTU) suites, and single-use-enabled production trains—offers a lower-risk bridge. These designs shorten construction timelines, improve sustainability through smaller energy footprints, and align naturally with the regulatory push for agility.

> "Continuous manufacturing is pretty firmly established in small molecules. Continuous or semi-continuous systems are particularly valuable for hazardous or thermally sensitive reactions, and the benefits are proven: reduced footprint, lower solvent use, improved impurity control, and faster tech transfers."
>
> **Small Molecules Panel Opinion**

> "Continuous manufacturing is starting to gain traction in biologics, but momentum is definitely cautious. Larger organizations have piloted perfusion and hybrid continuous systems, but for smaller CDMOs the upfront capital and validation complexity is a concern."
>
> **Biologics Panel Opinion**

> "What companies are asking us is: Can we use one integrated system that runs continuously through phase III and into commercial launch? That continuity eliminates handoffs and accelerates time to market."
>
> **Salvatore Mascia**
> Founder and President, CONTINUUS Pharmaceuticals

Validated Automation: Incremental, Not Idealized

The most meaningful advances are being realized in:

- Automated visual inspection and container closure integrity for sterile fill-finish.
- Automated material tracking and digital batch record review.
- Closed-system viral vector processing and automated aseptic connections that reduce contamination risk.

These technologies deliver operational resilience and reproducibility, exactly what regulators and sponsors value most. Automation done right is not about replacing people but reducing variability, allowing the workforce to focus on decision making and quality oversight rather than manual intervention.

Importantly, automation and digitalization are also converging with environmental, social, and governance (ESG) goals. Smart systems optimize energy use, minimize waste, and support data-driven sustainability reporting — further integrating environmental stewardship into the operational core of manufacturing.

> Automation is a wide spectrum; we need to distinguish between moonshot automation — fully autonomous facilities that are still years away — and validated incremental automation that is implementable now."
>
> **Drug Product Panel Opinion**

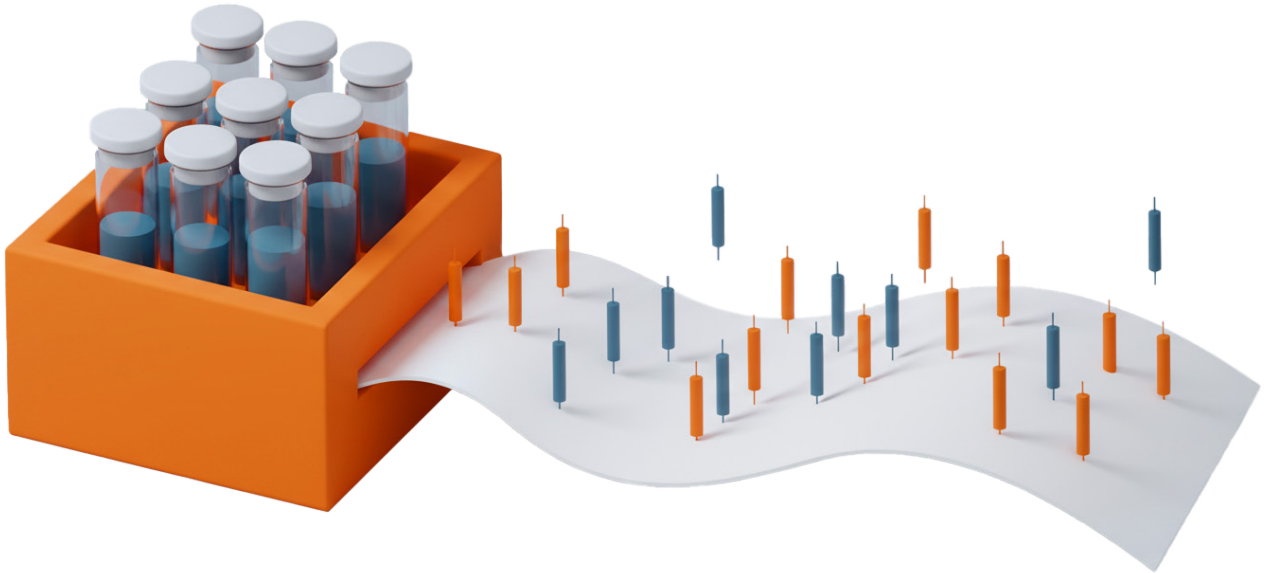
Technologies Enabling Next-Generation Biomanufacturing

The automation story now extends far beyond conventional robotics. In cell therapy manufacturing, a new generation of closed, automated systems is reaching commercial readiness, offering genuine competition to first-generation integrated devices like the Prodigy. These platforms aim to standardize previously manual, operator-dependent workflows for cell expansion, washing, and formulation, reducing variability and enabling multi-product flexibility.

Meanwhile, synthetic DNA is becoming a mainstream enabler for both gene therapy and mRNA platforms.

Similarly, cell-free protein expression systems, such as those developed by Leniobio, are gaining traction as an alternative to cell-based bioproduction. These platforms, which use plant or microbial extracts rather than living cells, promise faster protein synthesis, reduced contamination risk, and improved scalability for complex biologics. While still early-stage, they represent a step toward a future of on-demand, low-footprint biomanufacturing.

> DNA synthesis technologies from firms like Elegen and Touchlight are eliminating the plasmid bottleneck that constrains upstream processes, enabling shorter timelines, higher reproducibility, and simplified regulatory pathways for vector and mRNA programs."
>
> **Advanced Therapies Panel Opinion**



Sustainability as a Technological Imperative

Sustainability has moved from a compliance talking point to a strategic technology driver. The panels and SME inputs both pointed to growing investor and customer scrutiny of carbon intensity, waste, and energy use.

Digitalization and modularization support these goals: reducing travel, energy consumption, and raw material waste through data-driven optimization. Continuous manufacturing lowers solvent volumes and batch losses; modular cleanrooms cut HVAC demand; and single-use systems, when paired with recycling programs, can meaningfully reduce water and cleaning chemical usage.

Some CDMOs are even quantifying sustainability metrics — measuring grams of CO_2 per gram of API — as part of client scorecards. As one respondent noted, "Efficiency and sustainability have finally converged — they're now the same conversation."

From Technology Adoption to Cultural Integration

Taken together, these developments mark a cultural inflection point. Digitalization is no longer a "future trend" but a lens through which every CDMO strategy is refracted. The discussion has moved from what to adopt to how deeply to embed technology into daily operations and regulatory narratives.

