

Automated T cell therapy manufacturing in the Cocoon® Platform

Functionally closed and automated protocol for T cell therapy manufacturing in the Cocoon® Platform

Improving patient access to T cell-based immunotherapy

The Cocoon® Platform is a functionally-closed and automated platform that supports the manufacturing of T cell-based therapeutic products through customizable, robust, and reproducible processes. The Cocoon® Platform provides a solution to known challenges associated with T cell therapy by supporting manufacturing scalability and process flexibility, while helping to lower costs.

The following application note describes a standard T cell manufacturing process in the Cocoon® Platform, delineating a workflow that yields T cell products that consistently meet quality requirements for high viability and T cell purity.

Application summary

Optimized T cell therapy manufacturing

- Off-the-shelf, standard, T cell automated Cocoon® Platform workflow (Figure 1)
- Reproducible T cell expansion over 3 billion cells in 9 days¹
- High cell viability (> 90%)
- Continuous in-process cell culture monitoring (pH and dissolved oxygen) (Figure 1)
- Consistent T cell phenotype in-process and in the final product

¹Modifications to the process may impact the total cell yield

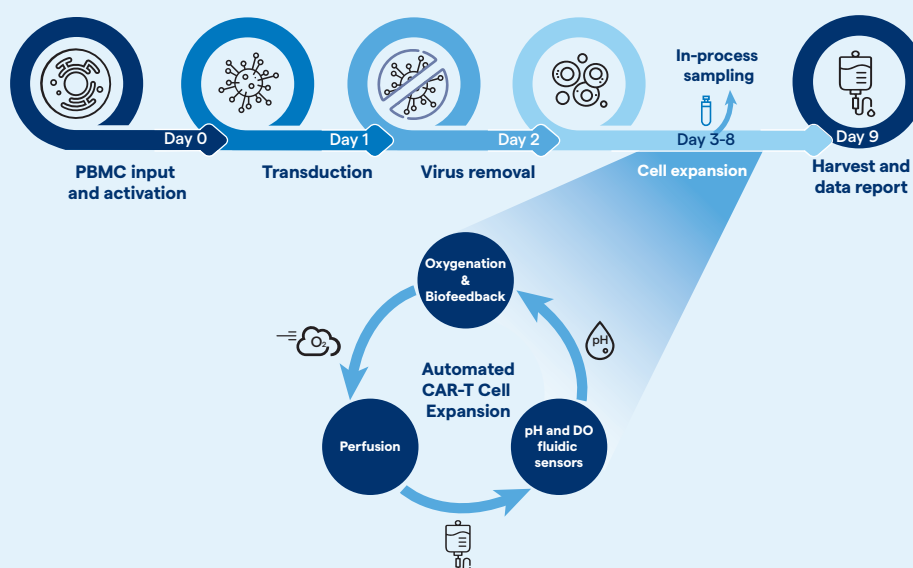


Figure 1: Process overview of a standard automated T cell manufacturing protocol on the Cocoon® Platform. The Cocoon® Platform runs customizable processes in a functionally-closed, single-use disposable Cocoon® Platform Cassette for automated cell selection, loading, activation, transduction, expansion, washing and harvest. There are programmable biofeedback features to maintain a balanced pH using fluidic dissolved oxygen (DO) and pH sensors. At the end of the process, electronic batch records and data logs can be exported digitally.

Performance data

Robust expansion of T cells yields products marked by high viability and purity

The Cocoon® Platform supports robust T cell expansion from 200 million peripheral blood mononuclear cells (PBMC) seeded, reaching over 3 billion T cells in the final cell product in 9 days maintaining greater than 90% viability during expansion (Figure 2). The starting PBMC

material composition ranged from 53% to 70% T cells and 1.8% to 34.9% monocytes (data not shown). Donor products consistently yielded > 96% T cells with comparable CD4/CD8 ratios on day 9 (Table 1), demonstrating reliable and reproducible product manufacturing.

