EXECUTIVE INSIGHTS

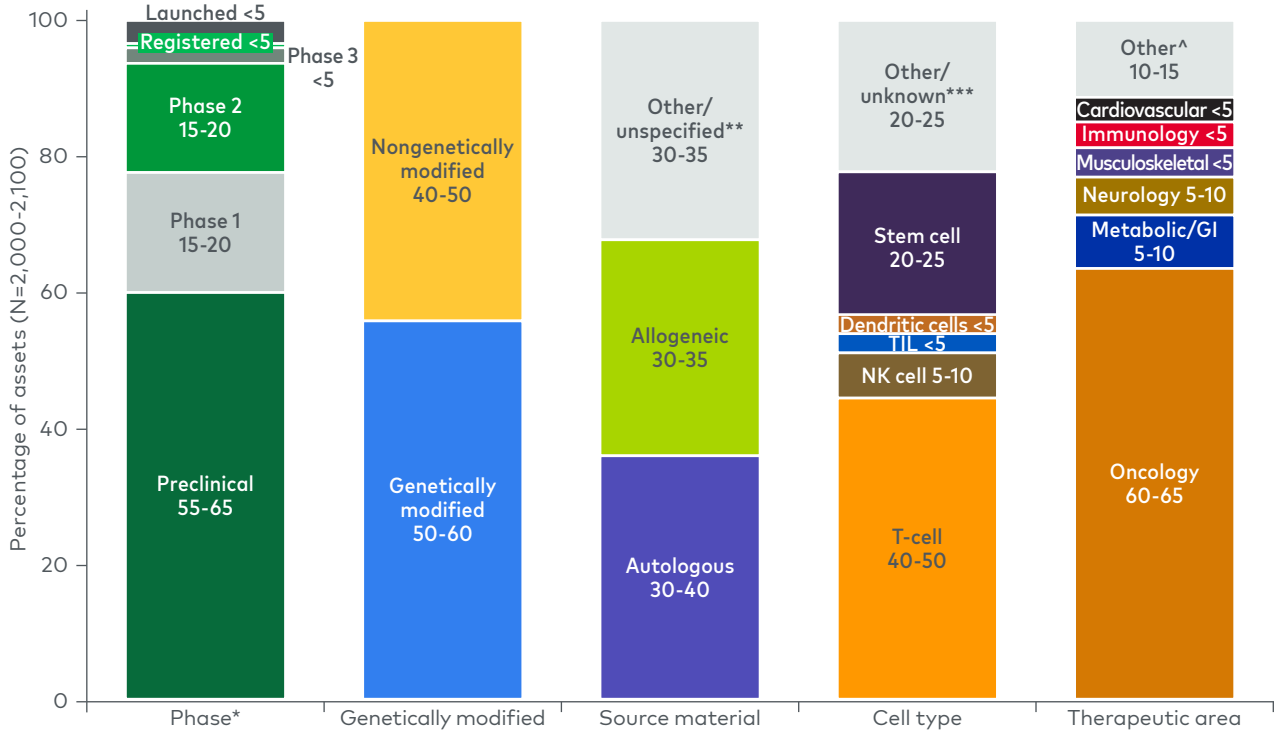
Key Trends for CDMOs Partnering With Cell Therapy Developers

Introduction

Cell therapies have emerged as a transformational modality for the treatment of cancer and are increasingly being investigated in broader oncology, autoimmune and regenerative medicine applications. In the early 2010s, cell therapy pioneers such as Kite and Juno established and industrialized their own manufacturing operations due to the limited manufacturing expertise available for cell therapies in the contract development and manufacturing organization (CDMO) ecosystem at the time. The landmark approvals of Yescarta (Kite/Gilead) and Kymriah (Novartis) in 2017 were major catalysts for investor and biopharma enthusiasm for cell therapies. Since then, the development of cell therapies has accelerated, with the pipeline growing at a double-digit compound annual growth rate and exceeding 2,000 preclinical and clinical programs to date (see Figure 1).