The most forward-looking CDMOs are no longer chasing novelty; they are building technological literacy into their culture, ensuring that process engineers, quality managers, and data scientists collaborate seamlessly. This convergence of digital capability, operational discipline, and human expertise is setting the benchmark for what "state of the art" really means in 2026.

> In 2026 and beyond, technology is no longer an enabler for those CDMOs specializing in advanced therapies, it is their defining edge. Automation, digital twins, and AI-driven analytics are transforming complex, handcrafted processes into intelligent, scalable systems. The CDMOs that thrive will be those that turn data into predictability, machines into collaborators, and innovation into reliability—building the digital backbone of the next generation of personalized medicine."

April Stanley, MS, MBA
Senior Scientific Research Director, That's Nice

> In short, the industry has outgrown its buzzwords. The next stage of transformation is less about invention than integration: making digital and continuous technologies invisible because they are indispensable. These technologies are not equally mature, but the last year has brought a lot of clarity in terms of which technologies are ready to impact operations with ROI today, which are just over the horizon and merit proactive investment, and which are distant enough to be considered in longer-term strategy but not worth the time and resources just yet."

David Alvaro, Ph.D.
Editor-in-Chief, *Pharma's Almanac*

The Ups and Downs of Advanced Therapies

RNA-Based Therapies and Vaccines

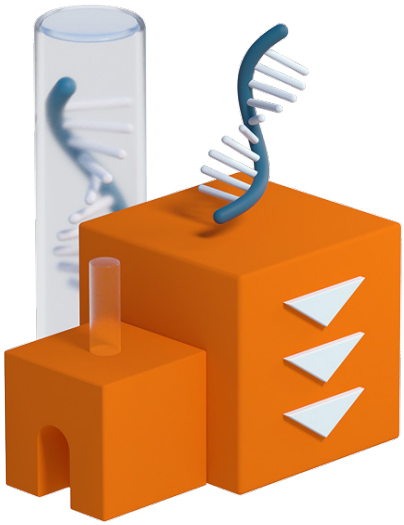
RNA therapeutics continue to expand beyond vaccines, into oncology and rare diseases, requiring CDMOs with expertise in lipid nanoparticle (LNP) formulation and cost-efficient manufacturing. There were nearly 1,300 RNA-based therapies in the preclinical and clinical pipeline during the first half of 2025, around 200 more than seen in the same period for 2024. However, in 2025 CDMOs that specialize in early clinical-phase development and manufacturing of mRNA-based products faced significant headwinds that are expected to remain throughout 2026. This was due in part to the U.S. Department of Health and Human Services (HHS) announcing the termination of nearly $500 million in mRNA vaccine development projects. As such, mRNA developers experienced drastically reduced funding, a situation reflected in the CDMO market. Many mRNA-focused CDMOs were competing for a very limited number of clients, resulting in the need to restructure resources and operations or shut down completely during 2025. For standalone CDMOs, strategic partnerships and collaborations became more critical during 2025, as they seek to mitigate financial risks and ensure the sustainability of their operations.

The CDMO ecosystem for RNA-based services can be divided into three focus areas; those offering mRNA generation via in vitro transcription technology (IVT); those with chemical synthesis of oligonucleotide RNA; those offering formulation of nonviral delivery and encapsulation technologies exemplified by LNPs; or the respective combinations of the three. Currently, there are 124 CDMOs offering RNA-based services. This represents an expansion in the number of companies offering a RNA service from 2024 (79 last year) but a reduction in single focus specialization (25% compared with 37% in 2024); in other words, existing CDMOs are adding a RNA offering to their repertoire of capabilities, even as the standalone mRNA CDMOs are struggling.

For those CDMOs offering synthetic RNA services, the situation does not appear as bleak, with the antisense oligonucleotide (ASO) and RNA interference (RNAi) pipelines seemingly more robust, and the FDA approving two RNA-based therapies (one ASO and one RNAi) during 2025. These CDMOs are perhaps more resilient, due to the differing cost structures involved in running banks of automatic chemical synthesizers typical for oligonucleotide production compared with operating a manual-based clean room approach for mRNA/IVT manufacture. Furthermore, a high percentage of these CDMOs offer the synthesis of guide RNA, an important component required to support gene editing research and development.

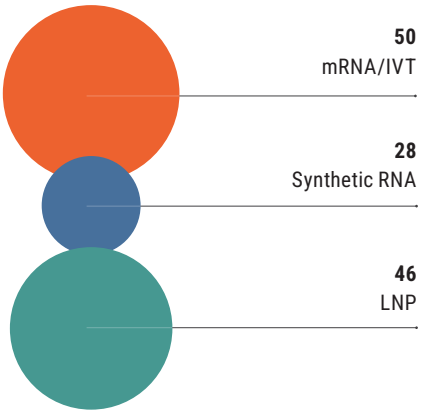
> “2025 has been a bleak year for mRNA CDMOs. The funding landscape hit emerging mRNA therapeutic developers particularly hard in 2024, and in 2025 a dwindling preclinical pipeline shrunk even further. Add to that the U.S. government termination of vaccine research programs, and larger-scale mRNA projects also came under threat. Despite this, many industry voices still see a bright future for mRNA therapeutics; the question is, how many CDMOs can survive long enough to realize this? Standalone or specialist CDMOs are likely to continue to struggle next year. Meanwhile, those who can focus on building mRNA expertise while bringing in revenue from other modalities, and can therefore “wait out” the next few years, might find themselves ahead of the curve in a few years’ time.”

