Finish strong.

FINIA™ Fill and Finish System

De-risking the final formulation, fill and finish step for manufacturing cell therapies.

TERUMO
BLOOD AND CELL TECHNOLOGIES

How will you control risk at the critical final step of your process?

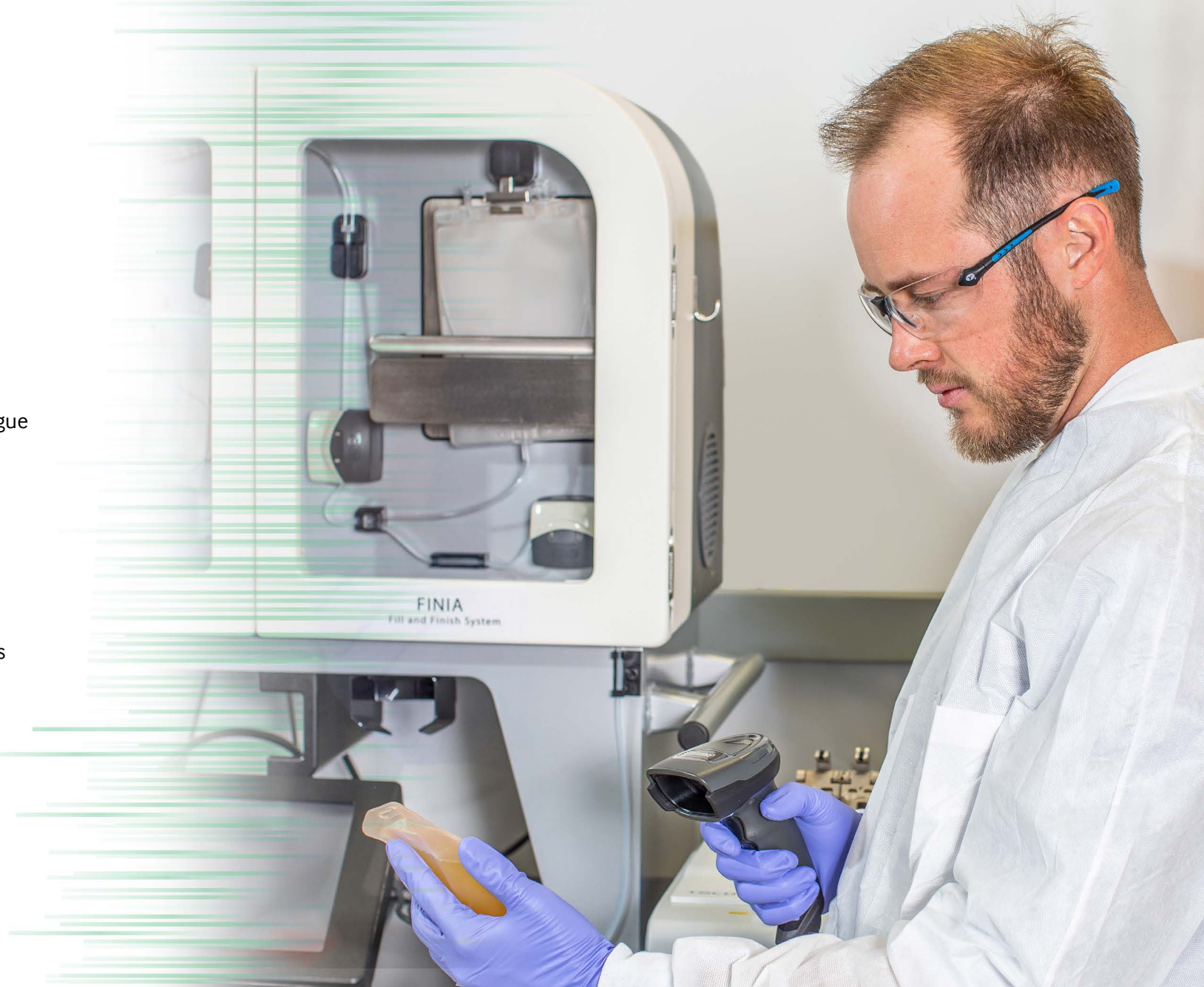
By the time you've reached the fill and finish step, you've invested a great deal. To fail now would result in a significant loss of time, resources, and ultimately a final therapy to a patient.

