



EXECUTIVE INSIGHTS

Autologous Cell Therapy: Key Challenges and Bioprocessing Innovations

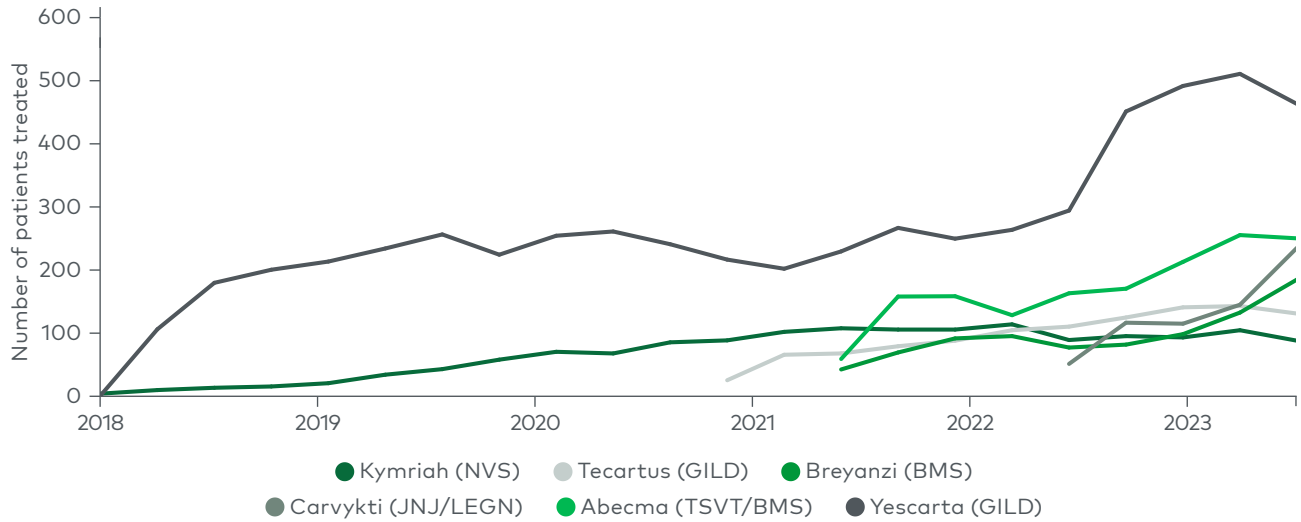
Introduction

Autologous cell therapy — isolating, engineering and expanding a patient's own cells and reintroducing them to combat disease — is an emerging modality that has garnered significant attention due to its transformative potential impact on patients: Cure-like efficacy (i.e., >10 years in remission) has been achieved for some treated patients with advanced hematological cancers. The vast potential of this new modality has driven significant biopharma interest and investment in the space, while the unique nature of the modality (i.e., personalized, often gene-edited cellular products) presents new challenges for the field to overcome.

Today's "first wave" of FDA-approved chimeric antigen receptor T—cell (CAR-T) therapies have seen moderate commercial traction in the United States (see Figure 1), and worldwide sales of approved CAR-T drugs estimated to reach \$4.1 billion in 2023.¹ It is estimated that >30,000 people have received CAR-T therapies across clinical trials and commercial use.² In parallel, clinical development continues in earlier lines of therapy, with Yescarta and Breyanzi receiving 2L approval for large B-cell lymphoma in 2022. These successes continue to drive substantial investment, with approximately \$3.8 billion³ of disclosed funding raised through the end of October 2023 and three initial public offerings of cell therapy-focused biotechs.

Figure 1

US patient volume* for first-wave cell therapies by quarter (2018-23YTD**)



