Optimize Through Automation

As a cell therapy developer, you know there are substantial risks involved in the fill and finish process, from operator variability to potential contamination. As you scale your operations and refine your procedures, mitigating those risks with automation will be critical.

In this guide, we've detailed five key challenges, best practices to address them, and how the **Finia® Fill and Finish System** from Terumo Blood and Cell Technologies can provide an optimal, automated environment.

Contact Us

How to Reduce Five Key Risks in Fill and Finish

01 Human Error

02 Process Variability

03 Contamination

04 Product Inconsistency

05 Documentation Inaccuracies

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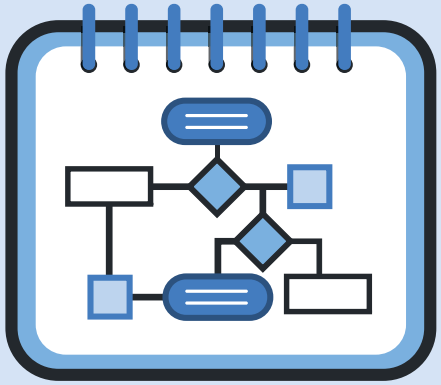
Human Error



Best-Practice Solution

Follow predefined, automated protocols.

International Society for Pharmaceutical Engineering (ISPE) recommends: Automate wherever possible to mitigate risk.[1]

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FINIA System Performance

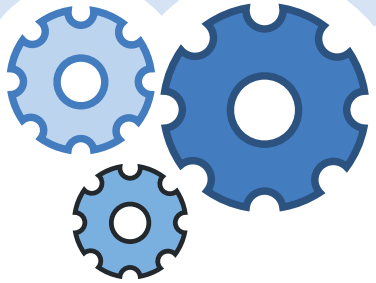
Intuitive user interface guides the operator, with little training needed, eliminating many error-prone steps

10.2 minutes

Average hands-on time, compared to 28.3 minutes for the manual process*

Requires less hands-on time, with fewer operators and touch points*

Automates **critical process steps**, including cryoprotectant addition and documentation

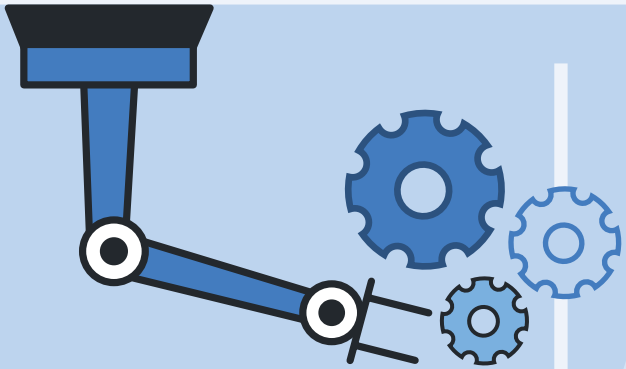


Allows you to **create protocols** and enforce workflow configurations

*Data on file.

[1]International Society for Pharmaceutical Engineering (ISPE). Guide: ATMPs — Autologous Cell Therapy. November 2021. Page 31. https://ispe.org/publications/guidance-documents/guide-atmps-autologous-cell-therapy.

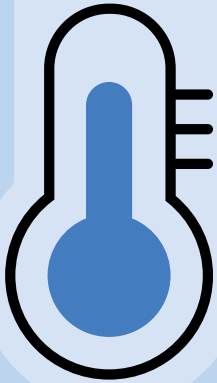
Process Variability



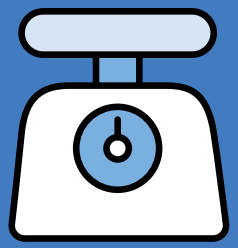
Best-Practice Solution

Eliminate operator-to-operator variability with automation versus manual or semi-automated steps.

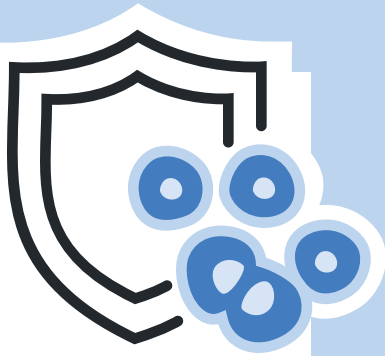
FINIA System Performance



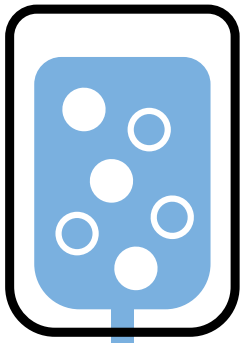
Active temperature control monitors and maintains final product temperature to within **3 °C (± 3 °C)** of the user-defined target*



Records and maintains accurate volume measurements using an **inbuilt weight check system** with a load sensor that weighs the contents of the mixing bag



Ensures accurate and **controlled cryoprotectant addition**, minimizing risk of mishandling, imbalanced ratios, and lengthy exposure of cells to DMSO



Automated mixing facilitates consistent, reproducible results

Reduces air in the final product bag to **less than 2 mL**

*Data on file.