Developers are seeking novel innovations such as scalable drug formats (e.g., allogeneic cell therapies) to reduce overall cost, streamline turnaround time and increase the potential to address larger patient populations (e.g., those in earlier lines of therapy). Others are investigating next-generation approaches such as armored chimeric antigen receptor T-cell and chimeric antigen receptor natural killer cell therapies to enhance drug targeting and improve safety profiles. Enthusiasm for cell therapies is expected to grow as more patients are treated with approved therapies and the modality demonstrates clinical efficacy against a broader range of diseases.

Figure 1
Current cell therapy pipeline and launched assets landscape (2024E)

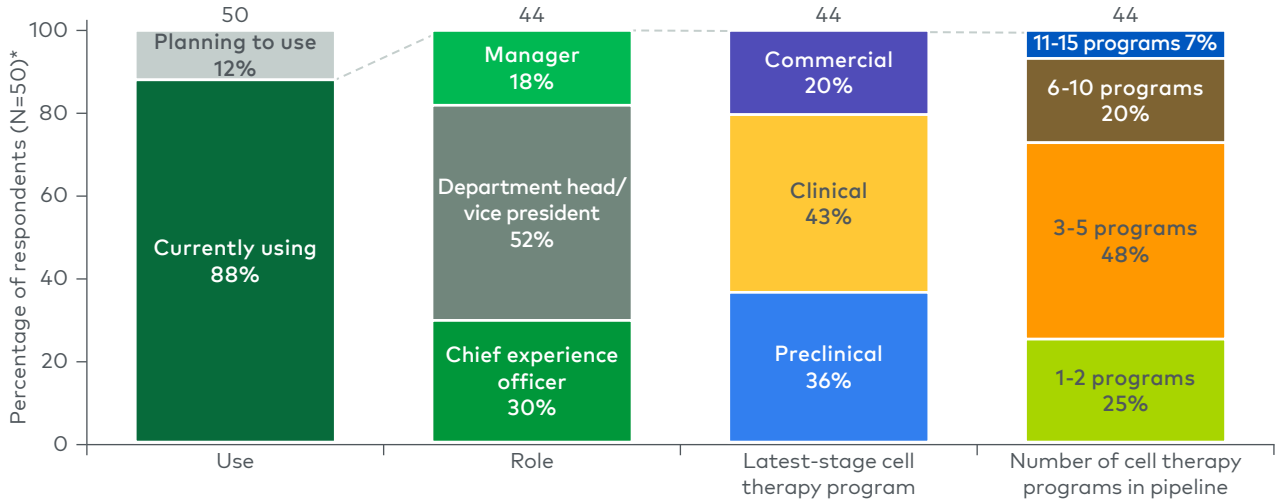


*Includes preclinical, phase I-III clinical trials and registered/launched assets in active development
**Other/unspecified cell technology
***Other/unknown includes immune cells such as monocytes and other cells such as skin, tumor and muscle cells
^Other therapeutic areas include dermatology, hematology, infectious disease and assets without a specified therapeutic area
Note: TIL=tumor-infiltrating lymphocyte; NK=natural killer; GI=gastrointestinal
Source: L.E.K. analysis of Citeline's PharmaProjects database and Cell & Gene Therapy dashboard (March 2024)

CDMO partners have played an increasingly pivotal role in asset development over roughly the past five years, supporting every stage, from early R&D through commercialization. They act as critical enablers of development by providing infrastructure and technical expertise to better design and scale cell therapy programs. Recent approvals highlight the essential role of CDMO partners; for example, Vertex's gene-edited cell therapy Casgevy and Iovance's T-cell therapy Amtagvi are manufactured by CDMOs Charles River Laboratories and WuXi Advanced Therapies, respectively. Continued innovation and investment in new approaches are expected to drive demand for a broader spectrum of CDMO capabilities given the unique manufacturing and development requirements associated with cell therapies.

