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# 2026 PHARMA PREDICTIONS & TRENDS

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# 2026 is the year of pharma manufacturing, supply chain efficiencies

**Biomanufacturing scaling and supply chain resilience are top priorities for biopharma companies as they look to mitigate risks and capitalize on growth opportunities.**

**BY GREG SLABODKIN**

2025 was a tumultuous year marked by rising global geopolitical tensions and rapidly evolving U.S. trade and drug price policies. However, the outlook for the biopharma industry in 2026 is cautiously optimistic as companies spent the past year adapting to a challenging business environment.

In a recent survey, data and analytics firm GlobalData found that 52% of pharmaceutical professionals felt optimistic or very optimistic about the industry's growth in 2026 — an increase of 10% compared to six months ago — while 39% of those surveyed reported being optimistic or very

optimistic on the recovery of biotechnology funding over the next year, an increase of 15% from results in May 2025.

Now, with the benefit of clarity on the Trump administration's threats to impose pharma-specific tariffs and push for Most-Favored-Nation drug pricing, the sector appears more resilient in their abilities to capitalize on growth opportunities while mitigating risks.

"Firms contended with inflationary pressures that raised manufacturing and operational costs, the introduction of new federal policies around international reference pricing, ongoing supply chain disruptions, and increasing regulatory scrutiny, particularly around drug pricing," according to consulting firm Milliman.

Looking ahead to this year, Milliman's assessment is that global tariffs and trade tensions will continue to pressure biopharma manufacturers, driving supply chain decisions and the economics of domestic production.

"Companies may face increased costs or be incentivized to shift manufacturing closer to home," Milliman argues. "Strategic assessment of sourcing, production, and distribution models will be critical to maintaining resilience and profitability amid fluctuating global market conditions."

### Supply chain resiliency

According to professional services firm BPM, supply chain resilience is no longer just a back-office concern but a board-level priority for life sciences companies, particularly as regulatory scrutiny and geopolitical trade dynamics introduce uncertainty into global manufacturing strategies.

"Organizations that can demonstrate agile, redundant, and compliant manufacturing capabilities will be better positioned to commercialize their pipelines successfully," BPM contends in its 2026 life sciences industry outlook.

The firm points to the proliferation of novel modalities — including cell and gene therapies, RNA-based treatments, and complex biologics — which are putting unprecedented demands on life sciences companies' manufacturing capabilities.

These advanced therapies require specialized facilities, sophisticated quality systems, and highly trained personnel that are in limited supply, according to BPM, which notes that companies are responding by securing flexible manufacturing partnerships, diversifying their contract manufacturing organization (CMO) relationships, and making strategic investments in internal capacity.

Among the trends shaping the life sciences landscape in 2026 are automation and the scaling of cell and gene therapy (CGT) processes, according to staffing and professional services firm Insight Global. Automation such as artificial intelligence (AI), blockchain, and the Internet of Things (IoT) is being leveraged to reduce costs and scale production, while minimizing human error, boosting throughput, and optimizing CGT workflows.

"Automations are allowing the industry to move faster and more efficiently, especially regarding manufacturing and the supply chain," argues Insight Global. "By 2026, we'll see broader adoption of CAR-T therapies, gene editing technologies like CRISPR, and off-the-shelf cell therapies. As a result of this shift toward scalable CGT solutions, life sciences companies must prepare for the operational complexities

that come with them, especially considering manufacturing, logistics, and patient access."

### Going regional, local

Consulting firms Deloitte and West Monroe also issued their respective insights on key trends expected to shape the life sciences industry in 2026. Deloitte's report indicates that geopolitical tensions are among the chief concerns weighing on life sciences leaders, who identified inflation, broader economic pressures, and supply chain risks as factors likely to shape organizational strategies this year.

Tariffs are increasing costs for active pharmaceutical ingredients (APIs), raw materials, and lab supplies which are causing companies to take steps to reduce exposure, according to West Monroe's life sciences industry outlook report.

