

Transition to Closed-system T Cell Expansion Leads to Process Optimization

The Problem

An autologous T cell therapy company was advancing toward pivotal clinical trials and needed to rapidly transition to a closed-system process for cell expansion. The company already validated Lovo® for automated upstream cell processing steps and wanted to build a business case proving G-Rex500M-CS closed-system bioreactors would meet their immediate cell production requirements and improve cell production efficiency, while adhering to their short timelines for going into clinical trials.

ScaleReady Solution

Cell expansion kinetics differ depending on the process (gas-permeable bags, flasks, spinner flask bioreactors), therefore transitioning from one expansion platform to another requires optimization. Due to the urgency of this company's request, ScaleReady offered the following plan:

1. **Validation of Cell Expansion in G-Rex500M-CS** – Based on company's targeted cell yield and desired phenotype, ScaleReady experts calculated seeding densities that would achieve the company's desired target cell yield (cell/cm²) in G-Rex500M-CS. *This experiment met their immediate and urgent need to confirm G-Rex could close their expansion platform and achieve the required cell yields.*
2. **Optimization Plan using G-Rex6M** – ScaleReady experts provided a plan for process optimization that incrementally identifies the best seeding density, the maximum cell density achievable, the minimum cytokine and media feeding schedule for their cell therapy process. *These experiments will identify a protocol that improves the efficiency of their process. All experiments are conducted at small scale, using G-Rex6M Well Plates.*

The Outcome

- **Proved Closed-system Process** – G-Rex500M-CS expansion protocol using ScaleReady suggested starting cell density, yielded similar expansion rates and target cell characteristics compared to the company's existing process. They were confident they could close their system using G-Rex 500M-CS and move forward with their pivotal clinical trials. *Continued Support: ScaleReady experts calculated expected number of G-Rex units needed to meet their patient treatment goal, providing cost and supply chain transparency for this unit operation.*

ScaleReady
helped quickly transition an autologous T cell therapy company into closed-system manufacturing. In doing so the company uncovered small cell culture changes that made a big impact on their process efficiency.

The Outcome

- **Identified Process Improvements** – Using small scale G-Rex6M studies, this company confirmed seeding cell density impacts fold expansion and cell yield of their product. They determined an optimal seeding density that improves their manufacturing efficiency. *Continued Support: ScaleReady offered a plan to scale the process improvements into G-Rex500M-CS bioreactors.*
- **Proved G-Rex Scales Predictably** – Running both G-Rex500M-CS and G-Rex6M experiments, this company observed similar expansion kinetics and yields (cells/cm²). This provided confidence that further optimization or reagent comparability studies could be performed in G-Rex6M and translate reliably to full scale manufacturing. *Continued Support: ScaleReady experts offered consultation on improving closed-system GMP reagent addition and culture performance.*

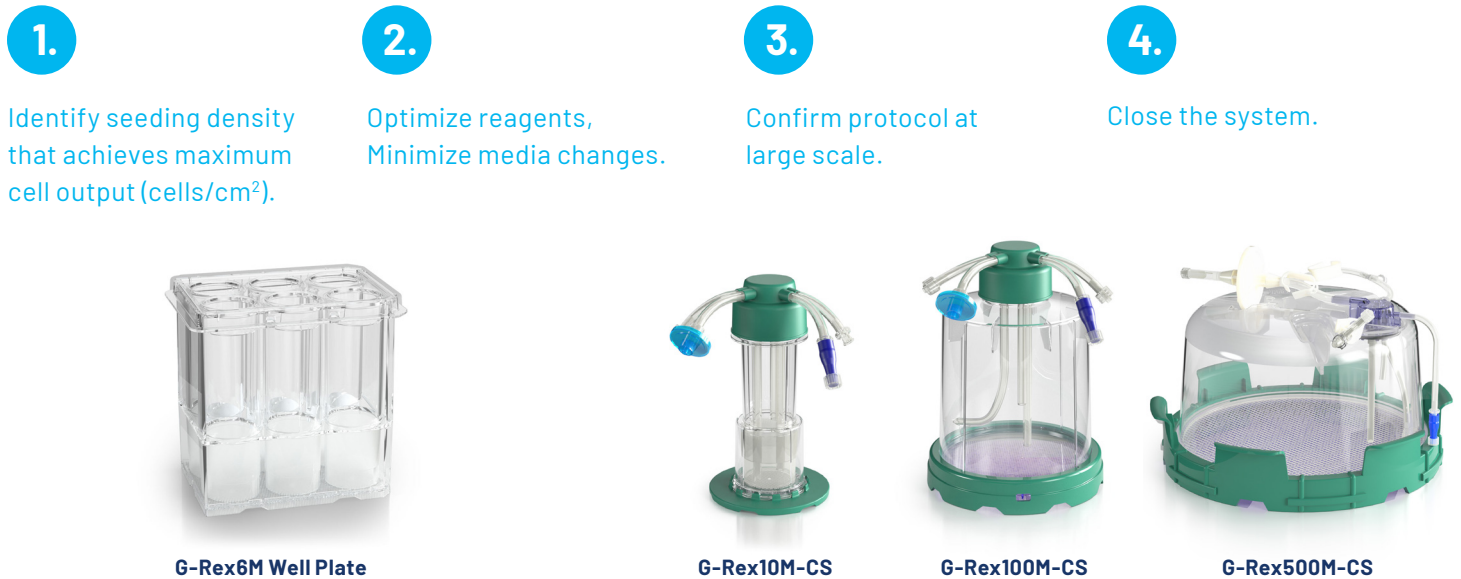


Figure 1. Cell Production Process Optimization and Scale-up

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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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