

# Forecasting a Commercially Viable T Cell Therapy Manufacturing Process

## The Problem

Company came to ScaleReady looking to build a business case for G-Rex®500M-CS bioreactors as the primary cell production platform for their autologous TCR T cell therapy pipeline. Company's Director of Process Development (PD) had already tested G-Rex at small and large scale with data indicating cell expansion and phenotype met quality requirements for their cell therapy.

## ScaleReady Solution

By design, G-Rex bioreactors linearly scale cell production. Because of this feature, ScaleReady can predict production needs during scale-up and scale-out to create manufacturing models that estimate product consumption and overall process cost. This transparency into operational costs provides company's to project the commercial viability of their cell therapy as they progress through escalating patient volumes during clinical trials and into commercialization. ScaleReady modeled this company's process using the following plan:

1. **Business Goal Consultation** – To provide the most accurate modeling, ScaleReady first outlined the Company's immediate and future business goals. In this confidential conversation we determine the desired number of cells per patient dose, the number of G-Rex needed to achieve a patient dose, manufacturing time for one patient, and the number of patients the company expects to treat at each stage of clinical trials through commercialization.
2. **Forecasted Cost and Product Consumption** – ScaleReady used details from the consultation to forecast G-Rex unit consumption and costs. In addition, ScaleReady modeled their manufacturing process incorporating the full ScaleReady platform, including GMP cytokines, culture media, and upstream and downstream automation of cell processing using Lovo® and Cue, respectively. This model projected costs across multiple manufacturing parameters, including **hardware & consumables, manufacturing space, labor, and reagents**. This analysis estimated cost and manufacturing space escalation as the company commercialized their cell therapy.

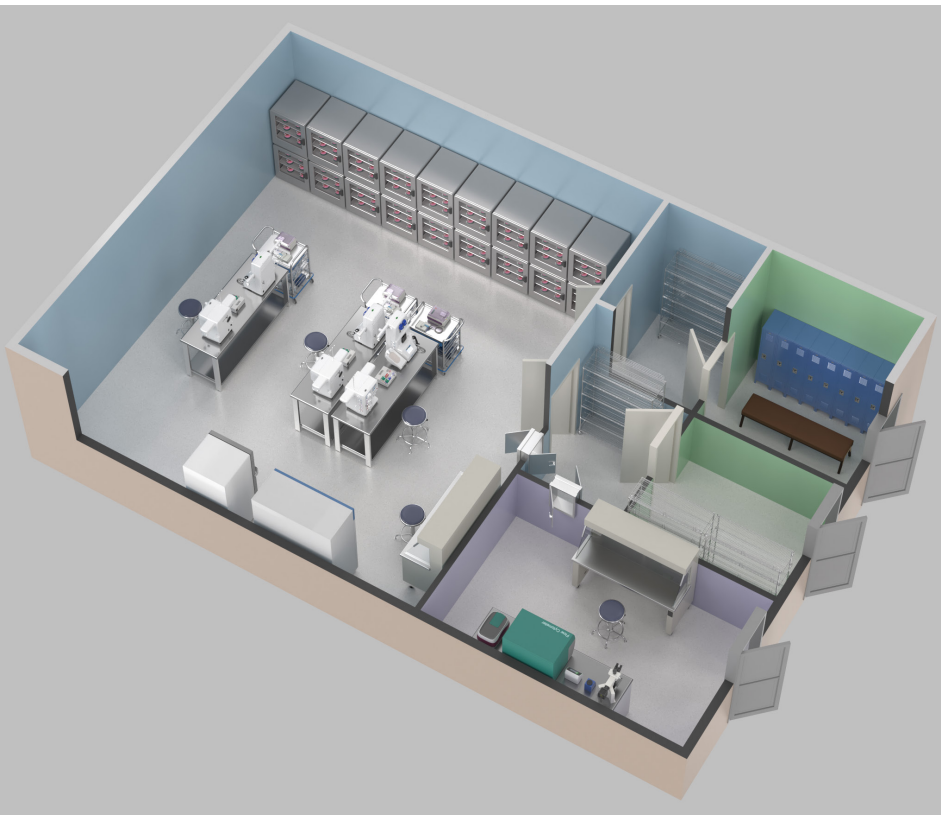
## The Outcome

The detailed forecast and platform comparison from ScaleReady was provided to the Company. Using this information, the Director of Process Development had the building blocks and competitive estimations to create a business case for the Company's leadership to onboard G-Rex as their cell therapy production platform.

**ScaleReady modeled operational costs for an autologous TCR T cell therapy company using G-Rex bioreactors. This provided transparency into long-term commercial viability of the ScaleReady platform.**



**Figure 1. The full ScaleReady platform is designed around G-Rex Bioreactors.** When paired with closed-system automated cell processing systems, G-Rex Bioreactors enable high throughput parallel processing of cell therapies within a small footprint. Multiple G-Rex bioreactors can be placed in one cell culture incubator.



**Figure 2. Model of a cell therapy manufacturing suite.** Multiple ScaleReady modules, shown in Figure 1, within one suite dramatically increase manufacturing capacity. Within a 500 sq. ft. suite, up to 2500 patients can be processed in a year.

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ScaleReady is a Joint Venture formed by Bio-Techne, Fresenius Kabi, and Wilson Wolf. Combining selected offerings from the three partners, the ScaleReady manufacturing platform combines tools and technologies for cell culture, cell activation and expansion, gene editing, and cell processing.

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