

Elevating Customer Support through Speed, Expertise, and Personalized Precision

Introduction

Cell therapies are at the forefront of medical research and innovation and have the immense potential to transform the treatment landscape of various diseases and malignancies. As research in this field advances, cell therapy manufacturing processes play a pivotal role in ensuring the success and accessibility of life-changing treatments. ScaleReady, a leading player in the biotechnology industry, has emerged as a trusted partner for groups seeking to optimize their cell therapy manufacturing processes.

AgonOX and their partner the Providence Portland Medical Center is an example of a group that benefited from the superior support from ScaleReady. The team at AgonOx is focused on providing personalized T-Cell mediated therapies to patients of varying stages of cancer. This case study delves into how the team at ScaleReady used their expertise to support AgonOx in implementing new technology that would streamline their manufacturing process before an IND filing.



The Challenge

AgonOx and Providence were at a pivotal juncture when discussions with the ScaleReady team began. This team was preparing for an IND filing and wanted to improve the manufacturing process in their current ACT clinical trial. However, critical stages of their cell therapy manufacturing process were still being completed using open and manual processing steps. AgonOx outlined the following concerns:

1

Risk of contamination: open systems are susceptible to contamination, which, in the downstream stages of a cell therapy manufacturing process, can lead to production delays, increased costs, and rejection of unsafe products.

2

Consistency and reproducibility issues: Variability in the environment and operator practices can lead to inconsistent yields in final batches. This variability can hinder the chances of demonstrating product safety and efficacy in a clinical trial.

3

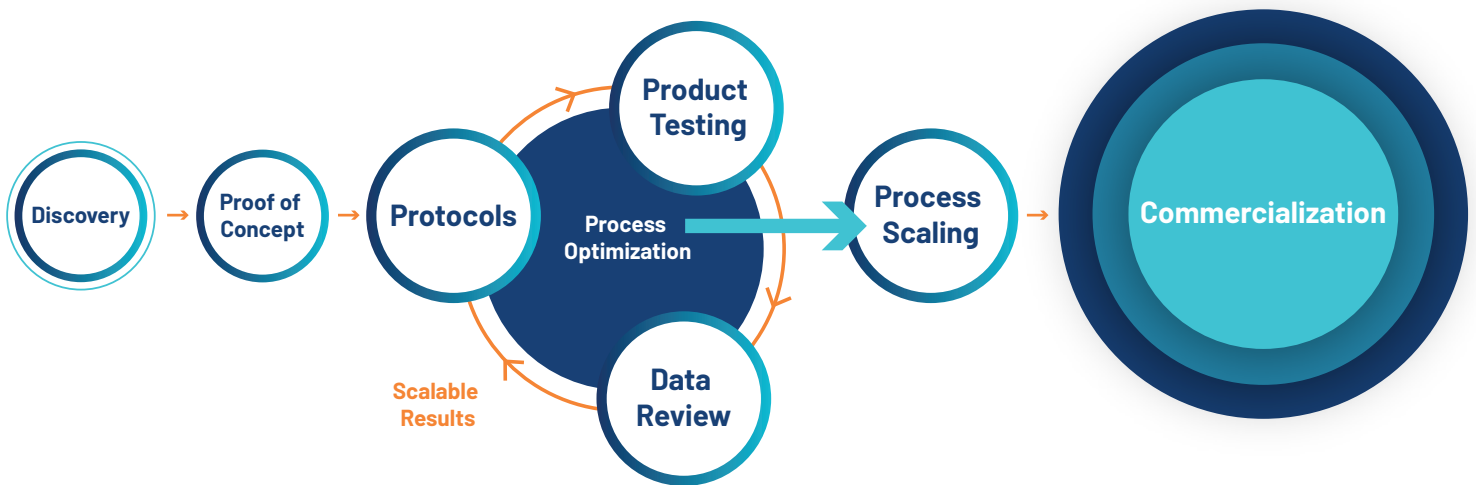
Regulatory Challenges: The FDA emphasizes the need for strict control over manufacturing processes to ensure patient safety.

Given these concerns, ScaleReady outlined a process using a few key products to close and streamline critical downstream processing steps. The team then quickly organized for samples and demo instruments to be shipped to test out this new process in the lab.