Benjamin Cappiello
Chief Business Officer, That’s Nice

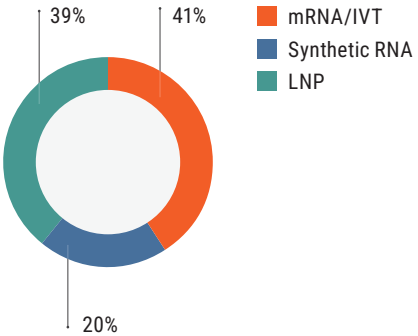


GEOGRAPHIC DISTRIBUTION OF RNA-BASED ADVANCED THERAPIES CDMO MANUFACTURING SITES

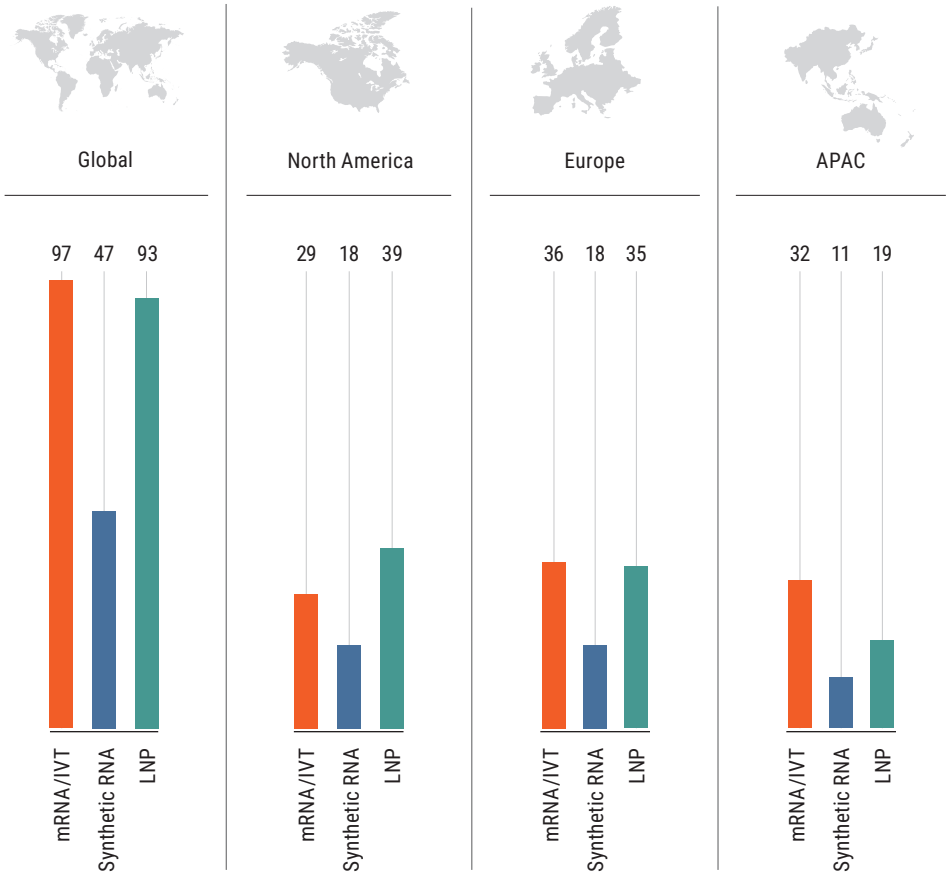
NUMBER OF CDMOs PER SUB-MODALITY



SUB-MODALITY FACILITY SPLIT, BY TYPE

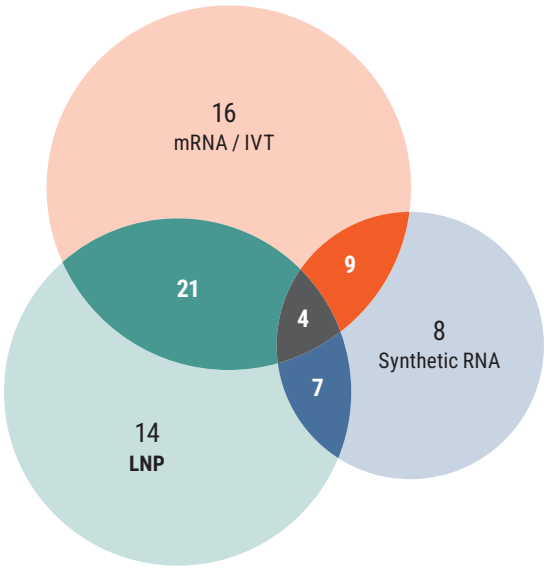


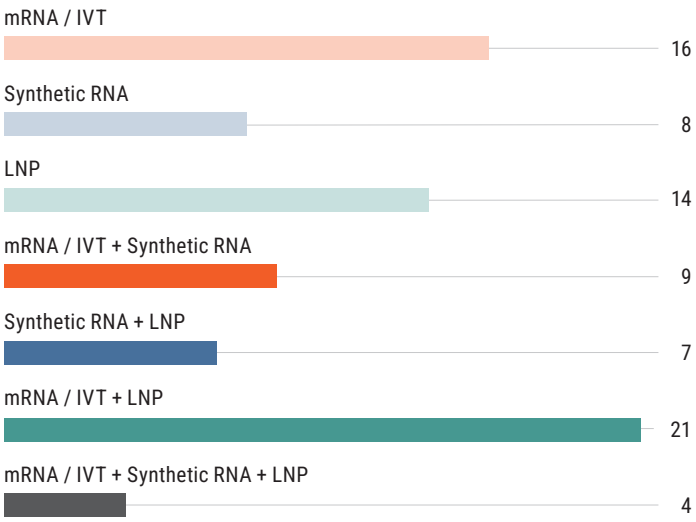
CDMO MANUFACTURING SITES



INTEGRATED AND STANDALONE SERVICES OFFERINGS

Total Number of CDMOs: **79**





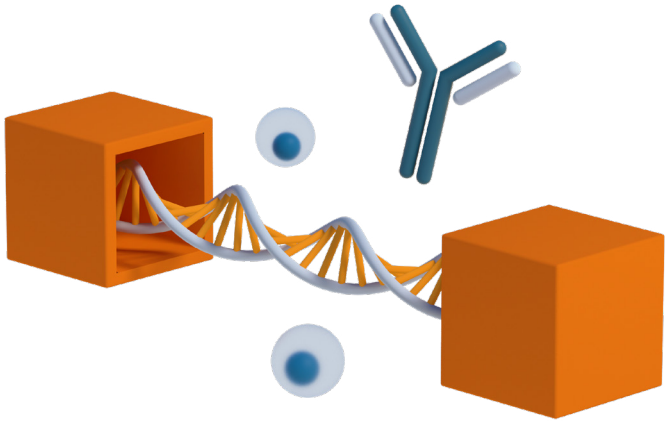
Cell and Gene Therapies

The global CDMO landscape for cell and gene therapy (CGT) currently comprises 83 CDMOs offering viral vector–based capabilities from 148 manufacturing facilities and 62 cell therapy CDMOs running 117 manufacturing sites. From 2021 to the end of the third quarter of 2025, nine gene therapies have obtained commercial approval, compared with 17 cell therapies; 62% of CGT products in the development pipeline are ex vivo gene-modified cell therapies.