*Volume calculated based on U.S. sales and pricing

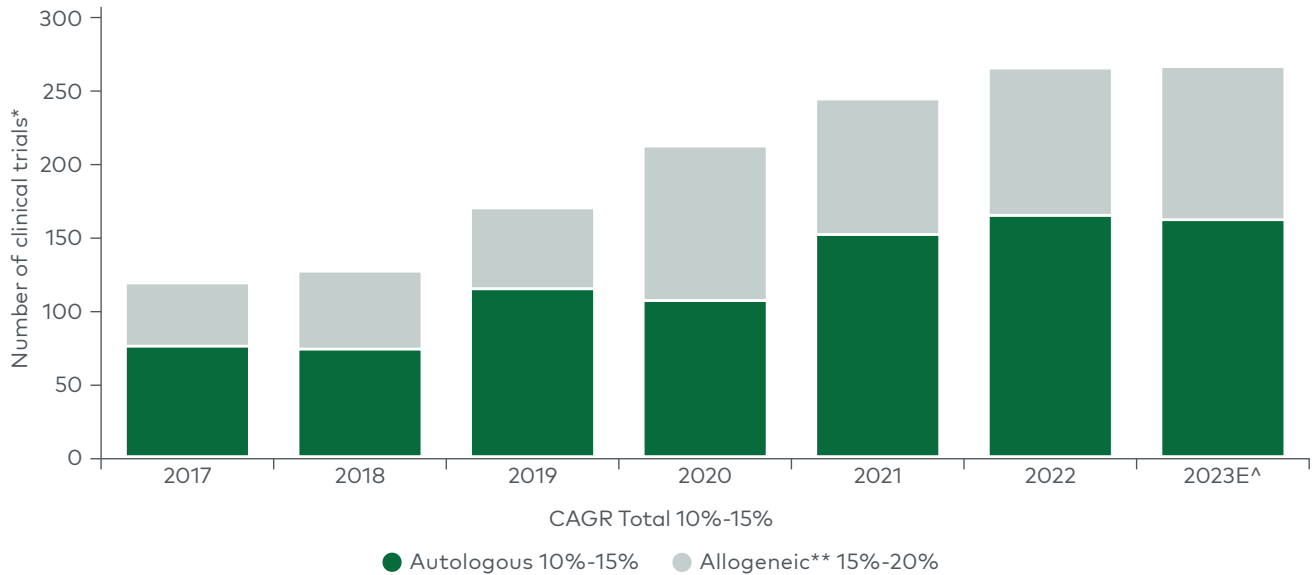
**Data through end of Q2 2023

Source: Leerink Partners; company websites; Centers for Medicare & Medicaid Services; PriceRx; L.E.K. IP, interviews, research and analysis

Concomitantly, the pipeline continues to grow (see Figure 2) and diversify (roughly 700⁴ autologous pipeline assets), and development continues at a rapid pace (around 160⁵ autologous clinical trial starts were expected in 2023).

Figure 2

Worldwide cell therapy clinical trial starts by year (2017-23E)



*Clinical trials that were completed or closed but listed without start dates were excluded from analysis, as were trials that were terminated or temporarily closed

