



Are you finishing strong in cell therapy manufacturing? Tackling your final fill and finish challenges with automation

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INTRODUCTION

Final formulation, fill and finish is a critical, high-value step in cell therapy manufacturing. Failure is both costly and time-consuming for the manufacturer and potentially catastrophic for the patient waiting to receive therapy. This key step is frequently done manually, which poses several significant risks, including operator-to-operator variability, contamination, and negative impact on the cellular product from DMSO [1]. A manual fill and finish step is performed in a high-grade GMP clean room and requires extensive GMP and hands-on training to reduce the risk of failure. In contrast, the Finia® Fill and Finish System, designed to automate this process, can maintain viability, improve reproducibility, and reduce process hands-on time and error.

STUDY SUMMARY

A comparative study was devised to compare a robust manual fill and finish process to the Finia automated process. Jurkat cells were expanded using the Quantum® Cell Expansion System. Cells from a single Quantum system expansion were harvested each day for three days and split into starting material for three runs. For each run, the cells were equally split between manual and Finia processes, performed simultaneously. Each Finia or manual process resulted in three different product bags with a target volume of 50 mL. Each bag was analyzed for product bag volume based on weight, cell count, and cell viability using trypan exclusion. Employee time was calculated for each process.

REPRODUCIBILITY OF AN AUTOMATED PROCESS

The product bag volume accuracy and cell health via absolute and relative viability were two of the studied parameters. On average, the Finia process came closer than the manual process to achieving the target volume of 50 mL (Figure 1), and high viability was maintained post-Finia process (Figure 2). These parameters show high reproducibility from Finia compared with the manual process.

SAVING TIME AND LABOR

Automation can save a cell and gene therapy manufacturer labor costs by reducing employee time needed to perform the fill and finish process. Employee time (FTE) for the manual versus the Finia process is shown in Figure 3. For the manual process, employee time was counted as the length of time for which operators were needed. It also includes a second operator acting as a QC person in the manufacturing area who

Figure 1. Mean calculated volume across all product bags for both manual (green) and Finia (turquoise) processes (n = 27). Volume was calculated by subtracting the weight of the empty bag from the weight of the post-process product bag and dividing by the specific gravity of the cellular solution. Statistically significant differences were observed (paired t-test; P < 0.05).



Figure 2. Mean viability from all product bags for both manual (green) and Finia (turquoise) processes (n = 27) were measured and recorded. No statistically significant differences were observed (paired t-test; P > 0.05).

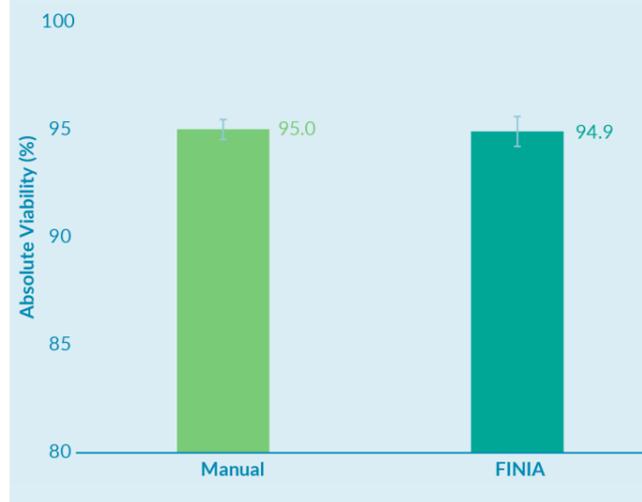


Figure 3. Employee time when using manual and Finia fill and finish processes. Each datapoint shown in blue is employee time during that run to perform the process. The average for manual (green) was 56.7 minutes, versus 6.4 minutes for Finia (turquoise). Statistically significant differences were observed (paired t-test; P < 0.05).



helps with documentation. For Finia, employee time was counted as the length of time for which the operator is interacting with Finia. It is important to note that with automation, an operator can multitask, or run multiple Finia systems at the same time. A second operator is not needed with Finia because it provides a report after each run that displays the volumes of materials that were used and the time taken for each step throughout the process. An average of 56.7 minutes for the manual process versus 6.4 minutes using Finia was recorded.

STREAMLINING CELL THERAPY MANUFACTURING WITH AUTOMATION

- ▶ The average fill volume across all product bags was more accurate with Finia than with the manual process.
- ▶ Finia maintains cell health during the fill and finish process.
- ▶ The automation provided by Finia significantly reduces employee time compared to the manual process.

REFERENCE

1. Sethi D, Cunningham A. De-risking the final formulation, fill and finish step in cell therapy manufacturing: considerations for an automated solution. *Cell Gene Ther. Insights* 2020; 6(10): 1513-1519.