West Monroe recommends that companies map out supply and tariff risks across their most critical inputs — from APIs and raw materials to reagents, single-use components, and replacement parts — and that companies collaborate with contract development and manufacturing organizations (CDMOs) that have both U.S. and global capacity, creating hybrid models that balance resilience, cost, and regulatory complexity.

Large CDMOs with global footprints — such as Lonza and WuXi AppTec — are well positioned to capitalize on the growing demand for their outsourced services. Tariffs, challenging funding environments, and intensified cost pressures are accelerating the biopharma industry's supply chain shift toward outsourcing, according to JLL's 2026 Life Sciences Real Estate Trends to Watch report.

At the same time, Insight Global called out AstraZeneca's strategic investments in internal capacity with a pledge to invest $50 billion in manufacturing and R&D in the U.S. by 2030 and a $2.5 billion investment in Beijing over the next five years to establish a new global strategic R&D center and expand partnerships in biotech and manufacturing in China.

"These decisions to globalize have broader implications, too, increasing demand for regional manufacturing hubs, localized supply chains, and resilience planning," Insight Global concluded. "Companies need to build local teams, training programs, and cross-border collaboration models to truly be successful."

AI, IoT, and robotics are critical to modern manufacturing and the "right partners to accelerate these efforts will be able to reference and adhere to good manufacturing practice (GMP) standards," according to Insight Global.

While digital transformation is progressing within the biopharma industry, it is still held back by a lack of talent, limited budgets, and organizational silos. However, in 2026, the shift to digitalization will continue with the integration of AI-powered tools, implementation of other advanced technologies, and formation of strategic partnerships.

## About the Author

*As Editor in Chief, Greg Slabodkin oversees all aspects of planning, managing and producing the content for Pharma Manufacturing's print magazines, website, digital products, and in-person events, as well as the daily operations of its editorial team.*

# 4 contract development and manufacturing organizations to watch in 2026

**Fujifilm Biotechnologies, Lonza, Samsung Biologics, and WuXi Biologics are poised to have the biggest impact this year on the biopharma industry.**

BY GREG SLABODKIN

While contract development and manufacturing organizations faced macroeconomic and industry-specific headwinds in 2025, this year the outlook for CDMOs is decidedly more optimistic. Setting themselves apart in 2026 are large companies with global footprints who are well positioned to capitalize on the growing demand for outsourced services.

The criticality of CDMO services to the biopharmaceutical industry has never been greater. Although the active pharmaceutical ingredient (API) segment has been the biggest historically and — together with finished dosage form — generates the highest growth, biologics has emerged in importance in recent years.

Currently, the biologics drug product space is one of the most attractive markets for CDMOs, according to William Blair analysts, who forecast a strong outlook for drug sales and continued increases in outsourcing penetration to drive a 10.6% sales compound annual growth rate (CAGR) from 2025 through 2029.

Antibody-drug conjugates (ADCs), monoclonal antibodies (mAbs), proteolysis targeting chimeras (PROTACs), and sterile filling are expected to drive demand in 2026, finds an analysis from Brian Scanlan, advisor of life sciences at Edgewater Capital Partners.

"CDMOs that differentiate through technology, equipment, and analytical expertise —particularly in RNAi, ADCs, PROTACs, and multi-specific antibodies — will be well positioned," according to Scanlan, who added that smaller CDMOs "may even hold an edge through niche specialization."

Still, size matters and it's no surprise that this year's list of CDMOs poised to have the biggest impact on the biopharma industry in 2026 — for biologics and advanced therapies — includes some of the world's largest CDMOs: Fujifilm, Lonza, Samsung Biologics, and WuXi Biologics.

### Fujifilm

It's hard to imagine a more pivotal year for Japan's Fujifilm than 2025. In September, Fujifilm Biotechnologies achieved a major milestone with the grand opening of its $3.2 billion biomanufacturing site in Holly Springs, North Carolina — one of the largest commercial-scale cell culture manufacturing sites in North America, according to the CDMO.

