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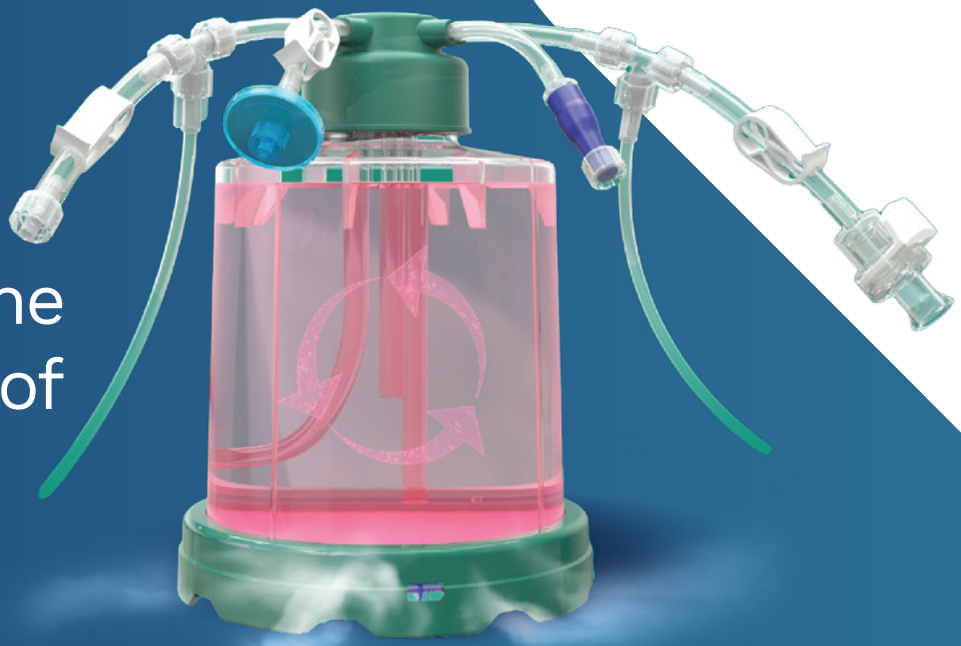
G-Rex: Expanding the Capabilities of Scalability



Using G-Rex Reduces Raw Material Consumption:

¼ of the starting material, ⅕ the volume of media, and ⅓ the number of consumables required when compared with the WAVE Bioreactor.

Efficiency Comparison: G-Rex Requires Fewer Cells than Wave for Seeding

50 million lymphocytes were required to seed the G-Rex 100M Series — ¼ less than the WAVE bioreactor.

Culture Yield of G-Rex 100M Series

3–5 billion T cells, consuming just 1L of media.

The Challenge

When global events affected the availability of products used in the manufacture of cell therapies, teams needed to explore alternative manufacturing methods. This supply chain crisis emphasized the need to establish redundant processes to address production obstacles for critical stages of cell therapy manufacturing.

The Process

One leading CAR-T cell therapy manufacturer focused on validating alternative starting material and culture vessels as a mitigation strategy for these supply chain issues. The cells produced by these alternatives needed to be comparable, if not better, than the cells produced using their established protocols. The existing process used full apheresis products as the starting material and the WAVE Bioreactor for the culture vessel. They decided to explore the feasibility of using peripheral blood and G-Rex closed system bioreactors within their process.

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The Solution

The G-Rex bioreactors were in stock and unaffected by supply chain issues, unlike the culture bags for the Wave Bioreactor. CAR-T cells were manufactured using peripheral blood as the starting material. Both G-Rex and the WAVE Bioreactor served as culture vessels simultaneously. Critical quality attributes, such as viability, transduction efficiency, and phenotype, were compared and assessed for the final T cell products.

The Result

G-Rex bioreactor produced CAR-T cells met the requirements for fold expansion, transduction efficiency, phenotyping, and critical quality attributes necessary to meet the specified dose. G-Rex required ¼ of the starting material, ⅕ the volume of media, and ⅓ the number of consumables throughout the culture duration when compared with using the WAVE Bioreactor. The team noted that operator effort was also decreased when using G-Rex. For starting material, peripheral blood yielded comparable results as full apheresis units.

The Impact

G-Rex culture vessel presents itself as an excellent option for integration into any CAR-T cell therapy manufacturing processes. Compared to traditional systems like the WAVE bioreactor, it consistently produces high-quality cells while reducing raw material usage and operator effort. This innovative technology can contribute to greater efficiency and cost-effectiveness in the production of cell therapies.

> “We generated in the 1L G-Rex, strikingly 3–5 billion T cells from starting seed of 50 million elutriated lymphocytes...”

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