**Allogeneic includes heterologous, while xenogeneic and uncategorized cell therapies are not included in this analysis

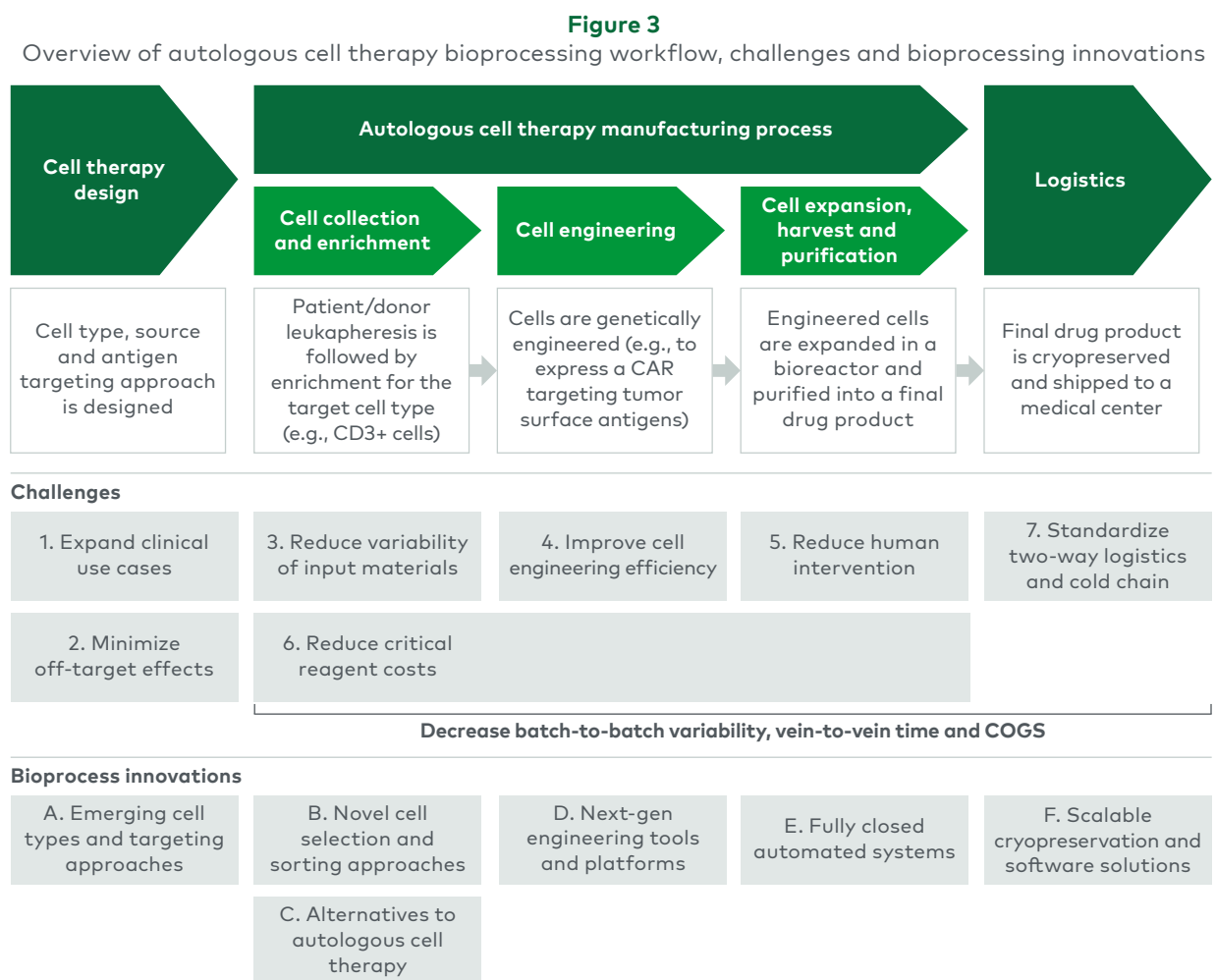
^As of November 2023

Note: CAGR=compound annual growth rate

Source: TrialTrove; L.E.K. research and analysis

The emergence of these personalized, patient-specific therapies creates unique challenges for the manufacturing paradigm that could compound with future demand growth. The early-stage pipeline is increasingly targeting indications with much larger patient populations, and step-change advances in manufacturability and cost of goods sold (COGS) must be realized for cell therapy to reach its full potential and successfully address the diverse range of patients who could benefit from the modality. In addition, strong out-of-class competition (e.g., bispecific antibodies) may pose a significant risk to the commercial viability of autologous cell therapy, especially if these challenges go unaddressed.

In this *Executive Insights*, L.E.K. Consulting reviews these challenges and the bioprocessing solutions that could facilitate the scaled, cost-efficient production of these transformative new therapies (see Figure 3).



Note: CD3+=cluster of differentiation 3; CAR=chimeric antigen receptor; COGS=cost of goods sold
Source: L.E.K. research and analysis

Key challenges and bioprocessing innovations

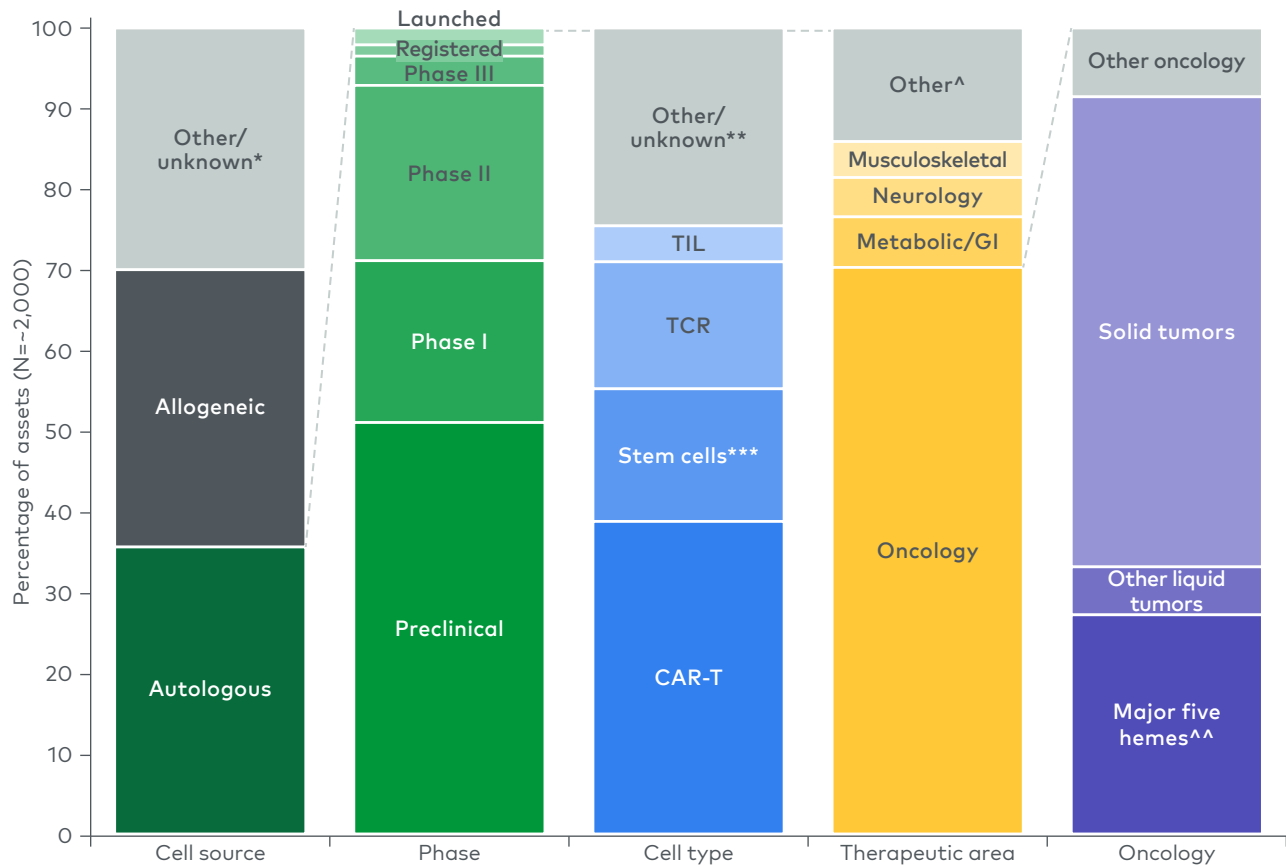
L.E.K. has identified seven challenges related to autologous cell therapy design and current manufacturing processes:

1. Expand clinical use cases
2. Minimize off-target effects
3. Reduce variability of input materials
4. Improve cell engineering efficiency
5. Reduce human intervention
6. Reduce critical reagent costs
7. Standardize two-way logistics and cold chain

Challenges in cell therapy design

1. **Expand clinical use cases:** Today, first-wave autologous cell therapies target highly conserved antigens in homogenous liquid tumors (e.g., CD19, B-cell maturation antigen) that are readily accessible by infused CAR-T cells (see Figure 4). To fully realize the potential of the modality, current cell therapy design concepts will need to be adapted to solid tumors and other heterogenous diseases. In particular, solid tumors have garnered concentrated interest from biopharma, as they represent a significant market opportunity and account for about 90%⁶ of all cancer cases. This has driven a pipeline shift, with approximately 40% of all autologous cell therapy pipeline assets now focused on solid tumors.⁴ However, from a drug design perspective, solid tumors are challenging to address due to increased tumor heterogeneity (and heterogenous antigen expression), the immunosuppressive tumor microenvironment (TME) repressing immune cell activity and the difficulty of solid tissue infiltration by infused cell products.

Figure 4
Worldwide cell therapy pipeline and launched asset landscape (2023E)



*Other/unknown vector type used to generate the cell therapy
 **Other/unknown includes immune cells such as dendritic cells and natural killer cells, CAR-M, CAR-B and other cells such as skin, tumor and muscle cells
 ***Stem cells primarily includes hemopoietic stem cells, mesenchymal stem cells and induced pluripotent stem cells
 ^Other therapeutic areas include cardiology, dermatology, hematology, infectious disease and assets without a specified therapeutic area
 ^^Major five hemes are ALL, B-NHL, AML, multiple myeloma and chronic lymphocytic leukemia
 Note: CAR-M=chimeric antigen receptor macrophage; CAR-B=chimeric antigen receptor B-cell; TIL=tumor-infiltrating lymphocyte; TCR=T-cell receptor; CAR-T=chimeric antigen receptor T-cell; GI=gastrointestinal; ALL=acute lymphocytic leukemia; B-NHL=B-cell non-Hodgkin lymphoma; AML=acute myeloid leukemia
 Source: L.E.K. analysis of Citeline's PharmaProjects database

2. Minimize off-target effects: Cytokine release syndrome (CRS) is among the most frequent adverse events of cell therapies. The current generation of commercial cell therapies target a single antigen with a somewhat heterogenous drug product (e.g., variations in T-cell potency and persistence), leading to an immune activation cascade and dose-limiting toxicology. Currently, immunosuppressants such as tocilizumab may be administered to treat CRS symptoms while the next generation of cell therapies (e.g., novel cell types, targeting approaches to improve specificity) aim to be designed to minimize the occurrence of CRS. In fact, more recently approved drugs (e.g., Breyanzi) typically exhibit lower CRS prevalence rates than older CAR-T therapies (e.g., Kymriah and Yescarta).^{7,8,9}

Challenges in the manufacturing process

Reductions in vein-to-vein time, processing costs and batch-to-batch variability are the overarching challenges inherent to personalized cell therapies. Currently, commercial autologous cell therapies have a vein-to-vein time of three to five weeks,¹⁰ driven by transportation of patient cells, lengthy manufacturing processes with batch failure rates that can exceed 10% and coordination of delivery for the final drug product. In some instances, this time delay may require bridging treatments that could lead to increased toxicity and complications or compromised efficacy of the eventual cell therapy.