Fujifilm has built identical large-scale production facilities in Denmark and the U.S., which are designed to modularly and seamlessly integrate manufacturing regardless of location. The launch last year of its North Carolina facility is the culmination of the company's $8 billion global manufacturing investment, with Fujifilm starting to generate revenue from its capital expenditures — about $4 billion of that infrastructure was expected to be operationalized by the end of 2025.

Looking ahead to 2026 and beyond, Fujifilm is growing its KojoX network — the Japanese word for "improvement" and "factory" — with the addition of a United Kingdom facility that opens in the spring of 2026 and Toyama in Japan in 2027, as well as a new clone to follow in Texas. This year, Fujifilm Biotechnologies plans to leverage an internally developed and fully automated downstream purification system called SymphonX, designed to help solve the complexities of bioprocessing by simplifying material demand and scale-up, at its microbial manufacturing facility in Billingham, U.K.

Last month, Fujifilm completed construction of one of Japan's largest bio CDMO facilities at its Toyama Second Factory in Toyama Prefecture, marking the company's first antibody drug manufacturing plant in Japan. The facility, operated by Fujifilm Toyama Chemical and slated to begin operations in 2027, will serve as its bio CDMO hub in Asia with two 5,000L and two 2,000L single-use mammalian cell culture bioreactors designed to support manufacturing of antibody drugs and ADCs.

The Toyama facility builds on Fujifilm's global bio CDMO operations across Europe and the U.S. and expands its manufacturing footprint in response to growing demand for biologics production in Asia. The site's KojoX modular facility design, which standardizes equipment and quality systems with Fujifilm Biotechnologies' U.K. operations, is meant to reduce construction timelines and support faster technology transfer.

### Lonza

Lonza's available U.S. capacity and global footprint are major competitive advantages, according to William Blair analysts. The Swiss-headquartered company is the only CDMO with available large-scale U.S. mammalian capacity and is also one of only a few contract manufacturers "with the global scale necessary to support customers across locations, modalities, and stage of development," the analysts contend.

The integration of Lonza's biologics site in Vacaville, California — one of the world's largest, acquired for $1.2 billion from Roche in 2024 — is progressing. The company has committed $500

million in upgrades to the quality system and IT infrastructure at the sprawling facility.

The IT systems at the site are being "aligned" to communicate with Lonza's global mammalian network, Diane Vallejos Lever, senior vice president and global head of sales for Lonza Integrated Biologics, told *Pharma Manufacturing* in late October at the CPHI Frankfurt conference.

U.S. capacity remains in high demand due to the threat of pharma-specific tariffs and Lonza is confident in its ability to sign more contracts for Vacaville in the near term. In its third-quarter 2025 qualitative update in October, the CDMO pointed to the signing of a "significant" long-term commercial supply agreement — with further signings expected in coming months — and said it plans to make additional investments over the next two to three years to upgrade Vacaville's automation system and multi-purpose capabilities.

Currently, Vacaville is a multi-product cGMP mammalian manufacturing facility with 12,000L and 25,000L stainless steel bioreactors, contributing to a total bioreactor capacity of around 332,000L. Citing a key opinion leader (KOL) who previously led a large multinational CDMO, Leerink Partners analysts in a note to investors said that stainless steel facilities in the U.S. are drawing new attention due to the potential risk that the Trump administration might impose industry-specific tariffs on pharmaceuticals.

"The KOL noted that large stainless steel (15K-25KL) facilities are now seeing better utilization and interest from sponsors given looming tariff risk and potential repatriation of manufacturing from Asia," according to the analysts. "This includes Lonza's new 332KL Vacaville facility, which the KOL noted had previously struggled to fully commercialize its available capacity, but interest has accelerated due to customers reassessing deals with offshore suppliers."

### Samsung Biologics

South Korea's Samsung Biologics is transitioning to become a pure-play CDMO by spinning off biosimilar developer Samsung Bioepis. Despite geopolitical and trade tensions last year, the company expected annual sales growth of 20% to 25% in 2025, driven by the launch of its fifth manufacturing plant in South Korea and growth in its ADC business.