Reduce these risks associated with a manual fill and finish process*:

- Loss of cell viability
- Operator-related product variability
- Manual process and documentation fatigue
- Contamination due to open events

Bring precision to your fill and finish step with the automated, functionally closed Finia system:

- Maintain > 90% post-thaw cell viability*
- Produce precise and reproducible results
- Facilitate current Good Manufacturing Practices (cGMP)
- Enable the ability to scale with a fully automated system



Meet FINIA
Elevates your process for formulation and final packaging of cell therapy products.

Finia is a closed, automated system that formulates and aliquots fluids, including cell suspensions, to prepare for cryopreservation — all with the convenience of a benchtop design.

Configuring the procedure

1. Help maintain process workflow and track the product chain of custody with the optical barcode reader.
2. Follow the proper workflow via the user-guided touch screen. Customizable settings allow for varying formulations and dosage ranges.
3. Specify up to three final product bags.
4. Provide visibility into your final product specifications.
5. Record accurate volume measurements using the inbuilt weight check system.

Mixing and cooling

6. Automatically adjust the product temperature with the active cooling system and continuously mix with the mixing assembly.

Aliquoting

7. Aliquot cells in the final formulation of the product bags using the peristaltic pumps.

Sealing

8. Automatically seal the final product and QC bags with sealing valves.
9. Maintain a functionally closed system with the single-use disposable tubing set.

Finia automated workflow
Supports process adherence. Reduces risk. Provides flexibility.

Configure procedure

Modify parameters and define temperature targets to meet critical process parameters.

Configure up to three product bags with user-defined volumes.

- **Reduce risk:** Manual process and documentation is replaced with electronic batch reporting and enforcement of process workflows.
- **Reduce risk:** Finia positively identifies the disposable set, ensuring the catalog number, lot number, and sequence number are correct and the set is previously unused.

Manage Finia with one operator and only 10.2 minutes of hands-on time per run.*

Load starting material

Connect your starting material bag with a sterile connection.

- **Reduce risk:** Finia is a closed system, reducing contamination risk.

Cool and mix

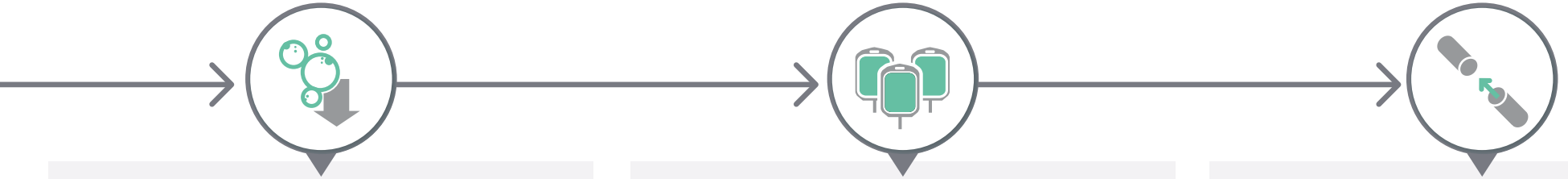
All materials are dispensed into the mixing bag based on your protocol.

- **Reduce risk:** The inbuilt weight check system and mixing assembly maintain precise volume control and batch/cell suspension uniformity.
- **Reduce risk:** Infrared sensor monitors temperature; environment is maintained to support cell health.