Manufacturing is a key driver of vein-to-vein time, a fact that underscores the need to both shorten the overall manufacturing timeline and reduce batch failure rates attributed to human error, contamination and batch-to-batch variability. Not only are batch failures costly from the financial and patient health perspectives, but manufacturing production issues could potentially delay the launch of a therapy, as seen with the U.K. launch of Johnson & Johnson and Legend Biotech's Carvykti. For commercial CAR-T products, it will likely take several years post-launch to improve the manufacturing process and reduce failure rates given that process development is typically not conducted with disease-state material.

3. Reduce variability of input materials: Due to the nature of autologous cell therapies, patient health, degree of pretreatment, associated lymphocyte levels and limited quantity (i.e., apheresis yield) can cause significant variability in critical input materials. Additionally, differences across apheresis facilities (e.g., collection process and device, freezing equipment, experience of personnel) leave manufacturers vulnerable to inconsistencies in input material, which may cause unwanted batch-to-batch variability downstream. Organizations such as the Association for the Advancement of Blood and Biotherapies and the Foundation for the Accreditation of Cellular Therapy are starting to create standards across the workflow (e.g., apheresis, final product labeling), and it is imperative to learn from post-commercial optimization of first-generation cell therapies. These efforts will be critical to future success as cell therapies are used to treat larger addressable patient populations, which may require additional apheresis or manufacturing facilities in a broader geographic dispersion.

4. Improve cell engineering efficiency: Today, engineered T cells are typically produced by viral-based methods, which use lentivirus (e.g., Kymriah) or gammaretrovirus (e.g., Yescarta) to insert the CAR into the target cells. Viral transduction is used because commonplace, low-cost chemical transfection methods such as those used for cell line transfection in viral vector manufacturing (e.g., polyethylenimine, lipofectamine) typically demonstrate poor transfection efficiency in immune cells. Advances in viral approaches (e.g., Penn Medicine's

24-hour preclinical CAR-T manufacturing process) have shown promise in accelerating cell engineering, which can have significant downstream benefits on cell therapy efficacy (i.e., reduced need for expansion may lead to higher-quality engineered cells). However, viral vectors remain a significant driver of COGS and a complicating factor for supply chains. For example, lentivirus can account for 10%-25%^{11,13} of the total batch costs due to expensive plasmid DNA, high variability and low yield. Furthermore, limitations on lentivirus supply can bottleneck the production of a drug product, as observed with Bristol Myers Squibb's lentiviral virus supply challenges for the manufacturing of Breyanzi.

Nonviral cell engineering methods have emerged as alternatives to viral transduction. For example, instrumentation-based transfection (e.g., electroporation) has emerged as a viable alternative but still faces several key challenges, including low cell viability due to the stress induced on cells (which is particularly problematic due to the patient-centric nature of each batch and limited number of input cells per leukopak), expansion times (e.g., cell doubling times) and scalability concerns (electroporation requires an additional unit operation before cell expansion).

5. Reduce human intervention: Current cell therapy manufacturing involves a greater level of human input relative to mature manufacturing workflows, such as those for monoclonal antibodies. Existing cell therapy equipment follows a modular approach that focuses primarily on either a singular unit operation (e.g., transduction/transfection, cell activation, cell expansion, fill/finish) or a small subset of unit operations that require trained workers to manually transfer the batch from step to step, driving up labor costs. There is an ongoing shift toward closed, fit-for-purpose, single-use systems to streamline process development and manufacturing while limiting the potential for contamination issues (e.g., the U.S. Food & Drug Administration (FDA) recently issued a Form 483 to Novartis for Kymriah manufacturing process issues). Today, Cytiva's Xuri is the primary system used for cell expansion within commercial scale processes, but it may be overtaken by automated systems that integrate multiple steps (e.g., selection, activation, expansion), such as the widely adopted Miltenyi Prodigy or Lonza's fully closed, automated Cocoon system that is gaining traction in the market.

While these solutions seek to simplify the process, labor is still a key driver of manufacturing cost, accounting for 25%-50%^{11,12,13} of the overall cost per batch depending on the development stage, the modularity of the equipment and the level of automation incorporated into the process. Modular equipment also creates connection points that require manual manipulation, increasing the risk of contamination or human error. Additionally, the current generation of processing equipment is optimized for CAR-T cells

and typically lacks flexibility for optimization for other cell types (e.g., natural killer (NK) cells may require larger volumes during cell expansion).