Last year, Samsung saw full utilization of Plants 1 through 3 and continued ramp-up at Plant 4, while bringing Plant 5 online at its Bio Campus II in Songdo, adding 180,000 liters of capacity. The facility features digitalized systems designed to boost quality and efficiency, raising Samsung's total antibody production capacity to 784,000L.

"The completion of Plant 5 marked the beginning of Bio Campus II, showcasing in record time, capacity growth with unmatched digitalization," according to the company. "Plant 5 not only meets established operational standards reflecting diverse client needs, it also integrates innovative infrastructure to support next-generation processes with agility and efficiency."

Samsung Biologics also expanded its ADC operations, launching a dedicated facility with a 500L reactor and extending its collaboration with LigaChem Biosciences. Plans for a sixth plant in South Korea are underway to keep pace with rising demand for biologics.

Last month, Samsung announced it is acquiring Human Genome Sciences' biologics manufacturing site in Rockville, Maryland from GSK for $280 million. It is the CDMO's first U.S.-based

manufacturing facility and is intended to strengthen its global network and U.S. supply chain presence.

In September, Samsung Biologics said it signed a $1.3 billion biomanufacturing agreement with an undisclosed U.S.-based pharmaceutical company. The multi-year agreement runs through 2029 and marks one of Samsung's largest deals to date. Last year, the CDMO also announced a contract with another unnamed U.S. drugmaker worth more than $500 million and running through 2031.

### WuXi Biologics

China-headquartered WuXi Biologics saw strong growth in 2025 driven by expanded services across its value chain, including discovery, pre-IND development, as well as clinical and commercial manufacturing. Demand was particularly robust for ADCs and multi-specific antibodies, with higher utilization of new and existing facilities — including the ramp-up of its Irish manufacturing site.

WuXi's Dundalk, Ireland facility received approval from the European Medicines Agency (EMA) as a commercial manufacturing site for a client's biologic. The authorization marked the first commercial launch of a biologic from its Irish site. The facility includes perfusion capacity of 6,000L and 48,000L fed-batch capacity, making it a key hub for the company's global network.

In 2025, WuXi's intensified perfusion culture process platform achieved end-to-end, fully automated continuous drug substance production at pilot scale. The company said the system will be deployed across its major GMP facilities to improve manufacturing efficiency and flexibility.

Last year, WuXi Biologics started construction for a new modular drug product (DP) facility in Singapore, a 30,000-square-meter building which will be one of the world's largest modular biologics DP facilities. Under the strategic collaboration between WuXi and Pharmadule Morimatsu, 470 modular components were being fabricated at Morimatsu's plant in Changshu City, China. Once completed, the components will be transported to Singapore's Tuas Biomedical Park for installation. Operations are slated to start in 2027.

In 2025, WuXi Biologics also began construction on a 95,000-square-meter microbial manufacturing facility in Chengdu, China, to expand commercial production capabilities. The site will be equipped with a 15,000L fermenter, with future expansion potential to 60,000L, and what the company claims will be China's first dual-chamber lyophilization line. Wuxi will use its microbial expression platform for high-yield, scalable production of non-mAb recombinant proteins, with GMP readiness targeted for the end of 2026.

Last month, WuXi Biologics announced a memorandum of understanding with the Qatar Free Zones Authority to establish its first integrated contract research, development and manufacturing organization (CRDMO) center in the Middle East. The site will combine WuXi's development and manufacturing services with Qatar's infrastructure and regulatory support, providing biologics development for modalities including bispecific and multispecific antibodies as well as ADCs.

