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Location considerations associated with the Growth in Cell and Gene Therapies (CGTs)

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The manufacturing approach for cell and gene therapies carries unique location considerations; access to talent and proximity to major treatment networks will be key in scaling manufacturing capacity.

Cell and gene therapies (CGTs) have experienced rapid expansion in clinical deployment

Since the first approval in 2017, the FDA has approved 32 CGT products and is expected to approve 10-20 therapies annually by 2025[1]. Additionally, there are more than 2,200 clinical trials already underway globally. Growth in CGTs reflects an enduring enthusiasm for their great potential, namely the ability to cure or significantly improve the management of diseases that have historically had no treatment options. Cell therapies – which involve the transfer of intact and live cells into the body in order to replace damaged or diseased cells – have made a significant impact on the treatment of blood cancers and hematological conditions (lymphomas, leukemias, and multiple myeloma), and are also showing success in clinical trials for the treatment of solid tumors. Gene therapies – which involve the use of genetic material for the treatment or prevention of disease by altering the genes inside the body – holds promise for treating diseases such as cancer, heart disease, and AIDS, as well as inherited disorders such as cystic fibrosis and sickle cell disease.

Manufacturing creates unique location dependencies

Gene therapies use DNA or other genetic material to edit the patient's cells, while cell therapies involve the transfer of whole cells into the patient.[1] Treatment follows

[1] Cell and Gene Therapy: Current Challenges and the Benefits of Automation | Technology Networks

a supply chain process that is essentially circular,[2] whereby cell tissue is procured via a single source directly from the patient/donor and transferred to a manufacturing location before finally being transported back to the patient. Both the starting material and the final product have strict time and temperature specifications, and there are also increased complexities and costs tied to chain of custody and chain of identity requirements. Most patients are admitted and treated as inpatients; those that are treated as outpatients must have suitable housing nearby to deal with issues that may arise[3]. Due to these location dependencies, proximity of the manufacturing location to the patient treatment center – and the ability to safely and efficiently transport the therapy itself – is a critical part of the manufacturing approach.

Production requires specialized workforce needs

The first generation of CGT manufacturing workflows required hours of manual manipulation of cells, media, and consumables – all through highly skilled labor[4]. The complexity of CGT manufacturing is distinct from traditional biologics and monoclonal antibodies. Here, the starting material comes directly from the patient/donor with shorter shelf lives, greater temperature sensitivities, and a nuanced chain of identity and chain of custody requirements. This has created a unique and very specific set of workforce needs. Production workforce typically account for half to two-thirds of overall staffing requirements, and include manufacturing associates as well as quality assurance personnel. Entry-level manufacturing candidates are expected to have four-year degrees with field-specific knowledge (e.g., FDA guidance, current cGMP), and experience with cell cultures and cell manufacturing is preferred but not required[5]. Meeting the demand for workforce will require a substantial coordination with technical colleges, four-year universities, and scientific and industry groups.

Manufacturing processes are being standardized and facility networks established

CGTs are notoriously expensive to produce – driven by the complexity and labor-intensive nature of the process described above – which has left significant areas of patient populations without access. Advancements in manufacturing are targeted at bringing down the cost of these treatments and expanding reach. First is the increasing trend in deployment of a closed loop system (and a shift toward allogenic delivery systems[6]) which eliminates open processing steps and facilitates greater automation[7]. Greater automation can reduce contamination risk, increase product consistency, and drive shorter product cycles. Second is the decentralization of manufacturing, which has been historically clustered in advanced biotech metros across the US (Boston, San Francisco, Philadelphia) associated with high costs of production. Expansion outside these traditional biotech markets is happening, with companies exploring different modes of moving their value chains closer to treatment centers and patients (e.g., hub-and-spoke models)[8].

Interested in expanding your CGT manufacturing footprint? Proximity to major treatment centers, utility costs and rate structures, logistics costs and service solutions, and skilled labor availability, are just a few of the factors that a company must consider when making a site selection decision. A comprehensive location strategy can help to assess the trade-offs associated with such cost and non-cost factors. Contact the Deloitte Location Strategy Life Sciences working group to learn more.

[2] While there is some variation between autologous and allogeneic treatments, the steps in the process typically include: cell collection from patient or donor, usually at the medical treatment facility, hospital or clinic, logistical transport to a manufacturing/processing facility, testing and analysis of samples to determine the manufacturing process to follow and the dosing quantity, cell modification to acceptable specifications, expansion of modified cells in bioreactor, cell harvesting and quality assurance, logistical return journey where product is packaged and returned to treatment facility

[3] Optimizing the gene therapy business model | Deloitte Insights

[4] Cell and Gene: the Next Generation of Manufacturing (themedicinemaker.com)

[5] Assessing workforce needs for the emerging CAR-T cell therapy industry | Nature Biotechnology

[6] Cell and Gene Therapy Manufacture - Scalability Using Close Systems - BioProcess InternationalBioProcess International (bioprocessintl.com)

[7] Scaling Cell and Gene Therapy Manufacturing Operations

[8] Cell and Gene Therapies: Expansions by CDMOs and CMOs and Key Trends - DCAT Value Chain Insights (dcatvci.org)

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