The CDMO landscape for viral vector manufacture divides between those vector types more suited to in vivo gene therapy (adeno-associated virus (AAV), herpes simplex virus (HSV), adenovirus) and those employed mainly for ex vivo cellular modification (lentiviral vectors (LVV)). Of the 83 CDMOs offering viral vector manufacturing services 73 offer vector production for *in vivo* usage, and 72 offer LVV production for ex vivo modification, with 63 of these offering both vector types. This diversification across virus types provides a degree of robustness in today's market and supports establishment of a core capability set aligned with a fundamental technology platform.

Throughout 2023–2025, many CGT CDMOs aimed to drive differentiation and build resilience by establishing integrated services across the supply chain. In the overall viral vector CDMO space, 23 companies offer an integrated pDNA and lentiviral vector service. For ex vivo gene-modified cell therapies, 32 CDMOs provide lentiviral and chimeric antigen receptor (CAR)-T cell therapy manufacturing, and only eight offer the comprehensive set of pDNA, LVV, and cell therapy manufacturing services.

Interestingly, the strategy of CDMOs positioning themselves as "one-stop shops" with extensive integrated service portfolios may have run its course; 2025 saw 10% increase in viral vector CDMOs with a single focus compared with 2024. Smaller and niche CDMO seem to be once again focusing on a specialized model with clear differentiation from the 'integrated' competition. Creating a tailored infrastructure with industry-leading technologies for a specific modality, such as exclusively focusing on LVV or AAV vectors, could possibly position a CDMO to become the first choice for all clinical programs within the modality.



"A very public AAV-based gene therapy safety issue in 2025 caused tragedy for patients and a loud wake up call for gene therapy developers. These therapeutics are not straightforward to manufacture. There are still significant issues to overcome with regards to dosing, targeting, and potency. And it is still incredibly important to work with a CDMO that understands the nuance and complexity of your viral vector approach. A few years ago, we might have described a "specialist" CDMO as one that focused only on viral vectors, not other mammalian biologics. Now, the industry seems to be recognising that specialisation really needs to extend down to the individual vector level."

April Stanley
Senior Scientific Research Director, That's Nice

"The maxim of AAV for *in vivo* and LVV for *in vitro* is set to be challenged over the next couple of years, as limitations in the size of payload that can be packaged into an AAV become more problematic, while molecular design of LVV moves towards optimization for *in vivo* use. CDMOs who want to get ahead of this trend should start thinking about efficient scale-up for LVV manufacture, as required batch sizes increase for *in vivo* use."

David Alvaro, Ph.D.
Editor-in-Chief, *Pharma's Almanac*

GEOGRAPHIC DISTRIBUTION OF RNA-BASED ADVANCED THERAPIES CDMO MANUFACTURING SITES

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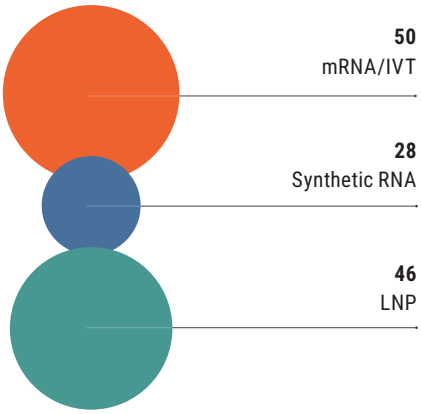

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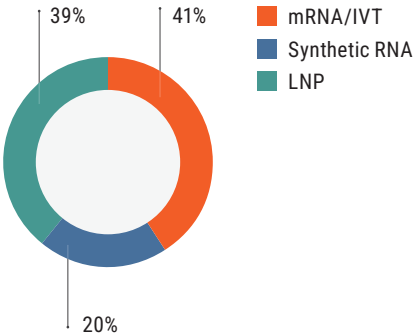
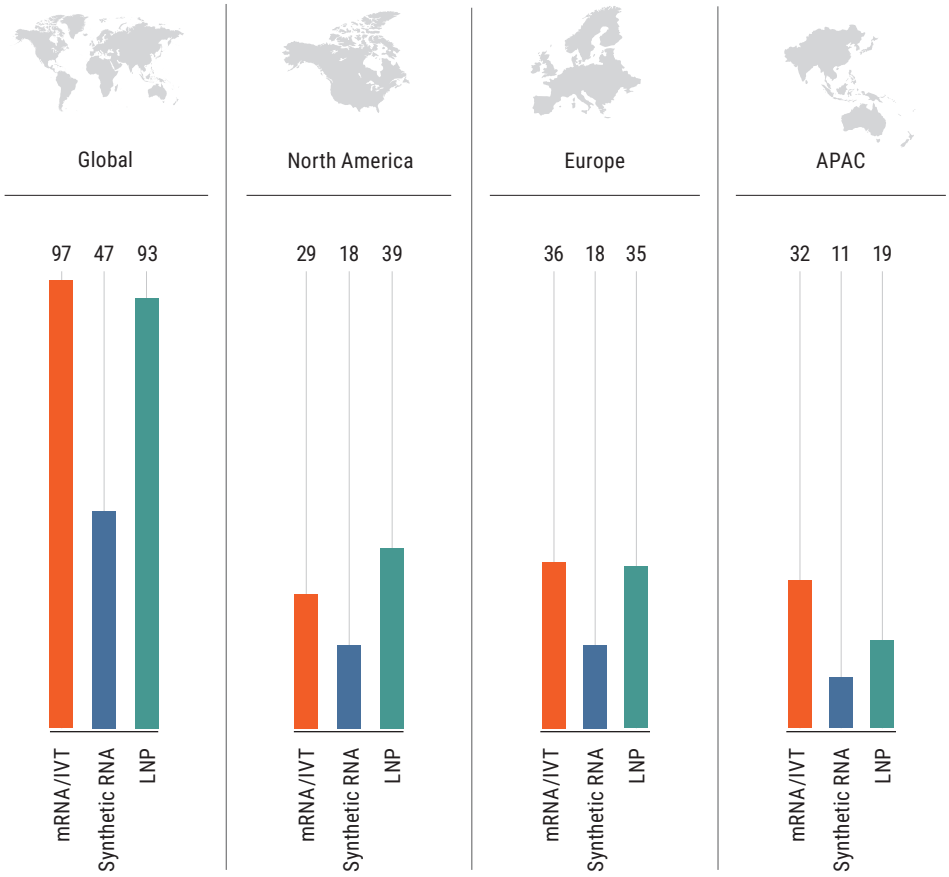