## About the Author

*As Editor in Chief, Greg Slabodkin oversees all aspects of planning, managing and producing the content for Pharma Manufacturing's print magazines, website, digital products, and in-person events, as well as the daily operations of its editorial team.*

# 2026 outlook for biopharma outsourcing is ray of light as JPM26 kicks off

**Analysts are optimistic about the industry's prospects this year, as CDMOs attend the J.P. Morgan Healthcare Conference in San Francisco, Jan. 12-15.**

BY GREG SLABODKIN

As contract development and manufacturing organizations (CDMOs) attend this week's annual J.P. Morgan Healthcare Conference in San Francisco, there are indications that 2026 could be a good year for the biopharmaceutical outsourcing and services sector. William Blair analysts in a report point to leading indicator data they say will drive demand.

While CDMOs faced macroeconomic and industry-specific headwinds in 2025, the outlook this year for the outsourcing and services space is optimistic based on the biopharma industry's funding levels, product pipeline, and research and development (R&D) spending, according to William Blair analysts.

"The strong funding momentum observed toward the end of the third quarter continued through the end of the year, with the $26.8 billion raised in the fourth quarter representing the highest amount raised in any period since fourth quarter 2021 (up 88% year-over-year and 55% sequentially)," states the report.

The analysts pointed out that, on an annual basis, capital raised by the biopharma industry in 2025 was $70.7 billion — approximately 6% below the $75 billion raised in 2024 "but comfortably above" the $57.7 billion and $66.1 billion raised in 2023 and 2022, respectively.

"Capital raised by the biotech industry in the fourth quarter of 2025 was $26.8 billion, compared to $17.3 billion in the third quarter, $12.6 billion in the second quarter, $13.9 billion in the first quarter, and $14.2 billion a year ago," the analysts wrote. "After five straight quarters of sequential declines in funding, this is now the second consecutive period in which funding has improved sequentially, with the amount raised in the fourth quarter the highest we have observed since the fourth quarter of 2021."

At the same time, the analysts called out the fact that product pipeline growth remained well below pre-pandemic levels. However, the data improved

in the fourth quarter of 2025 compared to the end of the third quarter of last year.

"Through the end of December, the number of preclinical programs in development was up 3% year-over-year, meaningfully below its pre-pandemic norm of mid- to high-single-digit growth but in line with the 3% year-over-year growth in preclinical programs observed both last quarter and in 2024," the analysts wrote.

The good news is that the number of preclinical programs in development increased sequentially in October, November, and December of 2025, resulting in a "nice step-up" in the total number of preclinical programs in development since the end of September, according to the analysts.

"Clinical programs also showed positive momentum, with the number of ongoing trials up a modest 1% year-over-year (compared to down 1% year-over-year at the end of September) and showing slight improvement since the end of September (versus a slight decrease sequentially from June through September)," states the report.

Growth continued to come mostly from Phase I programs, which were up 2% year-over-year and nearly 1% sequentially, found the analysts. Although the number of late-stage programs was roughly flat year-over-year, they said it "represents an improvement from the 3% year-over-year decrease in Phase II trials observed through the end of September and the 2% year over-year decrease in Phase III trials observed over the same period."

### R&D, M&A, and policy

Biopharma R&D spending as of the third quarter of 2025 — the latest data available, according to William Blair analysts — was up 9% year-over-year, significantly above the 5% growth in second quarter of last year and the mid- to high-single-digit average growth observed over the last decade.

R&D spending by large biopharma companies grew 9% year-over-year in the third quarter of 2025, well above the 5% growth rate in the previous quarter and mid-single-digit growth during the last decade, the analysts said.

While small and midsize biopharma total spend was up 7% year-over-year in the third quarter of 2025, which the analysts pointed out is consistent with the growth observed last quarter, it was "well below its low to midteens historical growth average."

Still, the report cited data from Evaluate Pharma forecasting that total biopharma R&D spending will "be up 4% in both 2026 (down slightly from 5% from our last key metrics update) and 2027 (consistent with our last key metrics update)."

As in previous years, biopharma dealmaking at this week's J.P. Morgan Healthcare Conference will be closely watched, as major drugmakers face a daunting patent cliff and M&A announcements typically make big news at the industry's annual investment event.

"We expect the recent uptick in pharma M&A, positive updates on tariffs and drug pricing, and another year of strong drug approvals to result in continued funding strength in 2026, ultimately leading to a rebound in demand from smaller innovators," according to the William Blair analysts.