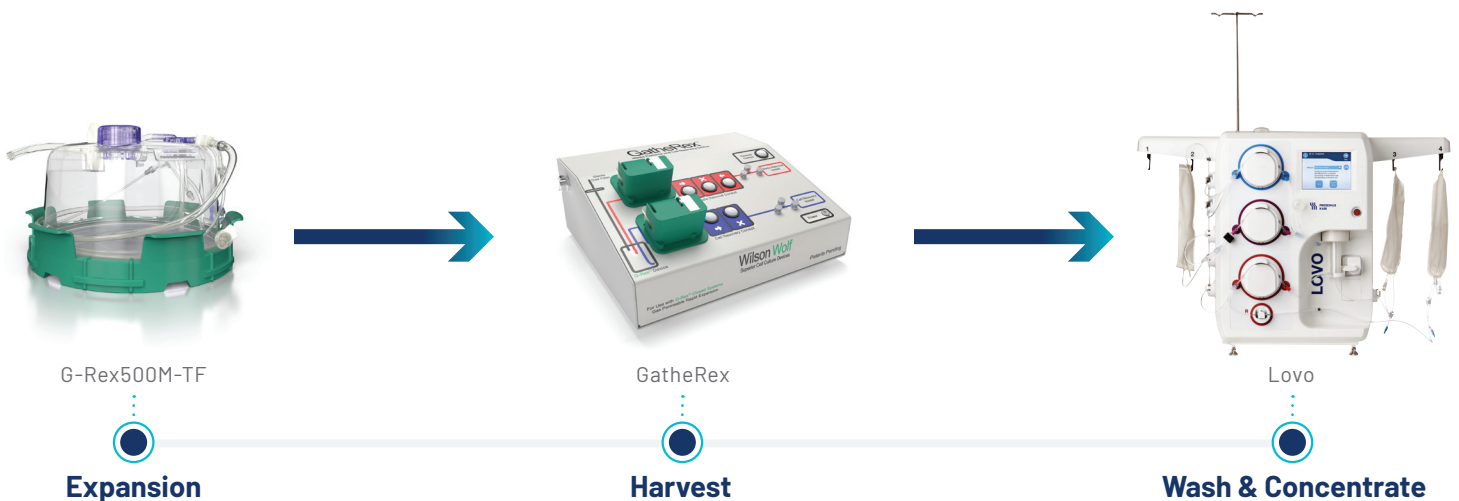
Activating The Proven Process

During the initial discussion with AgonOX and Providence, Scaleready gained an understanding of their current manufacturing process and the need for urgency to comply with established timelines. Since ScaleReady has a wide range of customers at various stages of development, the team was able to quickly define the critical stages where the process needed to be closed to progress through the planned regulatory filings and clinical trials. The proposed process improvements were presented and compared to the established SOPs of the manufacturing team. It was important to ensure the final cell product function would be maintained so previously collected data could still be used. A testing schedule was established to ensure the team would be able to complete enough runs with the new process to collect the necessary data. A testing schedule was established to ensure the team would be able to complete enough runs with the new process and collect the necessary data.



A Streamlined and Scalable Solution

The ScaleReady team recommended the use of the G-Rex500M-TF unit to replace the G-Rex 500M unit that had previously been validated as the culture vessel. The G-Rex500M-TF unit allows for sterile welding to containers, which closes the harvesting process while maintaining the same cell yields and quality that had been previously established. Because of the linear scalability and consistency between open and closed G-Rex systems, the removal of the 500M open-system and replacement with 500M-TF closed-system provided seamless translation and no change in the initial validation of G-Rex as the culture vessel. This unique ability of G-Rex saves critical time and avoids costly investment when transitioning from research to GMP for all clients. After the culture duration completes, the ScaleReady team suggested the use of the GatheRex Liquid Handling & Cell Harvest Pump to reduce the volume of each culture vessel and then harvest the cell suspension from the bottom of the G-Rex units into a transfer pack. For cell washing, the ScaleReady team recommended to then use the Lovo Cell Processing System to effectively wash and concentrate the cell product into fresh buffer to prepare for eventual freeze. Lovo can be used at the low end of the team's cell yield scale as well as the high end of their expected range. The proposed process from ScaleReady provided a solution to close critical stages of the original cell therapy manufacturing process, as well as shortened manufacturing time, decreased raw material usage, and provided automated consistency for their process.



To comply with the timeline set by the AgonOx and Providence team, testing for the proposed process had to complete within 2 months of the initial discussion. The ScaleReady team worked diligently to organize a demo by working with the ScaleReady partner companies to ensure rapid delivery of demo instruments and consumables. The field application team at ScaleReady designed and reviewed the intended process with AgonOx and Providence and ensured that the team had the necessary equipment and materials in-house. Ancillary equipment, like the CompoSeal Mobilea II from Fresenius-Kabi and a welder, was needed to evaluate the closed system process. Therefore, the ScaleReady team organized for these pieces of equipment to be sent to ensure testing went smoothly. Once the instruments arrived onsite, the field application specialist traveled to train the manufacturing team on the new process. The first engineering run was completed while a field application specialist was onsite to ensure the team was comfortable with the steps required from the new process. The lab team then completed the remaining engineering runs needed on their own without issue.



Lovo automated cell processing system. Custom protocol design to first full engineering run in less than 1 month.

Results

The timeline from initial discussion to completion of engineering runs as follows:



In Under 2 Months

ScaleReady service helped to replace critical manual processing steps with a fully closed and automated process by successfully supporting the integration of the G-Rex 500M-TF, the GatheRex Liquid Handling & Cell Harvest Pump, and the Lovo Cell Processing Instrument. By collaborating with the client and delivering instruments onsite, by collaborating with the client and delivering instruments on-site, designing custom protocols, and supporting testing all within this timeline, ScaleReady enabled the successful integration of an automated and closed process into the client's current ACT clinical trial and future IND filing.

ScaleReady provides clients with unmatched support and full service process optimization at every step.

Speed

Our swift instrument delivery and organization of the demo minimizes client wait time, ensuring that timelines can be met and maintained.



Scientific Expertise

Our team of skilled application specialists brings a deep understanding of your process needs, resulting in protocols that deliver high-quality and reproducible results.



Holistic Support

From protocol development to team training, ScaleReady offers a complete support package that maximizes your research capabilities.



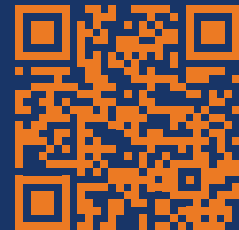
Dedicated Partners

We're not just a supplier; we're your partners in scientific advancement. Your success is our success.



Meet with the ScaleReady team today to learn how our experts can optimize your cell therapy process to reduce cost, deliver consistency and move your manufacturing process from bench to bedside at speed.

Contact us: info@scaleready.com



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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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