CDMO MANUFACTURING SITES



INTEGRATED AND STANDALONE SERVICES OFFERINGS

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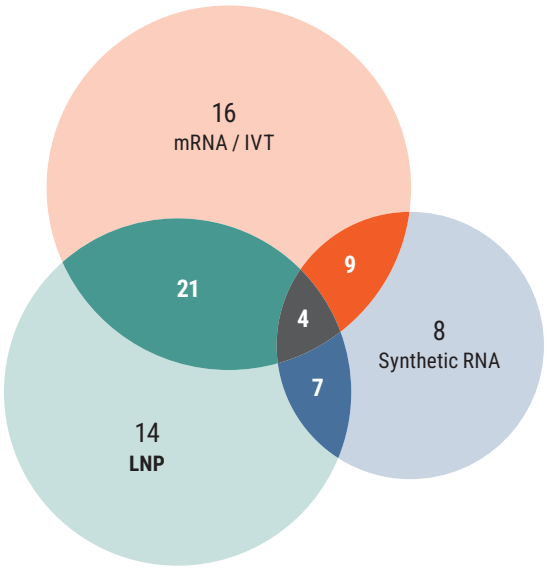
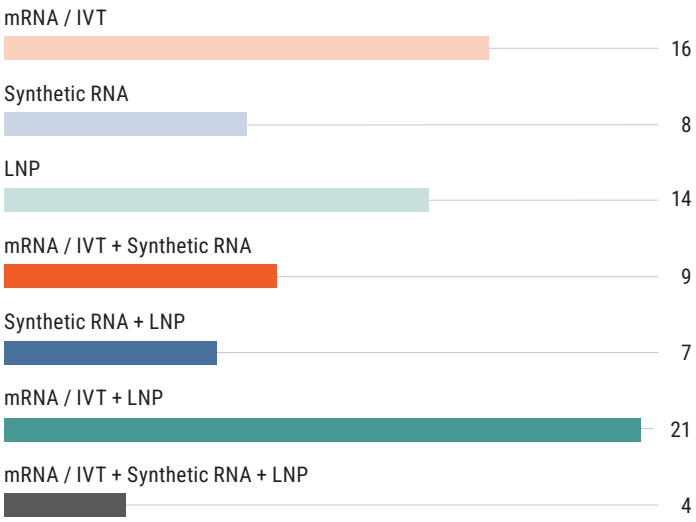
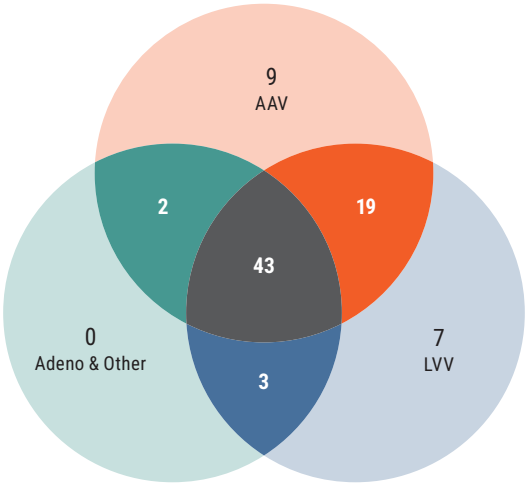
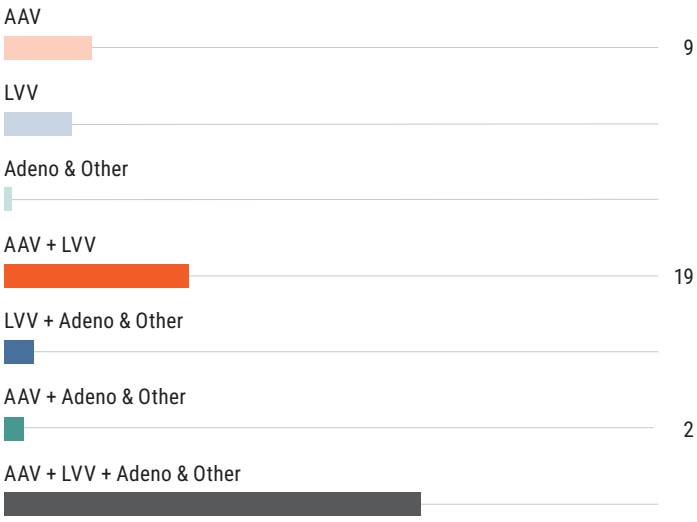




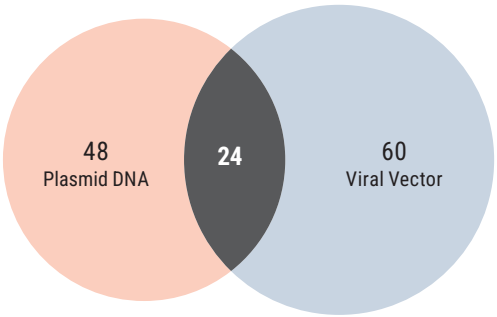
VIRAL VECTOR CAPABILITIES

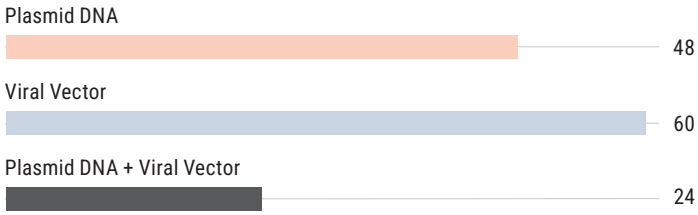
Total Number of CDMOs: **83**



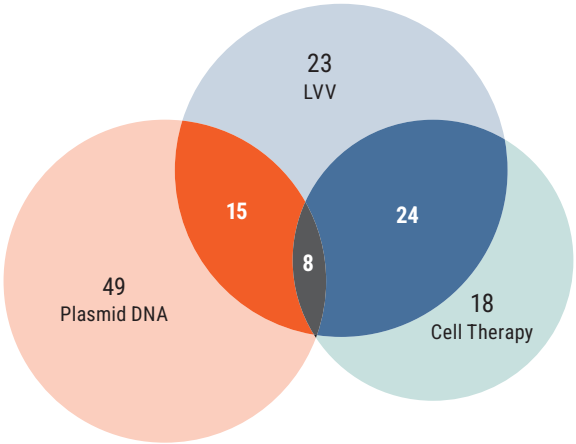


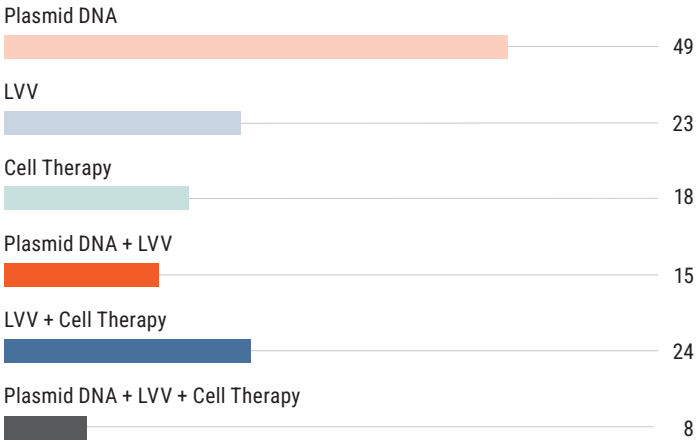
SUPPLY CHAIN INTEGRATION FOR *IN VIVO* GENE THERAPY