In addition to driving a rebound in biotech funding, they predict that the increase in M&A "should help large pharma deal with the significant loss of exclusivity headwinds that many of them are facing in 2027 and 2028."

On the policy front, the analysts concluded that the "recent clarity and positive updates that these drug developers have received over the last couple months around tariffs and drug pricing should free these companies up to start spending more aggressively to rebuild their pipelines after a couple years of culling or sitting on programs."

GlobalData's latest report, *The State of the Biopharmaceutical Industry 2026*, has similarly found that "optimism and investment sentiment have strengthened, although cautiously."

The J.P. Morgan Healthcare Conference "will be a pivotal indicator on the direction for the biopharma sector for 2026," argues GlobalData, setting the "tone for dealmaking, capital flow and R&D priorities in the year ahead" as companies look to strengthen their pipelines.

*Pharma Manufacturing* has identified four CDMOs to watch in 2026 — Fujifilm Biotechnologies, Lonza, Samsung Biologics, and WuXi Biologics — who are poised to have the biggest impact this year on biopharma.

## About the Author

*As Editor in Chief, Greg Slabodkin oversees all aspects of planning, managing and producing the content for Pharma Manufacturing's print magazines, website, digital products, and in-person events, as well as the daily operations of its editorial team.*


# Cell and gene therapy sector to enter disciplined, sustainable growth phase: ARM

**Tim Hunt, CEO of the Alliance for Regenerative Medicine, contends that CGT companies are emerging stronger in 2026 from "hard lessons" learned after years of volatility.**

BY ANDY LUNDIN

The Alliance for Regenerative Medicine (ARM) launched its annual Cell and Gene State of the Industry Briefing on Monday at the 2026 Biotech Showcase in San Francisco with a bullish message: The cell and gene therapy (CGT) sector is entering a disciplined and sustainable growth cycle, despite persistent headwinds.

ARM CEO Tim Hunt made his case as to why the sector is at an inflection point. Hunt pointed to an industry that he says better understands its challenges and is adapting accordingly, accelerating scientific and competitive forces that are modernizing the ecosystem, while expanding commercial opportunities.

## Commercial momentum, capital discipline

Hunt emphasized that commercial and investor interest in CGTs remains strong. Twenty of the 30 largest biopharma companies by market capitalization are currently investing in the development or commercialization of cell and gene therapies, he said.

Four CGT products launched between 2021 and 2025 — Zolgensma, Yescarta, Carvykti, and Breyanzi — have already achieved blockbuster status, according to Hunt, and are fueled by massive year-over-year growth. Collectively, these therapies are poised to reach $2 billion in revenue between 2026 and 2031. Furthermore, ARM is forecasting up to 10 CGT blockbusters by 2031.

According to Hunt, investors and strategic biopharma are driving a disciplined growth cycle. Despite 2025, the CGT sector attracted $11.1 billion in capital across multiple funding sources, with equity offerings accounting for 49% of total funding and venture capital representing 28%. Strategic acquisitions also accelerated during the year, with major transactions involving AbbVie,

Bristol Myers Squibb, and Eli Lilly underscoring long-term confidence in the space.

## Maturing industry learns hard lessons

During his presentation, Hunt drew on the historical development of monoclonal antibodies as an analogy for the current state of the CGT sector. Like cell and gene therapies today, monoclonal antibodies experienced cycles of advancement and setbacks before ultimately becoming a $250 billion global market.

"That non-linear path is just what you get when you have hot emerging technology, and cell and gene therapy will follow a very similar trajectory, in our view," Hunt says.

Learning from those earlier cycles, companies investing in CGTs are increasingly prioritizing best-in-class therapies aimed at larger patient populations with high unmet medical need. Hunt cited active development programs targeting Rett syndrome, Duchenne muscular dystrophy (DMD), Huntington's disease, AATD, Parkinson's disease, and Multiple Myeloma.