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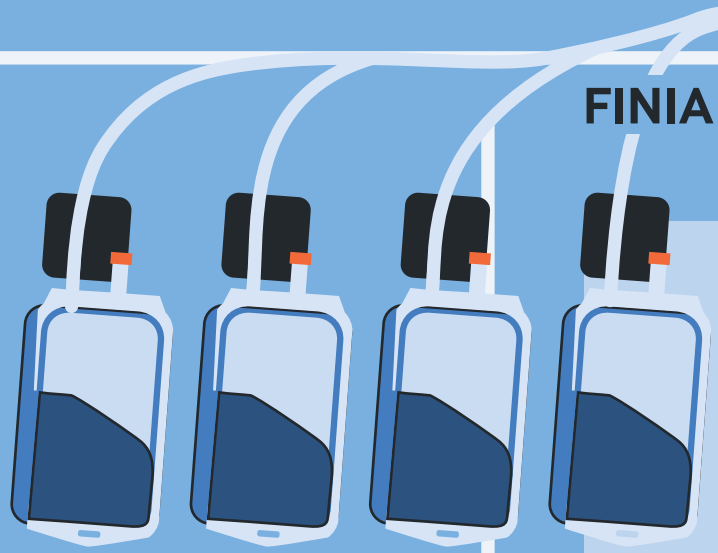
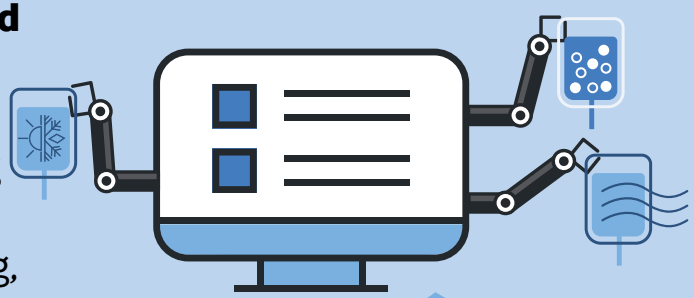
Contamination



FINIA System Performance

Provides a functionally closed, **automated system** for final formulation and fill-finish, including mixing, cooling, air removal, aliquoting, and sealing



Eliminates **open events**[1]

Automatically seals the final product and QC bags to help maintain sterility

Uses **gamma-sterilized,** single-use disposable sets

Best-Practice Solution

Minimize contamination risks by reducing manual handling and related operator errors.

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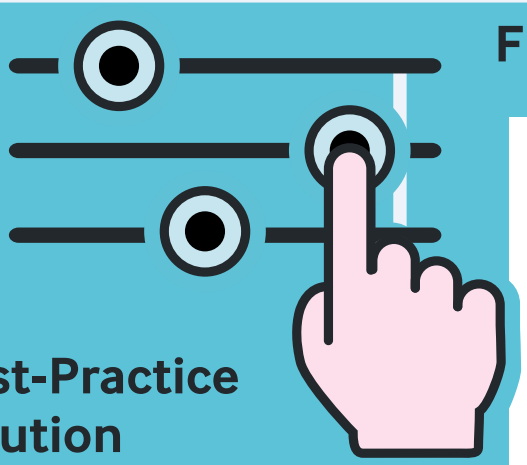
[1]Sethi D, Cunningham A. *Cel Gene Ther Insights.* 2021;7(9):1163-1171.

Product Inconsistency



Best-Practice Solution

Allow for precise control of temperature, filling volumes, and timing, and ensure accurate and controlled addition of cryoprotectant.

Automatically monitor and adjust the process to facilitate consistent, reproducible results that don't impact cell quality.

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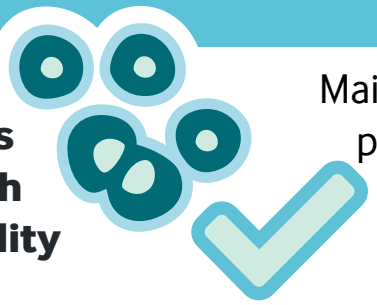
FINIA System Performance



Maintains cell health and viability

Maintains T-cell phenotype and functionality 24 hours post-thaw*†

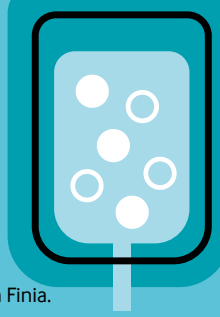
Comparable cell health, including densities and absolute/relative viabilities, to cells from manual processes*

> 90%
Post-thaw viability for cell products*

> 95%
Post-formulation cell viability*

Limits exposure to DMSO for cell therapies, reducing the risk of damage to cells

±2 mL
Maintains consistent, **accurate aliquoting** within 2 mL across all volumes*



5%
Maintains uniformity of cell concentrations to within 5% for all product bags and the QC bag*

† After expansion on the Quantum® Cell Expansion System and fill-finish on Finia.

*Data on file.

Documentation Inaccuracies

Best-Practice Solution

Use automated documentation systems to capture and record data accurately and consistently.

FINIA System Performance

Automatically logs events, actions, and information in support of a detailed process record

Automatically records target volumes, actual volumes, and procedural alarms and flags

Through automated features, facilitates current Good Manufacturing Practices (cGMP) compliance with electronic data recording and reporting

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Connect With Us to Learn More

De-risk your process and produce strong, consistent results with the Finia Fill and Finish System. For more information or to schedule a demo, email our team at **cellprocessing@terumobct.com**. Browse additional resources at **TerumoBCT.com/Finia**.

Finia users must qualify/validate the use of Finia and compliance with GMP within their own manufacturing (or laboratory) environment according to their own standard operating procedures (SOPs)/quality system.

The Finia Fill and Finish System availability is based on regulatory approval in each country.

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