As the market matures, CDMOs must understand how best to collaborate with and support cell therapy developers. To identify key unmet needs and emerging trends, L.E.K. Consulting conducted an artificial intelligence (AI)-assisted survey of approximately 50 decision-makers for CDMO services at cell therapy developers at various stages of pipeline maturity (see Figure 2). This edition of *Executive Insights* explores how CDMOs can engage developers and position themselves as essential partners throughout the cell therapy development process.

Figure 2
L.E.K. cell therapy CDMO survey respondent demographics

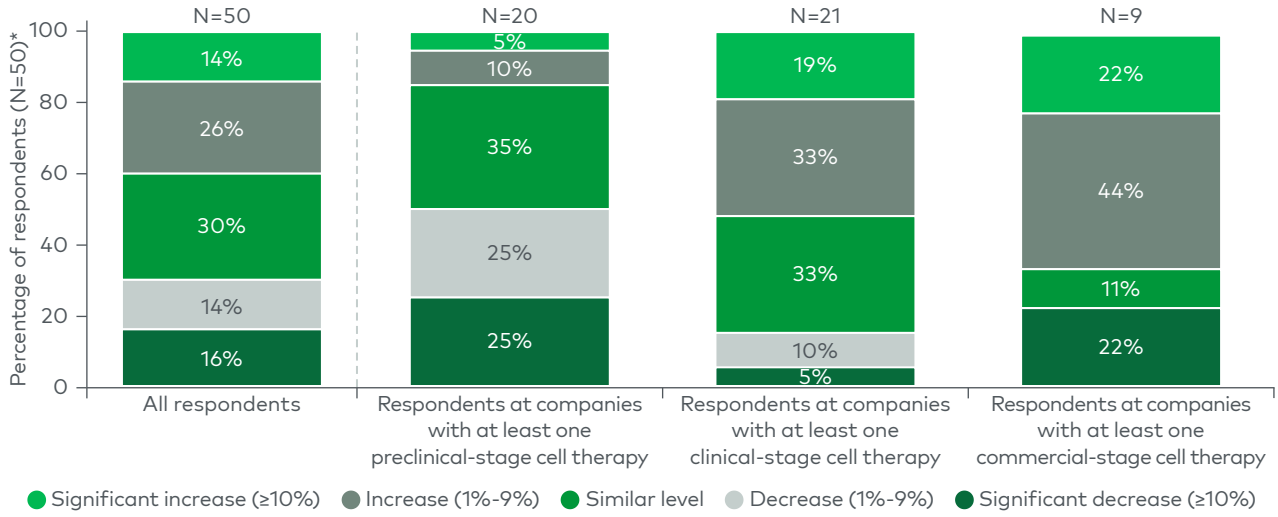


*Respondents self-reported company type
Note: CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

Funding/investment expectations

We first sought to understand the current funding environment and expectations for future pipeline advancement (see Figure 3). Over the past 12 months, approximately 65% of developers with a commercial asset noted an increase in funding. In contrast, about 15% of developers with only preclinical assets saw an increase in funding and roughly 50% saw a decrease in funding. In a constrained biopharma funding environment, cell therapy developers with clinical data experienced materially better access to funding than did those without.