SUPPLY CHAIN INTEGRATION FOR *EX VIVO* GENE THERAPY



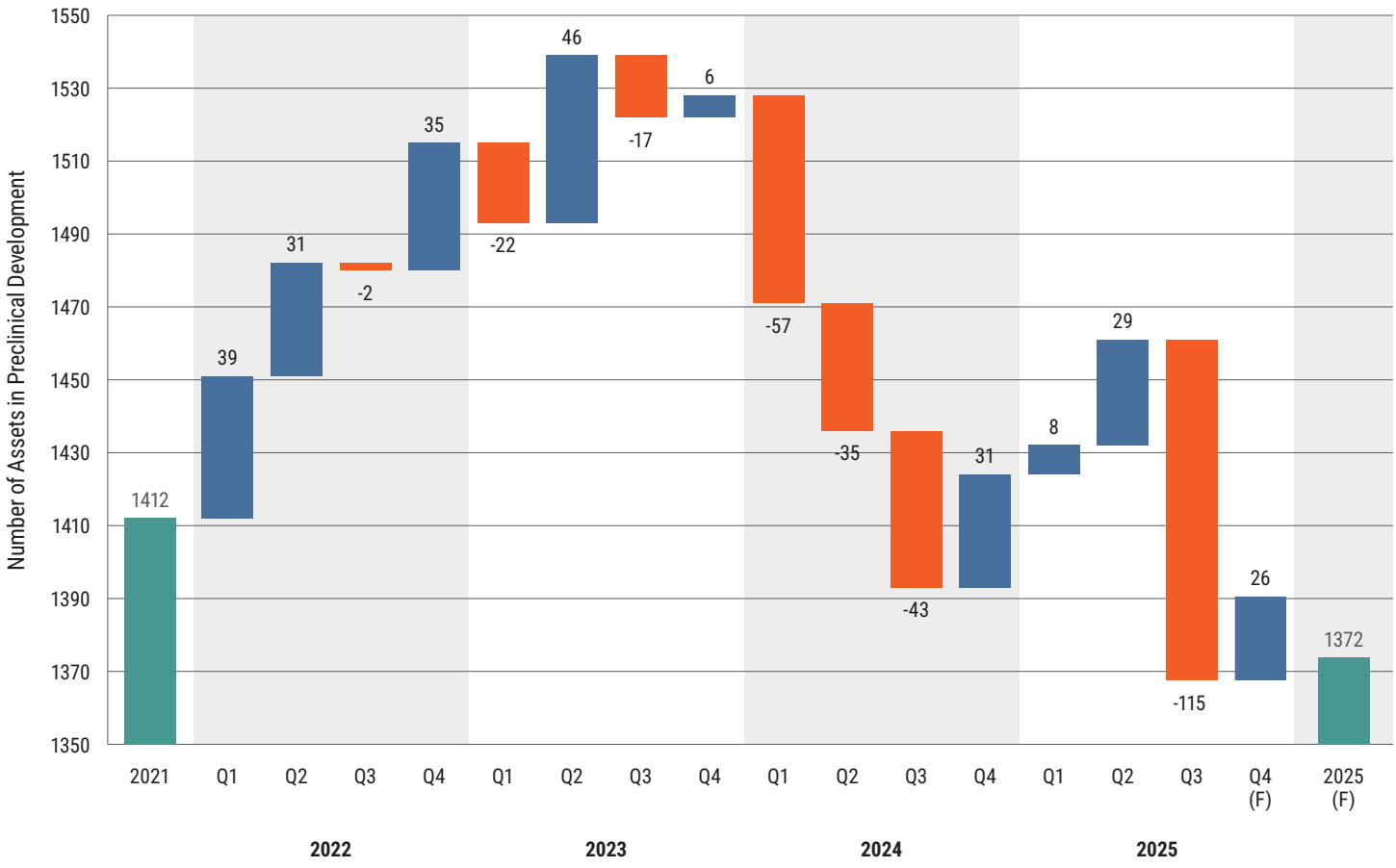


The headwinds encountered in 2023–2024 by the CGT CDMO sector are still blowing. The decline in the preclinical pipeline, resulting in five quarters of negative or little pipeline growth, seemed to be turning a corner during the first half of 2025. Since Q4 2024, the pipeline has started to refill, returning to a pipeline volume at the end of Q2 2025, not seen since Q2 2022, with 1,461 preclinical assets in development by mid-way through 2025. However, during the third quarter of 2025 there was a large decline in the number of pre-clinical assets in the CGT pipeline, decreasing by 115 assets in a single quarter to 1346. This now represents the lowest number of pre-clinical assets in development since mid-2021. Interestingly, Q3 2025, saw an increase in the number of CGT programs across all stages of clinical development. It remains to be seen if and when the decline in the pre-clinical pipeline will be reversed and how the late 2025 decline in pre-clinical development will impact the clinical pipeline. What is clear is that 2026 will most likely be another rocky year for CGT-focused CDMOs as the major fluctuations seen in pre-clinical development ultimately impact clinical projects requiring CDMO services.

> "Last year, and even at the beginning of 2025, the predominant feeling within the industry seemed to be that AAV was struggling, and that cell therapies would be the saving grace of the CGT landscape. However, in a remarkable turnabout, that prediction was proven untrue by the middle of 2025, as CDMOs reported multiple inquiries for clinical AAV projects. If the last couple of years have taught us anything, it's perhaps that what stands out most about the CGT market in the current economy is that anything might happen next."