- 6. Reduce critical reagent costs:** The requirement to homogenize critical material (e.g., CD4 or CD8 selection) for autologous cell therapy creates additional workflow steps (e.g., cell activation) that have cost and time implications.

T-cell activation is critical to cell therapy, with the most prevalent cell-sorting methods utilizing magnetic activated cell sorting (MACS) or fluorescence activated cell sorting (FACS) labels to identify cells. Magnetic beads (e.g., Miltenyi's MACS, Thermo Fisher's Dynabeads) are the preferred option for late-stage and commercial cell sorting and selection today but are a significant driver of costs at >\$5,000¹³ per selection (5%-10%¹³ of the overall per-batch costs). This can be greatly magnified if multiple markers are necessary, which would require sequential steps and associated beads. Additionally, these beads may require additional (typically manual) workflow steps to reduce residuals down to an accepted clinical quality attribute level, which incur additional time and costs. FACS is an alternative to magnetic beads that offers a greater degree of freedom to separate cells based on surface markers, but limited throughput, few good manufacturing practice (GMP) options and a significant full-time equivalent commitment from experienced personnel restrict the adoption of FACS for bulk isolation at scale.

Beyond beads, immune cells are highly reliant on specialized consumables (e.g., cytokines) and GMP media, which are significant drivers of COGS, particularly for early-stage development where some level of customization may be required. This customization drives significant cost, as achieving economies of scale on the supplier side is challenging due to low volumetric demand of consumables required at this stage of development.

- 7. Standardize two-way logistics and cold chain:** Autologous cell therapy manufacturing deviates from the traditional centralized manufacturing model in that patient cells must be collected from a medical center (e.g., apheresis facility), transported to a centralized manufacturing facility, processed into a drug product and then shipped to the patient's bedside. Pilot-scale processes were rapidly adopted to meet commercial demand, resulting in cryopreservation, chain of identity (COI) and chain of custody (COC) solutions that are not optimized for large-scale production.

Currently, most cryopreservation processes involve liquid nitrogen (LN2), which struggles to maintain temperature uniformity when freezing and has challenges with scalability and sustainability (e.g., bulk storage and shipment of LN2). These challenges will likely be further magnified as manufacturing demand increases. LN2 freezing also poses a contamination

risk due to off-gassing, which prevents LN2 controlled-rate freezers from being used in GMP suites. Transportation outside of the suite may cause prolonged exposure to cell-freezing media, such as dimethyl sulfoxide, prior to freezing. This could impact product quality as cell losses from biochemical toxicity and osmotic stress are correlated with pre- and post-freeze time of exposure.

The process for COI and COC has not yet been standardized, creating gaps in the value chain as stakeholders continue to transition to electronic systems and electronic batch records. This has caused the audit trail to be captured with a mix of paper documentation and multiple software solutions, resulting in challenges with software incompatibility between different stakeholders (e.g., developers, contract development and manufacturing organizations (CDMOs), medical centers) and regulatory differences across regions (e.g., stricter data residence rules in France).

Bioprocessing innovations

L.E.K. has identified six ongoing innovations with the most potential to address the aforementioned challenges and improve the cell therapy bioprocessing workflow:

- A. Emerging cell types and targeting approaches
- B. Novel cell selection and sorting approaches
- C. Alternatives to autologous cell therapy
- D. Next-generation engineering tools and platforms
- E. Fully closed automated systems
- F. Scalable cryopreservation and software solutions

A. Emerging cell types and targeting approaches: To advance beyond liquid tumors, key innovations — including the use of novel cell types — targeting approaches and mechanisms to improve cell therapy persistence are being investigated. An exhaustive discussion of these ongoing scientific efforts is beyond the scope of this report; however, we highlight below key focus areas within autologous cell therapy.

Currently, engineered T cells are the most well understood, but additional immune cell types (e.g., NK, tumor-infiltrating lymphocyte (TIL), dendritic, macrophage) are being investigated for the potential to increase clinical efficacy and/or safety. For example, NK cells show promise in lowering toxicity and infiltrating solid tumors but still need to overcome challenges related to durability, while TIL cells are specific to a patient's tumor, allowing for high specificity of a targeted antigen, and can be expanded in high volumes allowing for potential redosing of patients. Critically, cell therapies with novel cell types will convey different

bioprocess requirements (e.g., culture density, reagents, culture days, activation process) than today's T cell-derived therapies.