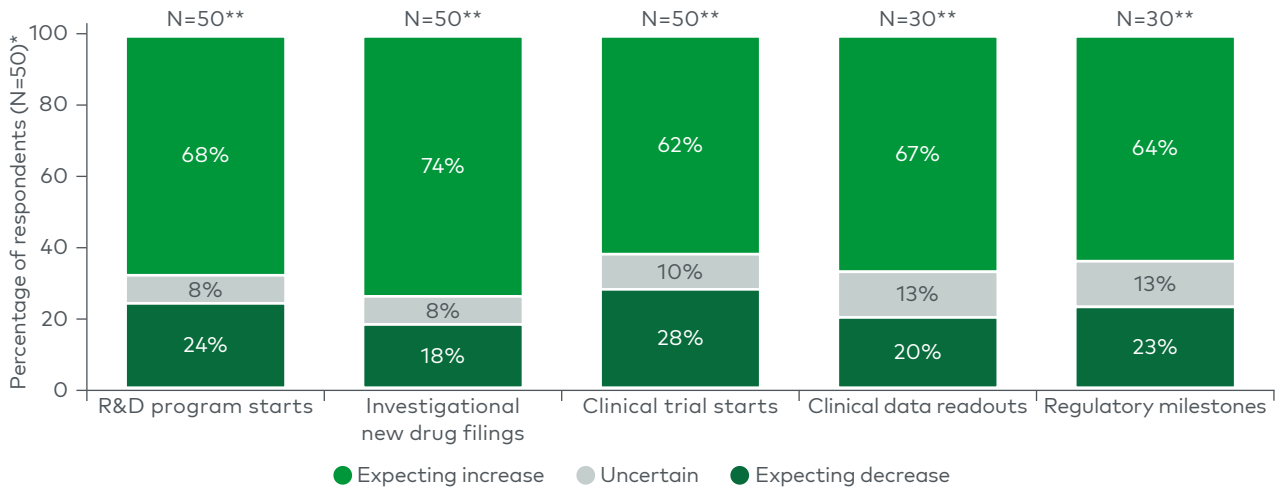
Figure 3
12-month historical change in cell therapy funding, by stage of development



*Survey question: How has your organization's cell therapy funding situation changed compared to 12 months ago?
Source: L.E.K. research and analysis

Despite the decrease in early-stage resourcing in the most recent 12 months, developers remain optimistic about future early-stage milestone expectations (see Figure 4). Approximately 70% of all respondents anticipated an increase in both new R&D program starts and investigational new drug (IND) filings over the next year. In parallel, approximately 65% of clinical-/commercial-stage respondents expected to achieve clinical data readouts or regulatory milestones. Optimism surrounding key development milestones may signal eagerness to demonstrate a program's potential and facilitate fundraising.

Figure 4
12-month future cell therapy program milestone expectations

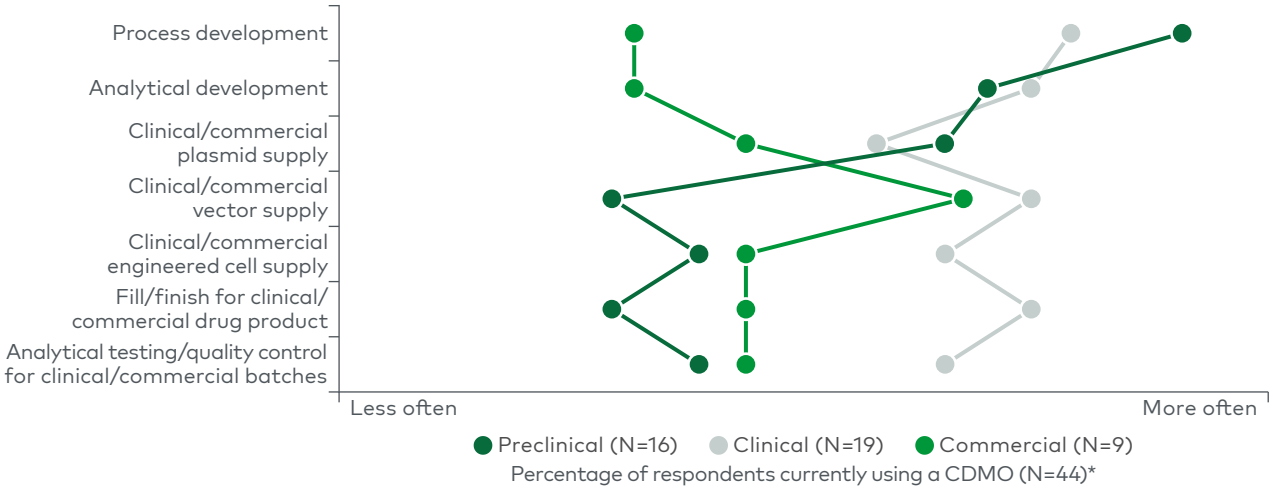


*Survey question: Could you please discuss expectations for the coming ~12 months regarding X anticipated at your organization?
**N used in data for anticipation of clinical data readouts only includes clinical- or commercial-stage cell therapy developers
Source: L.E.K. research and analysis

