

ScaleReady's G-Rex® Grant Program

For the Advancement of CGT Development and Manufacturing



WILSONWOLF

biotechne®



ThermoFisher
SCIENTIFIC

charles river



R&D SYSTEMS



MaxCyte®





G-Rex® Grant for the Advancement of CGT Development and Manufacturing

Program Overview:

The G-Rex® Grant Program is a \$20,000,000 initiative undertaken by ScaleReady, in collaboration with Wilson Wolf, Bio-Techne, and CellReady to benefit the cell and gene-modified cell therapy community.

The G-Rex® Grant Program is unique and unlike any other grant program. G-Rex® Grant Recipients will not be burdened with inflexible timelines, bureaucratic constraints, micromanagement, or invasive oversight.

The G-Rex® Grant Program is intended to be simple, flexible, and easily accessible from initiation through completion. The G-Rex® Grant Program will be successful due to a partnership based on mutual trust, respect, and understanding.

The purpose of the G-Rex® Grant Program is to provide interested academic and commercial institutions engaged in pre-clinical research, process development, and/or cGMP manufacture of cell and gene-modified cell therapies (the “**Recipient**”) with the devices, reagents, and operational know-how to:

1. Implement a highly efficient G-Rex® based cell manufacturing platform and/or
2. Optimize an existing G-Rex® based cell manufacturing platform quickly and at low cost.

Key Features:

The G-Rex® Grant will provide each Recipient between \$5,000 and \$300,000 worth of materials and services, along with free consulting support from ScaleReady G-Rex® Optimization Specialists, for up to 18-months (the “**Collaboration Period**”) to any academic or commercial institution that meets the criteria outlined below.

- The duration of the Collaboration Period may be extended upon mutual agreement by the parties.

At the onset of the G-Rex® Grant Program:

- ScaleReady will work collaboratively with the Recipient during a series of discovery sessions to create a thorough understanding of the Recipient’s goals.



- ScaleReady will interact with Wilson Wolf, Bio-Techne, CellReady and the Recipient to orchestrate a G-Rex® Grant Program Plan that aims to achieve the Recipient's goals.

Under the G-Rex® Grant Program, ScaleReady will provide the most appropriate combination of devices, reagents, and consulting support as follows:

- Wilson Wolf
 - G-Rex® devices including G-Rex® well plates, G-Rex® bioreactors (including closed system models), and the GatheRex® Cell Harvest Pump
 - G-Rex® ancillary products
- Bio-Techne
 - RUO and GMP Reagents
 - RUO and GMP cell culture media
 - TcBuster® transposon/transposase system
- ScaleReady
 - G-Rex® Optimization Services
 - Technical Application Support
 - Marketing Support
- CellReady
 - Process Development and Manufacturing Services and Consultation

During the Collaboration Period, the G-Rex® Grant Recipient and ScaleReady will work together to meet the Recipient's program goals, which will typically include creating a process and data package sufficient:

- To be included in the CMC section of an applicable IND(s), or
- Used to support further research or collaborative efforts in the Recipient institution.

To be eligible for the G-Rex® Grant Program, a Recipient must satisfy the following criteria:

- Be engaged in research and development of cell and gene-modified cell therapies based on or derived from T cells, NK cells, HSCs, or the like.
- Be working towards, or have, an existing Investigational New Drug (IND) application.
- Be interested in quickly establishing an optimized cGMP manufacturing process at low cost with minimal investment required.



Inquiry Process:

All interested parties should contact ScaleReady at info@scaleready.com with a brief description of how a G-Rex® Grant Program can be beneficial. A ScaleReady G-Rex® Optimization Specialist will quickly respond to every inquiry with the goal of advancing the inquiry to an actual application.

The Application and Award Process:

The application process for a G-Rex® Grant is intended to be very easy and will be initiated by a simple form that will lead to a deeper dialogue with ScaleReady to help hone the application to a form suitable for receipt of a G-Rex® Grant.

G-Rex® Grants will be awarded to applicants that provide ScaleReady with:

- A compelling overview of why a G-Rex® Grant would be beneficial.
- A strong willingness to interact with ScaleReady to achieve program goals.
- Confidence that the recipient has wherewithal in program management.
- The collaborative nature of the applicant.
- Provision of a well understood set of G-Rex® Grant deliverables such as the following by way of example only:
 - Data package to support the creation of IND enabling data
 - Data package to support an IND amendment
 - Pre-clinical data generation and publication
 - Data package to support a manufacturing change control to improve/simplify existing manufacturing processes
 - Data package to support switching cytokine or reagent suppliers
 - Implementation of closed system G-Rex® manufacturing
 - Data package to support the Adoption of G-Rex® “M” Series Models

Once a G-Rex® Grant is Approved:

Upon G-Rex® Grant approval, ScaleReady will provide a high-level Non-Binding Memorandum of Understanding to the Recipient indicating the loosely agreed upon goals, estimated timelines, deliverables, actions, and respective responsibilities that were identified in the discovery phase.



- Of importance, the Non-Binding Memorandum of Understanding is a guideline document only
- The relationship between a G-Rex® Grant Recipient and ScaleReady is based entirely on mutual trust and understanding that flexibility will be needed to reach the Recipient's program goals.
- During the Collaboration Period, the Recipient and ScaleReady will work openly and collaboratively to achieve the mutually agreed upon outcomes of the G-Rex® Grant.

G-Rex® Grant Partner Exclusive Offer Catalogue:

ScaleReady has enlisted a legion of like-minded collaborators to bring additional value to help our G-Rex® Grant Recipients **save time and money**. All G-Rex® Grant Recipients will be provided a catalogue of exclusive offers from our official G-Rex® Grant Partners. The current list of Official G-Rex® Grant Partners and core contribution is listed below:

- Bio-Techne (R&D Systems) – Discounted GMP reagents and GMP media
- Bio-Techne (Protein Simple) – Discounted automated analytical equipment
- Fresenius Kabi – Discounted LOVO® and Cue® cell processing instrumentation
- MaxCyte – Discounted electroporators and consumables
- Thermo Fisher – Discounted cleanroom-ready incubators (specifically designed for G-Rex®)
- Charles River Labs (Cell Solutions) – Discounted RUO and GMP apheresis products
- Discovery Life Sciences (AllCells) - Discounted RUO and GMP apheresis products
- VectorBioMed – Discounted GMP lentivirus
- Applied Cells – Discounted cell isolation technology
- Akadeum Life Sciences – Discounted cell isolation technology

G-Rex® Grant Program Impact:

The array of expected impacts of the G-Rex® Grant Program typically includes:

- **Enhancing company valuation** by expediting and cost reducing the path to meaningful clinical data.
- **Quickly and inexpensively** implement an optimized G-Rex® centric manufacturing platform that is suitable for each stage of the path to commercial drug production.



- Establishing a seamless link, via G-Rex® platform continuity, between the research labs, process development labs, and the GMP manufacturing center to enable **faster translation of new therapies into the clinic.**
- Increasing patient access to cell and gene modified cell therapies by making **significant reductions in process complexity.**
- Increasing the value of academic institution's technology by allowing licensor's to **save valuable time and money** by inheriting an expeditious pathway to clinical inflection points.

Contact Information:

G-Rex® Grant inquiries can be submitted directly to info@scaleready.com or to your designated G-Rex® Optimization Specialist.