In addition to novel cell types, new approaches like dual targeting may help address the heterogeneity of solid tumors, while leveraging alternative receptors (e.g., T-cell receptor) facilitates a broader selection of targetable antigens (i.e., through improvements to tumor cell detection and killing due to increased sensitivity and coupling with physiologic signaling). Additionally, other mechanisms are being explored to better infiltrate TME (e.g., armored cells) and evade unwanted immune responses (e.g., cloaked cells) to target difficult tumors and/or increase persistence and potency.

These innovations can unlock the full therapeutic potential of cell therapy but may also introduce new bioprocessing challenges or variations (e.g., NK and TIL cells have higher cell expansion volumes, rendering current equipment nonoptimal) of those associated with first-wave CAR-T therapies.

B. Novel cell selection and sorting approaches: Cell sorting can be accomplished using approaches that either use a label (e.g., MACS, FACS) or are label-free. New label-based technologies (e.g., Cellular Highway's vortex-actuated cell sorting, Akadeum's buoyancy-activated cell sorting) were developed to overcome the challenges related to cost, throughput and cell loss associated with conventional MACS and FACS methods, but validation at scale has yet to be confirmed.

Novel label-free methods have emerged as intriguing alternatives for both bulk isolation and finer selection to avoid unwanted cell activation, remove the risk of reagent contamination of the final drug product (e.g., beads), and potentially expand the number and diversity of selection markers that can be used without linear growth in COGS (e.g., use of two selection markers doubling batch spend attributed to selection beads). Among the emerging approaches is cell separation based on physical properties (e.g., size, density, compressibility) using either ultrasonic waves (acoustofluidics) exemplified by Aenitis, Draper and FloDesign Sonics or microfluidics by companies such as Curate Bioscience and Cytonome. While primarily focused on R&D, ThinkCyte is using *in silico* methods to apply a nonphysical "label" in combination with flow cytometry to sort cells based on phenotypes (e.g., activated versus rested) which, if viable, could pave the way for other *in silico* approaches for bulk isolation at scale.

C. Alternatives to autologous cell therapy: While there is a significant focus within the industry on autologous cell therapies (35%-40%⁴ of the cell therapy clinical pipeline), other emerging approaches (e.g., allogeneic, *in vivo*) aim to circumvent many of the bioprocessing challenges for autologous *ex vivo* engineered cell therapy. Should these approaches succeed, these alternative therapies will likely coexist with autologous cell therapy, given the impressive

efficacy and durability observed with autologous therapies, rather than replace the autologous modality entirely. While the manufacturing process will differ greatly (e.g., allogeneic cell therapy following the scale-up approach of conventional biologics), these approaches carry an entirely different set of challenges to address, such as cell donor management, transplant cell persistence and immune rejection for allogeneic therapies, or cell-specific transfection and risk of off-target editing for in vivo approaches. Furthermore, processes supporting allogeneic cell therapies currently lack the tools and fit-for-purpose manufacturing processes developed for autologous T-cell therapies today; they will require distinct manufacturing workflows, infrastructure and process solutions.

D. Next-generation engineering tools and platforms: Moving beyond viral-based and legacy electroporation transfection methods, the next generation of transfection platforms aims to reduce manufacturing cost (e.g., eliminating the need for expensive lentivirus), increase compatibility with a broader suite of cell engineering approaches (e.g., CRISPR, transposases), improve commercial scalability and enhance post-editing viability.

Flow electroporation platforms, including those from MaxCyte, Kytopen and Draper, represent an evolution of traditional electroporation and aim to reduce processing time and minimize scalability and cell viability concerns. The recent approval of Vertex's sickle cell gene therapy exa-cel represents a key regulatory milestone for MaxCyte's ExPERT platform, as well as establishes precedent for FDA acceptance of nonviral cell engineering alternatives within commercial processes. Other players, such as CellFE, Avectas and SQZ Biotech, utilize a microfluidic-based mechanical approach (e.g., rapid cell compression/expansion). This approach reduces the consumables required (e.g., buffers) and may increase transfection efficiency as well as improve cell recovery/viability. Consequently, it could unlock the therapeutic potential of more fragile and harder-to-engineer cells (e.g., NK cells) as well as reduce expansion time and ultimately vein-to-vein time.

E. Fully closed automated systems: The first generation of cell therapy manufacturing relied on disjointed equipment that performed singular unit operations, requiring an operator to transfer materials from unit to unit. The industry is increasingly integrating flow path connectivity and automation for key unit operations through modular product ecosystems (e.g., Thermo Fisher's Cell Therapy Systems product line), but true stand-alone, fully closed automated systems are still somewhat rare today.