CDMO services used

Next, we investigated the expectations for the current use of CDMOs among cell therapy developers (see Figure 5). Outsourcing rates are high among all respondents, preclinical through commercial, who seek at least one service; services outsourced to CDMOs correlate closely to which phase of development the respondent is in. Preclinical respondents expressed the most interest in using process and analytical development, which they require to enter clinical trials. Of note, some preclinical-stage respondents, including those nearing IND submission, expressed interest in clinical-/commercial-stage services, indicating the potential for longer-term CDMO partnerships or the sourcing of phase 1 materials. Conversely, clinical-/commercial-stage respondents more often seek material supply and analytical testing for their batches, reflecting their focus on scaling programs. Especially as the market evolves to incorporate more novel technologies, CDMOs will need to bolster the breadth and depth of their technical expertise to address emerging needs across the diverse developer ecosystem.

Figure 5
Current and planned usage of cell therapy CDMO services, by stage of development

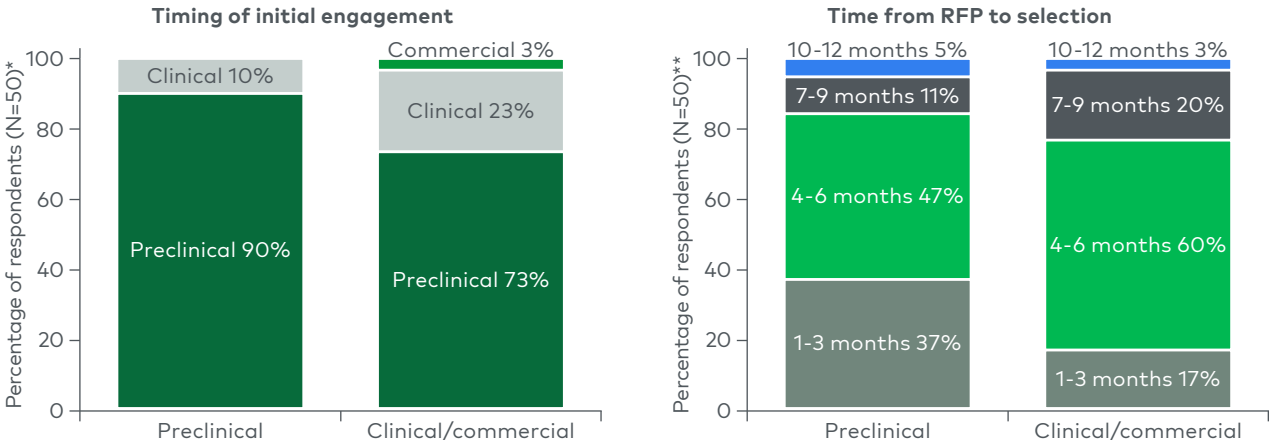


*Survey question: What cell therapy services does your organization use (or plan to use) from your CDMO partners? (select all that apply)
Note: CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

CDMO engagement and selection process

We subsequently inquired about the engagement and selection process to better understand how CDMOs can establish collaborations with developers (see Figure 6). Cell therapy developers typically engage CDMOs early in their assets' development, with approximately 80% initially reaching out during preclinical development prior to dosing their first patient. Most respondents (about 80%) selected a CDMO within six months from the time of their initial request for proposal (RFP), highlighting the importance of timeliness and efficiency in securing partnerships.

