Application Note

Automated CAR-T cell manufacturing using IRO®

Overview

IRO is a next generation platform that automates and standardizes critical steps in the cell and gene therapy manufacturing workflow. IRO's core innovations include a bellows-based Bioreactor, which allows for customizable mixing (static, rocking and compression), and the OriConnect™ tubeless connection technology enabling automated fluid handling. IRO is digitally native, with continuous in-process cell culture monitoring (pH, dissolved oxygen, temperature, CO_2).

This application note provides an overview of a CAR-T cell manufacturing process using the IRO platform, highlighting process workflow.

Application Summary

- Automated CAR-T cell manufacturing in IRO
- Operating volume range: 50-1000mL
- Minimum starting cell number: 50M
- Flexible process parameters, including adjustable mixing modes (static, rock and compression mix) for optimal cell growth and transduction efficiency
- Continuous in-process cell culture monitoring (pH, dissolved oxygen, temperature and CO_2)

Materials Required

- Bioreactor (1000mL capacity)
- Small volume consumables (SVC) for additions and sampling
- Large volume consumables (LVC) for additions
- Isolated T cells (from CD3+ or CD4+CD8+ selection)
- T cell media (including serum/serum replacement/activation reagent/cytokines, as required)

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CAR-T Manufacturing Process Workflow

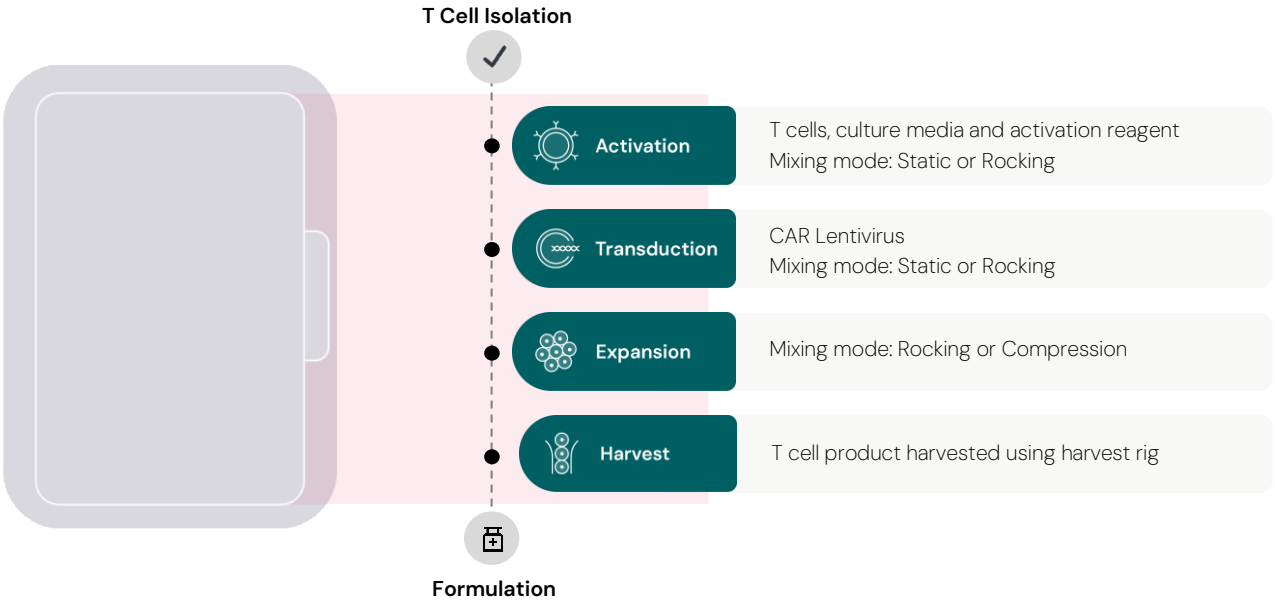

Figure 1: CAR T cell process on the IRO platform.

T cells are seeded into the Bioreactor using LVC and OriConnect tubeless connection technology. Activation and transduction reagents are transferred using SVC. Additional culture media feeds are provided using LVC, and automated sampling is carried out using SVC.

Flexible mixing modes enable optimization across each phase of the process:

- Static and Rocking mix can be used during the activation and transduction phase. Rock mixing can increase cell to cell, and, virus to cell interactions leading to improved activation and transduction efficiency.
- Compression mix is used to support expansion, generating superior potential for mixing and oxygen mass transfer, enabling higher cell yields.

IRO automates the activation, transduction and expansion phase of the CAR T cell manufacturing process, reducing manual operations and optimizing performance. IRO software can be monitored and controlled remotely via a web application reducing physical visits to the instrument. Sensors within the platform allow continuous monitoring of pH, dissolved oxygen, temperature and CO_2.

T cells grown in IRO show higher transduction efficiency and cell growth, shortening the time it takes to reach required CAR T cell yields compared to a widely-used manufacturing platform control.

Scale Your Impact

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About Us: Ori Biotech is a London and Philadelphia-based manufacturing technology company pioneering flexible process discovery with seamless translation and scalable commercialization of cell and gene therapies.