Finia maintains uniformity of cell concentrations to within 5% variation.*

It maintains final product temperature to within 3 ˚C (± 3 ˚C) of the target.*

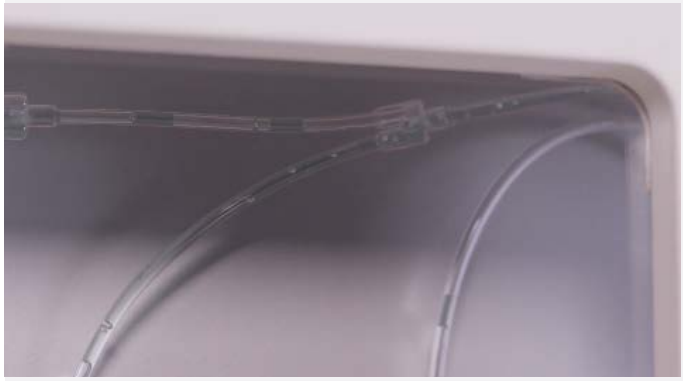
Finia automated workflow
Supports process and product reproducibility. Reduces risk. Provides flexibility.



Remove air

Prepare for cryopreservation by minimizing air in your final product.

- **Reduce risk:** Finia automatically removes air in the final product bags to less than 2 mL per bag.



Aliquot

Automatically aliquot the final product in up to three predetermined dosages and a QC bag.

- The system maintains precise volume control.
- **Reduce risk:** The load sensor and peristaltic pumps work together to ensure volume accuracy and reduce product bag variability.

Seal

Finia automatically seals the final product and QC bags to help maintain sterility of the final product.

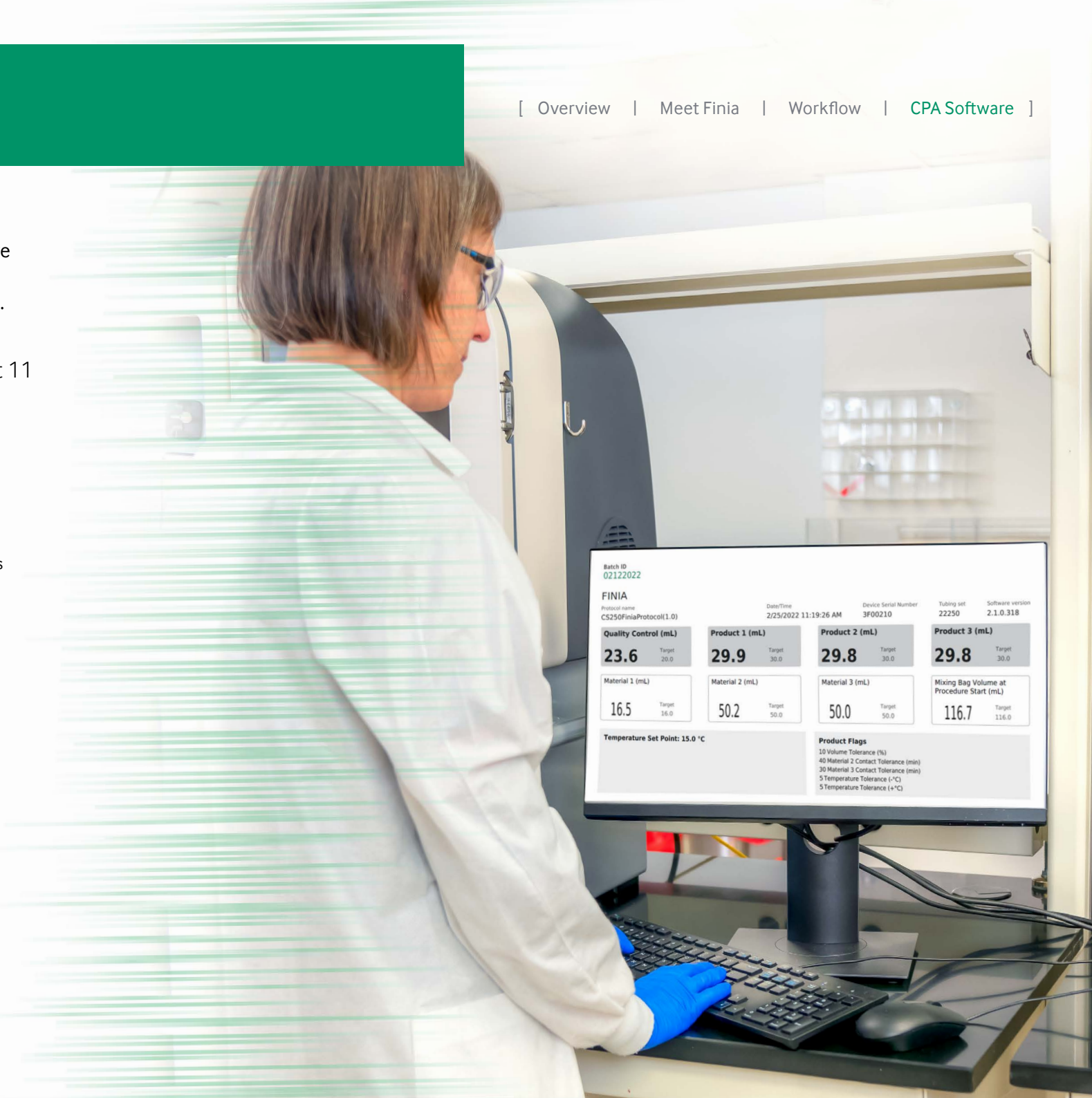
- **Reduce risk:** Automatic sealing in a closed system reduces contamination risk and the need for manual intervention.