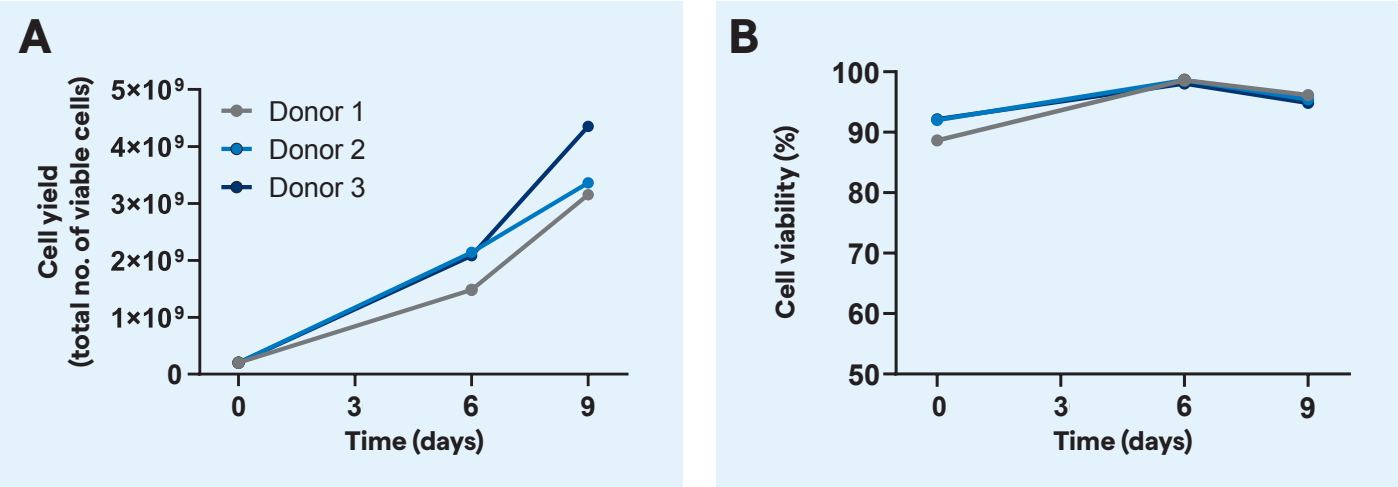


Figure 2: T cell expansion and viability on the Cocoon® Platform. PBMC were seeded in the Cocoon® Platform proliferation chamber on Day 0. Culture medium was used in the mock transduction step. Manufactured T cells were sampled in-process on day 6 and expanded to day 9 to assess cell yield (A) and viability (B).

Table 1: Consistency in T cell phenotypes among cell products mid-process (day 6) and at harvest (day 9) across three independent donors (D1, D2, D3).

	Day 6				Day 9			
Donor (n=3)	D1	D2	D3	AVG ± SD	D1	D2	D3	AVG ± SD
T Cells (CD3+)	96.2%	98.0%	97.2%	97.1 ± 0.9%	96.1%	96.4%	97.0%	96.5 ± 0.4%
CD4+ CD8-	40.2%	39.6%	57.0%	45.6 ± 9.9%	37.0%	36.3%	51.0%	41.4 ± 8.3%
CD4- CD8+	53.0%	54.4%	36.9%	48.1 ± 9.7%	56.1%	56.2%	42.2%	51.5 ± 8.1%

Contributors

Carlene Petes, Kathleen Zohorsky, Kelly A. Purpura, Matteo Da Ros, Seyedehosna Hadavi, Aman Mehrotra, Michele Vicentini-Hogan, Steven Bouman, Janet J. Sei, Tamara Laskowski.

The information contained herein is intended for general marketing purposes only. While Octane makes efforts to include accurate and up-to-date information, it makes no representations or warranties, expressed or implied, as to the accuracy or completeness of the information provided herein and disclaims any liability for the use of this publication and that all access and use of the information contained herein are at their own risk. Octane may change the content of this publication at any time without notice but does not assume any responsibility to update it. All trademarks belong to Octane and are registered in Switzerland or to their respective third party owners.