Figure 6
Timing of initial engagement and time from RFP to select a cell therapy CDMO, by stage of development

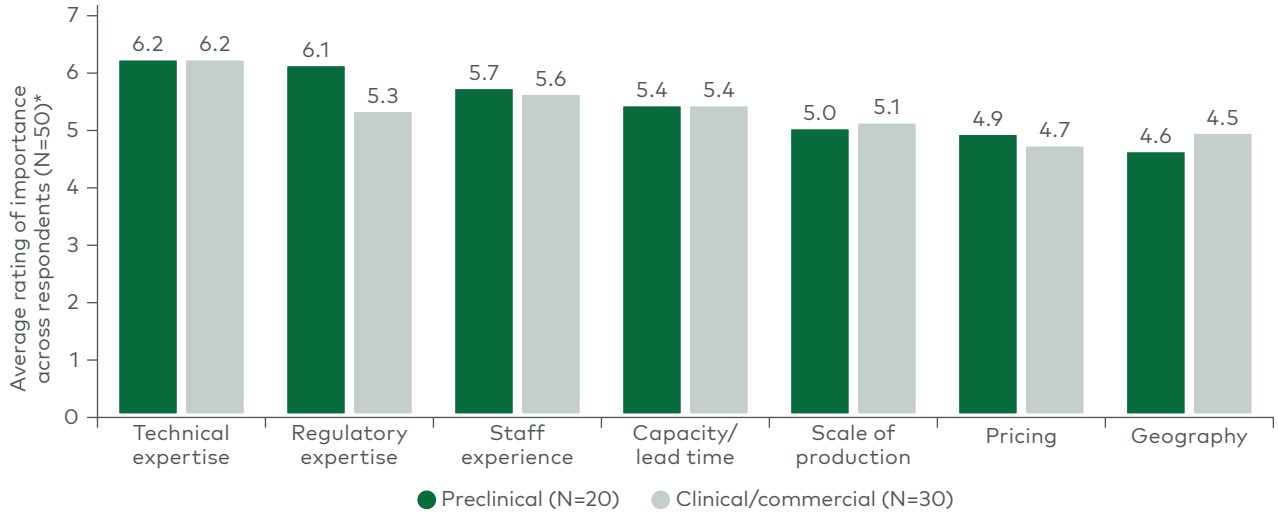


*Survey question: For a given cell therapy program, at what stage of development does your company engage a CDMO?
**Survey question: How long does it take your organization to select a CDMO vendor? (i.e., from initial RFP to making a vendor decision, how long does it take?)
Note: RFP=request for proposal; CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

To stay competitive, CDMOs must track key customer expectations and understand key selection criteria during the RFP process (see Figure 7). Customers seek clear, detailed proposals that showcase CDMOs' credibility and transparency regarding program cost and timing. Qualitative respondent feedback also highlighted transparency regarding access to critical manufacturing inputs, inspection reports and available capacity as crucial inclusion requests during the RFP stage.

Respondents across all stages of development ranked their key selection criteria similarly, especially among clinical-/commercial-stage respondents who indicated very similar importance ranking of criteria. Technical and regulatory expertise were clearly ranked as top priorities, which may speak to the level of support required when designing/progressing cell therapy assets. Of note, preclinical-stage companies expressed greater interest in regulatory expertise than did their clinical-/commercial-stage counterparts, which may be driven by a lack of in-house capabilities or regulatory obstacles when transitioning to their first in-human studies.

Figure 7
Key selection criteria for cell therapy CDMOs, by respondent stage of development



*Survey question: Where does [criteria] rank as a key vendor selection criterion for choosing a CDMO partner? Please score on a scale of 1 to 7, with "1" being "not at all important" and "7" being "very important"
Note: CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

Respondents confirmed a trend toward multisourcing CDMOs, with approximately 45% using multiple CDMOs to build redundancies into their supply chain or to leverage different CDMO offerings. Later-stage developers use multisourcing to mitigate supply chain disruptions and ensure consistent product, whereas earlier-stage developers typically seek a wider set of capabilities in CDMOs (e.g., sourcing for viral vector or plasmid manufacturing). Many respondents currently using a sole CDMO acknowledged their risk exposure and are actively seeking support from an additional CDMO.