David Alvaro, Ph.D.
Editor-in-Chief, *Pharma's Almanac*

EVOLUTION OF THE CELL AND GENE THERAPY PRECLINICAL PIPELINE (2022-2025)



The CDMO Talent Landscape

2025 appears to have marked an inflection point where talent became a little-discussed but clear determinant of competitiveness. Every panel, regardless of modality, returned to a single recurring constraint: even when funding is available and infrastructure exists, the work can only move as fast as qualified people allow it to.

The industry's talent shortage is no longer a short-term aftershock of the pandemic or the "great resignation." It has evolved into a structural limitation that threatens to slow regionalization and stall innovation. Rapid facility expansion across the United States and Europe — spurred by tariffs, onshoring incentives, and diversification away from China — has outpaced the available labor pool. Even leading CDMOs report difficulty recruiting and retaining experienced operators, process engineers, analytical scientists, and quality professionals.

> "You can add bioreactors faster than you can train operators. Projects are increasingly constrained by the availability of people rather than equipment or capital. The most acute pain points are in high-skill areas, such as aseptic manufacturing, analytical development, and viral-vector processing, where hands-on expertise cannot be quickly replaced by automation."
>
> **Biologics Panel Opinion**

As CDMOs diversify their portfolios, the ability to move talent flexibly across modalities has become a competitive advantage. In small molecules, experienced chemists are being retrained for continuous and flow processes. In biologics and advanced therapies, operators are learning to manage both adherent and suspension systems or to support sterile drug product operations alongside upstream manufacturing.

This cross-training imperative extends to management and business development as well. Teams that understand multiple manufacturing paradigms can design more coherent development pathways and reduce the friction that often occurs at the interface between biologics, advanced therapies, and drug product work. Several SMEs noted that "the best people are no longer just specialists; they are translators across technologies."

Location decisions are increasingly shaped by workforce proximity as much as by tax or infrastructure incentives. The trend toward onshoring and dual sourcing has revealed a new imbalance: the United States has capacity, but not always the human capital density required to run it efficiently. Regions with strong academic ecosystems — Boston, San Diego, Houston, and Dublin — remain talent magnets, while rural or emerging biomanufacturing clusters struggle to attract skilled staff despite offering competitive pay.

> "The real pinch point for us isn't scientific staff; it's quality assurance personnel. There's a definite shortage there, and that's where recruitment is hardest… I think the most important thing you can invest in is your people. Equipment is essential, of course, but the time and effort it takes to train staff in your culture, your quality standards, and your customer-first mindset is enormous. Retention is more important than recruitment."
>
> **Ian Lafferty, Ph.D.**
> Chief Technical Officer, Upperton Pharma Solutions

These geographic realities are now part of the ESG conversation. Local employment generation has become a measurable sustainability metric, especially for global CDMOs seeking to demonstrate social impact. In parallel, remote oversight models, hybrid training programs, and carbon-budget constraints on travel are encouraging companies to develop local expertise rather than flying in global teams. This shift links talent strategy directly to environmental responsibility and long-term operational resilience.

The African' Union's stated goals to increase their manufacturing capabilities may further enhance the talent shortages, as we would expect they would begin by hiring experienced workers from abroad to train homegrown talent for the future.

A tantalizing set of data was published in Nature in October 2025: applications for European research grants have risen dramatically in 2025. While applications for all types of grants in 2025 saw dramatic increases, applications for postdoctoral fellowships increased by a whopping 65% over 2024. It is not clear what accounts for the new applications, but the uncertainty within the U.S. market in 2025 could mean that more people living in the United States are looking to move to Europe to work. Anecdotal evidence suggests this may be the case, but hard data is so far not illustrative. If this is the case, American CDMOs may experience an even more difficult time acquiring talent, especially for the key scientific roles.

Ultimately, the talent equation is not simply about numbers — it is about capability, adaptability, and culture. The most successful CDMOs of 2026 will be those that treat workforce development with the same strategic intent once reserved for capital investment. In a constrained market, human capital may prove to be the only asset that compounds.

Conclusions: 2025 in Practice, 2026 in Prospect

What 2025 Really Looked Like

Across all four panels and in Nice Insight's data, 2025 emerged as a year of pragmatic execution under persistent constraint. The anticipated investment rebound never materialized; instead, sponsors and CDMOs alike accepted that they could no longer wait for more favorable capital conditions. Biotechs broke traditional end-to-end programs into milestone-based work packages, tightened scopes, and demanded measurable return on investment from every outsourced engagement. In turn, CDMOs adjusted their models with risk-sharing frameworks and success-based pricing that better aligned throughput with client viability.

This pragmatism extended into pricing dynamics. What emerged was not a single market trend but a pattern of asymmetric pricing: a buyer's market for commoditized capacity and a seller's market wherever complexity, risk, or speed dominated. Utilization was uneven — excess in mature modalities like clinical-scale mAbs contrasted with scarcity in sterile fill-finish, cartridge and PFS formats, HPAPI suites, and device-integrated drug products. In parallel, GLP-1 demand and the push toward high-concentration subcutaneous biologics amplified the sterile bottleneck, creating both opportunity and pressure for CDMOs with flexible isolator-based systems.

Small molecules proved resilient, buoyed by oncology, GLP-1 analogs, and other HP chemistries increasingly produced through continuous and flow processes. Biologics remained the bedrock of outsourcing, though growth concentrated in bispecifics and ADCs, where end-to-end conjugation capacity remains scarce. Advanced therapies, by contrast, endured headwinds — funding constraints slowed pipeline progress and pushed many programs toward feasibility or manufacturability studies rather than full GMP campaigns. Even so, synthetic DNA began to alleviate the plasmid bottleneck that had hampered gene therapy and mRNA developers. Within RNA therapeutics, the distinction between mRNA and ASO/RNAi pipelines sharpened: mRNA capacity consolidated, while chemically synthesized oligonucleotides maintained steadier momentum.