The next wave of cell therapy bioprocessing equipment aspires to enable centralized parallel processing (e.g., batches for multiple patients in the same clean room) and pave the way for decentralized manufacturing by addressing key concerns regarding the contamination (and

cross-contamination) risks of open systems, heavy reliance on trained personnel and batch-to-batch variability.

In addition to Lonza's Cocoon system, companies such as Adva and Ori Biotech are focusing on turnkey GMP-in-a-box solutions that integrate multiple workflow steps in a fully closed, fully automated system to enable both centralized parallel processing and point-of-care (POC) manufacturing. Xcellbio aims to improve potency through metabolic conditioning during transduction and expansion of cell products with its AVATAR Foundry platform that automates liquid handling to streamline unit operations. Alternatively, Cellares' Cell Shuttle approach can operate 16 concurrent batches in a preassembled, fully automated, ISO 8-compliant pod. MultiplyLabs and Cellular Origins are augmenting the existing manufacturing and quality control testing approach by utilizing robotic arms to execute unit operations from market-leading equipment (e.g., Cytiva's Xuri) to avoid significant process development and revalidation.

Technological advancement in process equipment could progress decentralized manufacturing or even unlock POC manufacturing, where batches are produced in nontraditional GMP environments such as medical centers. Such manufacturing strategies have been a point of emphasis for FDA's Center for Drug Evaluation and Research but will come with additional challenges, including site-to-site variability and analytical comparability between sites, which may further increase the need for more advanced in-line analytical testing solutions in the future.

F. Scalable cryopreservation and software solutions: Limited LN2-free options currently exist in the market — most notably, Cytiva's electricity-based controlled-rate freezer (VIA Freeze) and shipper (VIA Capsule). The economics of LN2-free options are still a hurdle due to the considerable cost of the electricity to operate LN2-free systems and backup power systems (i.e., during outages) for storage. Other players such as Cryoport Systems, BioLife Solutions and CSafe are looking beyond freezing/thawing and focusing on end-to-end cryopreservation solutions to simplify the process for manufacturers. However, more broadly, fully closed automated systems may be the long-term solution for scalable cryopreservation by unlocking accessible POC manufacturing of autologous cell therapies and obviating the need for cryopreservation altogether.

While equipment is a key challenge for cryopreservation, software to manage the audit trail is equally as important for commercial-scale workflows. Software is an integral part of the ecosystem to connect various stakeholders (e.g., apheresis centers, developers, CDMOs) and minimize the delays to patient delivery caused by incomplete or inaccurate documentation. Integrated software solutions such as OCELLOS by TrakCel exist to eliminate the need

for overlapping systems to manage COI and COC data across the entire value chain. For example, TrakCel offers a platform to track data from initial cell collection through drug product transportation that encompasses both clinical- and commercial-scale processes.

Conclusion

Autologous cell therapy holds significant therapeutic promise, but key bioprocessing challenges must be addressed to fully realize the modality's unique opportunities. While autologous cell therapies have demonstrated truly transformational clinical outcomes, the current commercial processes for manufacturing these therapies are too costly, time inefficient and difficult to scale to meet the demand of even modest patient populations. Unaddressed, this dynamic could create significant headwinds against the long-term commercial viability of the modality. As the pipeline shifts toward larger indications with more intense biopharma R&D efforts, cell therapies will be increasingly competing with out-of-class competition (e.g., bispecific antibodies) that may have substantially lower COGS and prices. This prospect may pose significant market access and reimbursement challenges for autologous cell therapies unless their current economics improve markedly. Together, these dynamics may create a challenging business case for autologous cell therapies. Thus, innovations in both cell engineering and manufacturing are critical to unlock the full potential of autologous cell therapy as a modality, bending the cost curve to enable developers to bring the massive therapeutic potential of this class to more and more patients who could realize life-changing benefits.

For more information, please contact healthcare@lekinsights.com.

Endnotes

¹EvaluatePharma database

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¹³L.E.K. research, analysis and interviews

About the Authors



Jeff Holder

Jeff Holder, Ph.D., is a Managing Director and Partner in L.E.K. Consulting's San Francisco office and a member of the firm's Life Sciences practice. Jeff has expertise in the life sciences tools, bioprocessing, biopharma services and diagnostics space with a particular focus on growth strategy, portfolio planning, new product opportunities and business development support.



Adam Siebert

Adam Siebert is a Managing Director and Partner 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 eight 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 Chin

Brian Chin is a Consultant in L.E.K. Consulting's Boston office. Brian is a member of the Life Sciences practice and has experience advising clients on growth strategy and M&A within bioprocessing.

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