Given the influx of new entrants over the past couple of years, we gauged market awareness of players in the CDMO landscape (see Figure 8). Over 60% of respondents were aware of Charles River, Lonza, WuXi Advanced Therapies, Fujifilm and Catalent. A total of 20%-30% of respondents were aware of a second set of players such as ElevateBio, KBI Biopharma, Resilience, AGC Biologics and Catapult, and <10% of respondents acknowledged a third set including Cellex, Minaris, Cellipont, the Center for Breakthrough Medicines, Celonic, Kincell and Roslin.

Figure 8
Cell therapy CDMOs, by degree of awareness

N=50*

*Survey question: What best describes your familiarity with [company]?
Note: CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

Feedback on working with CDMOs

Next, we sought to understand how CDMOs have historically performed in their collaborations and how they can better deliver services moving forward (see Figure 9). Respondents noted significant improvements in technical performance in recent years, whereas challenges with lead time, quality and communication persist. Delays and long lead times are major pain points for about half of respondents. Slow project initiation and batch processing as well as lack of agility, especially for collaborative troubleshooting, were also noted as significant pitfalls, all of which further delay internal development timelines.

Figure 9
Key pain points for cell therapy developers working with CDMOs*

~50% cite delays and long lead times particularly for slow project initiation, batch processing and overall execution speed	**~20% cite quality and consistency issues** with concerns over maintaining batch quality, troubleshooting and quality system strength	**~20% cite communication and transparency concerns** including need for real-time updates and clear discussions about challenges	**<20% cited technical/expertise gaps** underscoring emphasis sponsors place on assessing CDMO technical expertise during the RFP process

*Survey question: What are the key pain points (i.e., challenges or frustrations you experience) with cell therapy CDMO services today?
Note: CDMO=contract development and manufacturing organization; RFP=request for proposal
Source: L.E.K. research and analysis

Respondents rarely mentioned technical or expertise gaps, indicating that customers may prioritize validating CDMO expertise or relying on peer reviews/experiences early in the RFP process. While technical performance was not perceived as a major pain point, developers highlight that they anticipate an increasing need for technical expertise in the future. When asked about unmet needs, respondents were most interested in emerging technical capabilities and a desire to drive scale and process industrialization (see Figure 10). CDMOs should be cognizant of and seek to address these unmet needs as they further integrate themselves into the cell therapy space.

Figure 10
Key unmet needs reported by cell therapy developers*

Advanced technical capabilities for next-generation cell therapies (i.e., nonviral platforms)	Respondents anticipate seeking advanced technical capabilities, requiring a broadening of CDMO capabilities or expertise such as equipment automation or virus-free cellular engineering platforms
Commercial manufacturing scale	Improved scalability and commercial manufacturing were underscored as crucial needs to meet patient demand and manage costs effectively, indicating a gap in CDMOs' current ability to transition cell therapy manufacturing from clinical to commercial scale efficiently
Speed and efficiency for cell therapy development	Respondents continue to express need for faster project timelines and more agile process development from CDMO partners, both of which directly impact internal development timelines

*Survey question: What are the key unmet needs (i.e., long-term areas where innovation or improvement would be beneficial to you) with cell therapy CDMO services today?
Note: CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

Future role of CDMOs in cell therapy

We then explored how developers may use CDMOs moving forward and found that most are optimistic about increasing their use of CDMOs over the next three years (see Figure 11). About 50% of all respondents expect to increase their spending with CDMOs, and approximately 30% expect to maintain a similar use of CDMOs as they progress and broaden their pipelines. Growth in patient demand for cell therapies, strategic cost saving and supply chain de-risking, and requirements for specialized equipment and broader expertise all contribute to the continued use of CDMOs. However, note that about 20% of respondents expect to decrease their spending, driven by an intent to build in-house capabilities for long-term cost savings and greater control over production processes. Rising CDMO utilization and a growing appetite for innovations of cell therapies underscore the necessity for CDMOs to address emerging capability gaps and provide technical expertise on behalf of developers.