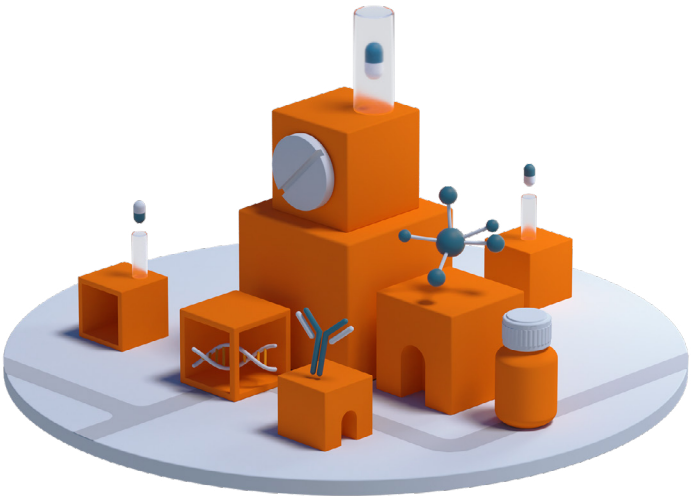
Amid these operational shifts, technology quietly matured from differentiator to baseline. Audit-ready AI became ubiquitous in ERP, MES, QMS, and LIMS systems, supporting predictive maintenance, deviation trending, and automated batch-record review. Digital twins bridged the gap between process development and manufacturing, enabling faster, more confident scale-up. Continuous and modular manufacturing extended beyond pilot phases, particularly in small molecules, while modular perfusion and single-use systems gained cautious traction in biologics. At the same time, frontier technologies — automated cell-therapy platforms, synthetic DNA synthesis, and cell-free protein expression systems — signaled the next horizon of biomanufacturing.

Ultimately, every discussion returned to people, with talent becoming the defining constraint on growth. Regionalization and onshoring have far outpaced the supply of trained operators, process engineers, and analytical scientists. Cross-training across modalities has become a survival skill, and proximity to academic or industrial talent pools now rivals tax incentives in determining site strategy. Even sustainability entered the conversation here: the drive to cultivate local expertise rather than flying in global teams now doubles as both a workforce and an ESG imperative.

What 2026 Is Likely to Reward

The coming year is not expected to bring a sudden rebound but a gradual consolidation around resilience and specialization. Sponsors are increasingly drawn to CDMOs that demonstrate depth rather than breadth and can offer measurable expertise in HPAPI containment, ADC payload–linker conjugation, complex sterile/device integration, or vector-specific CGT manufacturing. The "one-stop shop" narrative is giving way to "best-in-class within a network," where interoperability across trusted specialists replaces vertical integration.

Pricing power will remain uneven but predictable. Margins will persist in areas defined by risk, scarcity, or regulatory complexity, while commoditized biologics and high-volume sterile fills begin to normalize. At the same time, enabling technologies are setting new baselines for performance. Synthetic DNA is poised to mature from a novelty to a critical upstream enabler as both CGT and mRNA developers depend on faster and more reliable DNA



inputs. Similarly, audit-ready AI, digital twins, and continuous or modular manufacturing will no longer signal innovation but competence. CDMOs that quietly integrate these technologies into everyday operations rather than marketing them as differentiators will lead on both cost and compliance.

The sterile sector will remain a bellwether for the broader industry. GLP-1 programs and other high-value injectables will continue to dominate capacity, but the winners will be those that marry formulation, fill, and device assembly under one roof, supported by robust component sourcing. Meanwhile, talent management will shift from operational concern to board-level strategy. CDMOs that invest in local training academies, apprenticeship pipelines, and flexible staffing models will insulate themselves from the chronic workforce shortages that have slowed regionalization efforts across North America and Europe.

What Could Upend These Trajectories

Even the most grounded predictions come with caveats. The global CDMO market remains sensitive to policy swings and technological inflection points that could rapidly alter today's equilibrium. Chief among these are geopolitical developments such as the BIOSECURE Act and the uncertain trajectory of U.S. tariffs and trade policy. If the legislation is enforced aggressively, work could shift swiftly from China to Western suppliers, overwhelming inspection and staffing capacity in the short term. Conversely, if implementation stalls or exemptions broaden, dual-sourcing strategies will likely persist without triggering full-scale reallocation. Similarly, abrupt tariff adjustments or retaliatory measures could alter total landed-cost calculations overnight, driving opportunistic site migrations that ripple through supply chains.

Regulatory dynamics pose additional uncertainty. A single high-profile safety event, such as the recent concerns around AAV dosing, could reset expectations across entire modalities, tightening oversight and redirecting development budgets. Conversely, a breakthrough approval — whether for a next-generation ADC, GLP-1 oral formulation, *in vivo* LVV, or cell-free protein therapy — could trigger localized demand spikes and swing the pricing pendulum back toward capacity scarcity. Broader macro-capital movements remain an omnipresent wildcard: a reopened IPO or venture window would quickly refill preclinical pipelines, reigniting early-stage demand, while prolonged financial conservatism could entrench the feasibility-study model that defined 2025.

Global supply-chain fragility also endures. Dependence on specific consumables (e.g., PFS components, specialized membranes, linkers, and isotopes) continues to threaten timelines, while new build-outs in Africa, Southeast Asia, and Latin America may shift global flows faster than expected, absorbing skilled labor from mature markets and creating new competitive hubs. These factors ensure that even the best-informed forecasts should be read with contingency in mind.

What the Industry Must Do Next

Taken together, the lessons of 2025 point toward a single imperative: convert constraint into capability. For CDMOs and sponsors alike, the path forward lies not in expansion but in disciplined specialization. Success will depend on choosing a specific technical focus, whether process intensification, digital integration, or containment mastery, and investing deeply enough to make them measurable in yield, turnaround, and compliance. Strategic duality — the ability to qualify a second site and transfer data packages seamlessly — will be essential insurance against policy volatility.

Upstream dependencies, especially in DNA supply and device components, must be treated as strategic assets, not transactional purchases. Digitalization must become invisible as a quality narrative rather than a marketing claim, and human capital must be cultivated with the same rigor once reserved for capital assets. The companies that follow this blueprint will be best positioned to outperform regardless of whether 2026 brings renewed growth or further austerity.

In the final analysis, 2025 proved that resilience is not passive endurance but active adaptation. The CDMO sector has emerged from its post-pandemic overhang leaner, more focused, and more self-aware. If 2024 was about correction and 2025 about consolidation, then 2026 is shaping up as the year of disciplined evolution and a test of which organizations can thrive not by waiting for favorable conditions but by engineering their own stability in a perpetually unsettled world.

> "In 2026, the global CDMO market will pivot on three critical axes: technological sophistication, capacity resilience, and transformative challenges. Advanced digitalization, AI-enabled process predictability and control, automated manufacture, and strategic supply chain resilience, will shift CDMOs from service vendors to innovation engines. Capacity expansion, especially sterile filling and cell-therapy manufacturing, will become a strategic battleground, with regional diversification and flexible modular plants scaling rapidly. However, challenges will intensify: regulatory harmonization will lag, talent shortages will persist, and pressure on margins will grow. Success will favour CDMOs that marry technological agility with operational robustness and strategic foresight."

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