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Addressing Challenges in Cell Therapy Manufacturing

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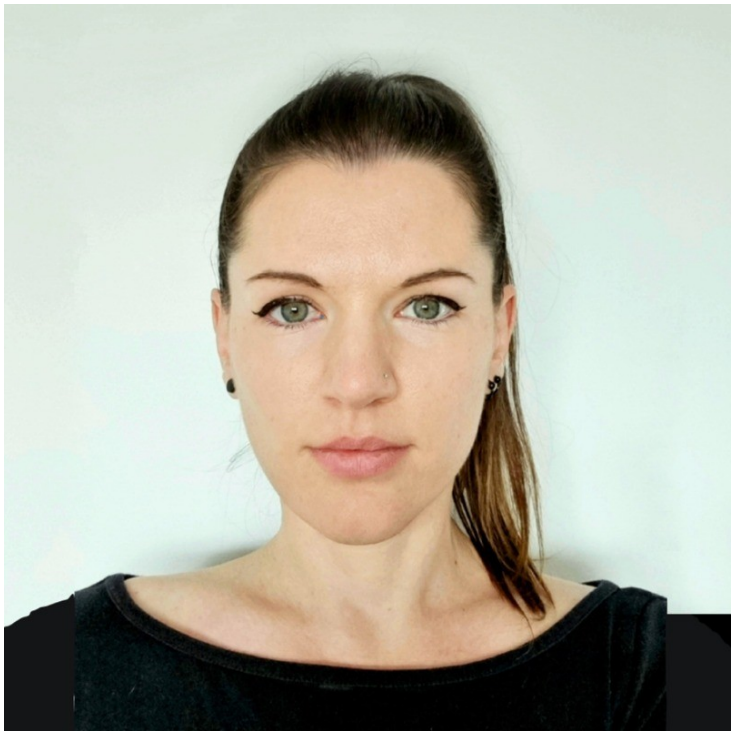
Even with significant advancements, there are still a number of issues with cell therapy manufacturing that need to be resolved as production grows.



Cancer research has come a long way. Along with technology advancements, the basic options for treating cancer, such as surgery, radiation, and chemotherapy, have expanded their mainstays when immunotherapy is developed. Individualised CAR-T cell therapy uses a patient's immune system to fight specific types of cancers or a broad spectrum of immuno-oncology and infectious diseases. Cell-based therapies aim to treat diseases by altering or restoring certain sets of cells or using cells to carry a therapy through the body.

Despite substantial progress in this field, cell therapy manufacturing presents multiple challenges that must be addressed as production scales up. At Agilent, our cell analysis team works closely with cell therapy manufacturing companies to explore innovative technologies that can overcome some of these challenges locally, regionally, and globally.

Complexity of Production

Cell therapies involve complex biological processes that are difficult to standardise and scale. These include manipulating living cells and viral vectors, which can be highly variable and sensitive to environmental conditions. Building on automation and closed-system technologies can help reduce the complexity and variability of production processes and standardise procedures while reducing the risk of contamination and increasing manufacturing efficiency. Agilent offers specific instruments like the Bravo Automated Liquid Handling Platform for high-throughput and precise liquid handling to facilitate the

automation and optimisation of various processes in cell therapy production.

Quality Control and Regulatory Compliance

Ensuring consistent quality and compliance with regulatory standards is a significant challenge due to the personalised nature of many cell-based therapies. Employing advanced analytics and real-time monitoring technologies can enhance quality control over the manufacturing process and quicker adjustments when issues are detected.

Agilent supplies professionals with essential tools such as guide RNA (gRNA) sequences and comprehensive oligonucleotide libraries, which are instrumental in refining the process of genetically modifying patient cells. By utilising advanced technologies like Flow Cytometers, xCELLigence systems, Seahorse XF analysers, and BioTek instruments, specialists can monitor and enhance the engineering of these cells with greater precision and efficiency.

Each of these tools offers unique capabilities, from the detailed analysis of cell characteristics and populations and facilitating real-time monitoring of cellular functions to providing insights into cellular metabolism and versatile solutions for cell imaging and analysis. Together, these innovative technologies support the optimisation of T-cell engineering, paving the way for innovative treatments in personalised medicine.

Supply Chain and Logistics

The supply chain for cell therapies is complex, involving transporting temperature-sensitive materials and products, often across long distances. Companies are exploring improved cryopreservation techniques and logistics solutions to enhance the stability and viability of products during transportation. Blockchain technology is also being considered to improve traceability and security throughout the supply chain.

Scalability

Due to the nature of cell therapies, scaling up production while maintaining quality and efficiency is a significant challenge. Companies are exploring modular and flexible manufacturing systems that can easily be scaled up or adapted to different therapies. Continuous manufacturing processes are also being developed to replace batch-based processes, potentially increasing scalability and efficiency.

Cost of Production

The high cost of manufacturing cell therapies can hinder their widespread adoption. To address this, process optimisation and the use of more cost-effective production methods, including leveraging synthetic biology to reduce the cost of raw material expenses and enhancing viral vector production methods, are crucial.

Enhancing Precision Medicine

Globally, governments and policy-makers are increasing investments in the cell therapy field to enhance precision medicine so that more patients can receive treatment tailored to their immune systems. In 2023, Agilent signed a Memorandum of Understanding with the Advanced Cell Therapy and Research Institute, Singapore (ACTRIS), to develop cell therapy advancement.

ACTRIS is Singapore's largest national cell and gene therapy process development and manufacturing facility that aims to produce more efficient, accessible, and affordable cell-based therapies. Agilent's state-of-the-art cell-based potency assays and metabolic analysis technology facilitate the development of next-generation therapeutics and new application discoveries, potentially increasing patients' access to cell-based therapies locally. This partnership reflects a strong testament to Agilent's innovative technology advances in supporting the most promising areas of medical research, bringing great science to life.

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