Figure 11
Drivers of increased CDMO use for cell therapies

*Survey question: Looking ahead over the next three years, what are your expectations for your organization's use of cell therapy CDMO services?
Note: CDMO=contract development and manufacturing organization
Source: L.E.K. research and analysis

Finally, we queried developers to understand in which key areas they will have development and manufacturing needs for which they will seek CDMO support. Consistent emerging technology themes that respondents communicated include:

- **Automated, closed systems:** Greater automation and use of closed-system manufacturing to transition away from manual equipment and single unit operations, overall reducing labor costs and training required for on-site personnel
- **Novel nonviral gene delivery and gene-editing technology:** Use of nonviral technology (e.g., electroporation and lipid nanoparticles) and gene-editing tools (e.g., CRISPR) to push beyond viral-based cell therapy methods, broaden the toolbox of cell engineering approaches and enable multiple, precise edits for next-generation cell therapies
- **AI/machine learning (ML) process optimization:** AI/ML approaches for process optimization and workflow standardization incorporating multimodal datasets
- **Allogeneic cell therapy development:** Allogeneic cell therapy programs to replace the fit-for-purpose tools that were developed for the autologous space and expand use in broader treatment settings and larger addressable populations

Conclusion

CDMOs are increasingly indispensable for cell therapy development and manufacturing, providing essential infrastructure and technical expertise to developers. New cell therapy developers value CDMOs for their flexibility, cost efficiency and ability to scale globally as their therapies progress through clinical trials and near approval. As developers anticipate an acceleration in cell therapy pipeline velocity and increased manufacturing outsourcing, CDMOs must ensure they are equipped to meet emerging customer needs and enhance their technical expertise and capabilities to support next-generation cell therapies.

If your organization is evaluating its ability to address current and emerging developer needs or its growth strategy, consider the questions below. If you have a clear answer to most of these questions, you are probably in a great place to focus on other strategic initiatives. If you find that you are unsure or unable to answer some of them, it would be an excellent idea to conduct a more thorough diagnostic to understand current pain points and potential solutions.

1. How can a CDMO enhance its awareness level or market position? What does an emerging CDMO need to demonstrate to be considered established and expand its presence?
2. What are the capabilities/services that biopharma companies seek from a leading CDMO? How can a CDMO communicate differentiated capabilities that meet those companies' current and evolving needs?
3. How can a CDMO identify and establish partnerships with cell therapy developers at the most opportune time (e.g., early in development when developers seek support)?
4. How can a CDMO demonstrate commercial excellence and solve for customer pain points (e.g., communication, transparency, project management) to streamline its partnerships?
5. How can a CDMO prioritize its investments to maximize growth potential in the future of the cell therapy modality and its ability to address customer needs?

As you assess your capabilities or weigh different growth strategies, please contact us at **strategy@lekinsights.com** for an informal discussion about your situation with a holistic, structured approach.

For more information, please contact us.

About the Authors

Jeffrey Holder
Jeff Holder, Ph.D., is a Managing Director in L.E.K. Consulting's San Francisco office. Jeff specializes in strategic engagements that advise clients who are looking to commercialize advanced research tools and novel technologies across the biopharma, clinical diagnostics and bioprocessing markets.

Adam Siebert
Adam Siebert is a Managing Director in L.E.K. Consulting's New York office and a member of the Life Sciences practice. Adam has been with L.E.K. for over 10 years and has experience across diagnostics and research tools, bioprocessing, and pharma services as well as emerging, mid-cap and large pharma. He has helped a number of clients in the life sciences industry with growth strategy, life cycle management, portfolio optimization and M&A projects.

Brian Weil
Brian Weil is a Consultant in L.E.K. Consulting's Boston office and a member of the Life Sciences practice. He has experience advising clients on growth strategy and M&A within the research tools, diagnostics, pharma services and bioprocessing markets.

Jason Dorr
Jason Dorr is a Consultant in L.E.K. Consulting's New York office and a member of the Life Sciences practice. He has experience advising biopharma clients on portfolio strategy and transaction support with an emphasis on advanced modalities.

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