At the same time, developers are addressing long-standing barriers to access by emphasizing outpatient treatment models, advancing *in vivo* approaches, and refining development strategies to improve safety and durability.

## Accelerating modernization

Global competition has emerged as a powerful catalyst in the CGT landscape. Hunt noted that in 2025, the Asia-Pacific region surpassed North America in the number of CGT clinical trials for the first time, driven by China's efforts to attract development.

Other regions are becoming increasingly invested in this space as well. Countries in the Middle East are launching ambitious national strategies to attract biotech investment, while the European Union is advancing the EU Biotech Act, which was released in December 2025, and is designed to strengthen and streamline regulatory processes for clinical trials and advanced therapies, including CGTs.

That international momentum is reshaping expectations for how quickly and efficiently CGTs must be developed and evaluated worldwide.

## US regulatory evolution

Amid intensifying global competition, Hunt described how ARM and its board engaged throughout 2025 with U.S. policymakers and regulators, including FDA Commissioner Marty Makary, CMS Administrator Mehmet Oz, and HHS Secretary Robert F. Kennedy Jr.

According to Hunt, those discussions reinforced alignment between ARM's mission and the Make America Healthy Again (MAHA) initiative, particularly around shifting healthcare toward addressing root causes and away from chronic disease management.

That alignment was underscored by new FDA guidance issued on Jan. 11, which grants increased regulatory flexibility around chemistry, manufacturing, and controls (CMC) requirements for cell and gene therapies in an effort to expedite patient access.

The guidance is intended to better accommodate the characteristics of CGTs while maintaining rigorous quality standards through appropriate control measures.

"The agency's more flexible approach has been, and is expected to continue to be, helpful in

expediting product development and will help guide the FDA's evaluation of development strategies in preparation for a Biologics License Application (BLA) submission," the FDA said in a release.

According to Hunt, ARM hopes these regulatory changes will help unlock new development pathways and reduce costs for both ultra-rare diseases and broader patient populations, including through the FDA's New Plausible-Mechanism Pathway and the use of umbrella trials for gene-editing therapies.

## Patients are the industry's north star

Hunt identified patient impact as a guiding light for the CGT sector. While not every therapy works for every patient, he argued that when cell and gene therapies succeed, their effects are life changing.

"The patient impact is irrefutable, I think most people would agree with that," says Hunt. "Not that every product is perfect, not that every patient has a great response to every therapy, but when these therapies work, they're transformative."

Hunt highlighted two key patient stories in this space that have come to define the promise of CGTs. Among them was Baby KJ, whose life was saved through a bespoke CRISPR-based treatment, and Marci McCue, the first patient to participate in a CAR-T clinical trial for multiple sclerosis.

Hunt also addressed a critical industry concern that continues to shape perceptions of the field: patient mortality. Across all adeno-associated virus (AAV) gene therapy programs, treatment-related mortality has remained approximately 0.2%, a rate lower than that associated with several comparable, one-time medical interventions.

He highlighted AAV gene therapy programs showing resilience for Rett syndrome, Duchenne muscular dystrophy (DMD), and Danon disease as examples where clinical benefit has consistently outweighed risk.

## Friction points that could impact 2026

Despite a more constructive regulatory outlook, Hunt acknowledged several unresolved issues that could slow progress in 2026.

These issues include questions about whether the FDA's Office of Therapeutic Products (OTP) is adequately staffed, how improved communications can curb unexpected road bumps in the industry, and whether excessive emphasis on methodological purity could limit flexibility for therapies targeting serious diseases.

To bring greater transparency to these concerns, ARM announced it is rolling out a new scorecard designed to track OTP performance against real-world product milestones.

"We want to just have the data on how OTP is performing vis-à-vis some of these major therapies," Hunt said.

### About the Author

*Andy Lundin has more than 10 years of experience in business-to-business publishing producing digital content for audiences in the medical and automotive industries, among others. He currently works as Senior Editor for Pharma Manufacturing and is responsible for feature writing and production of the podcast.*

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