Finish strong.

Throughout the automated workflow, Finia is collecting procedure data. When your procedure is complete, the server-based Cell Processing Application (CPA) offers a wealth of information.

CPA Software facilitates cGMP, 21 CFR Part 11 and Annex 11 compliance

- Automatically transmits procedure data between Finia and the application
- Generates post-procedure reports
- Records target volumes, actual volumes, chain of custody, and any alarms during the procedure
- Creates protocols and enforces workflow configurations
- Controls multiple Finia systems at one time to enable scaling



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Next Stop: Cryopreservation

It's critical at this stage that cells survive not only formulation but also freezing and maintain safety and potency profiles post-thaw. Because of Finia's ability to automate these processes and enforce process controls, final product bags are ready and optimized for cryopreservation.

Finia can:

- Maintain post-thaw viability greater than 90% for cell products from healthy T-cell donors*
- Maintain post-formulation cell viability of greater than 95%*
- Maintain T-cell phenotype and functionality throughout the process*

It's time to bring precision to your fill and finish step. Request a demo at cellprocessing@terumobct.com.

> "It is also crucial for biological materials to retain high viability, structural integrity and functionality after cryopreservation and thawing."[1]
>
> *Xiaoming He, PhD, University of Maryland*

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

*Data on file.

[1]Tay A. Cryopreservation to improve cell manufacturing and biobanking. *Genetic Engineering & Biotechnology News*. 2020;40(S5):S10-S12.

Availability of product is based on regulatory approval in each country.

TERUMO BLOOD AND CELL TECHNOLOGIES

Terumo Blood and Cell Technologies is a medical technology company. Our products, software, and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees around the world believe in the potential of blood and cells to do even more for patients than they do today. **TerumoBCT.com**

Terumo BCT, Inc.
Lakewood, CO, USA
+1.303.231.4357

Terumo BCT Europe N.V.
Zaventem, Belgium
+32.2.715.0590

Terumo BCT Asia Pte. Ltd.
Singapore
+65.6715.3778

Terumo BCT Latin America S.A.
Buenos Aires, Argentina
+54.11.5530.5200

Terumo BCT Japan, Inc.
Tokyo, Japan
+81.3.6743.7890

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