Automated Fill and Finish for Cell Therapy

Enhancing Precision, Sterility, and Viability with the CellBri Gentle P-Pac

Final formulation and fill are critical control points in the manufacture of cell-based therapies. These steps directly impact dosing accuracy, product consistency, and patient safety. The Gentle P-Pac system is an automated, closed-system platform designed for precise, low-stress formulation and dispensing of high-value cellular products, including CAR-T, NK, MSC, and iPSC-derived therapies.

This application note presents its performance metrics across multiple validated trials, highlighting its suitability for clinical and commercial production.

Introduction

Cell therapy products are inherently complex, with high sensitivity to physical stress, temperature fluctuations, and process variability. During the fill and finish stage—where final cell suspensions are formulated and aliquoted into cryobags—any inconsistency can compromise product potency, dosing accuracy, or sterility. Manual workflows often introduce risks such as volume inaccuracy, air entrapment, and contamination.

The **Gentle P-Pac** platform addresses these challenges through:

- Low-shear, adaptive mixing
- Temperature-controlled formulation
- Precision dispensing with volume monitoring
- Inline air removal (degassing) to support fill accuracy and bag integrity
- Closed-loop processing with minimal operator intervention

By automating the most delicate stage of cell manufacturing, Gentle P-Pac enables manufacturers to improve product consistency, scalability, and compliance with GMP standards.

CELLBRI

Extensive Application Scenario

The **Gentle P-Pac** supports a wide range of biological products including:

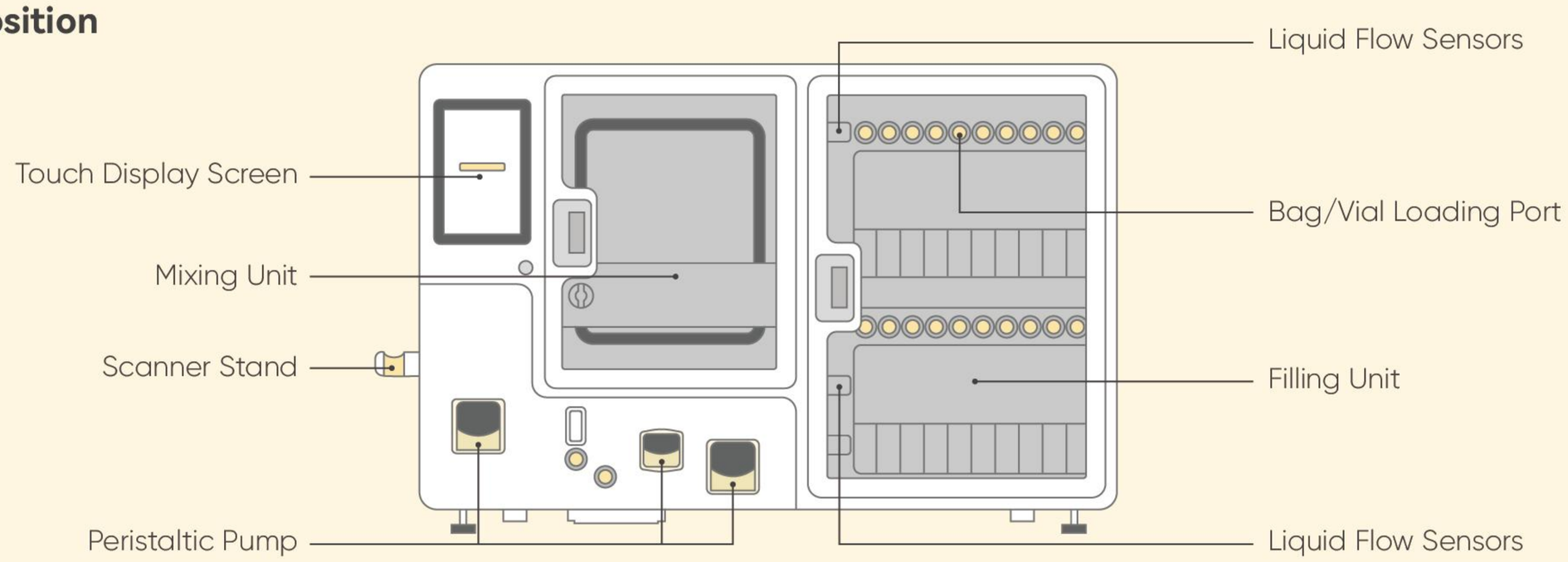
Core Capabilities

Biologicals
Lentivirus,
AAV, plasmids, Etc.

Cell & Fluid Types
T cells, NK cells,
MSCs, iPSCs, Etc.

Media
Formulation buffers,
cryopreservation solutions, Etc.

Composition



High Throughput Processing Capability

Feature	Capability
Fill Volume Range	2-150mL
Viability Retention	>95% across all major cell types
Fill Precision	±2% at 50mL fill volume
Fill Uniformity	<5% CV
Throughput	20 Bags simultanous, up to 200bags/hour
Temperature Regulation	2–8°C
Air Management	Built-in gas removal to minimize air bubbles

Performance Data and Validation

1.Cell Viability Retention

Cell viability is a key metric for release testing and therapeutic efficacy. Gentle P-Pac demonstrated consistent viability retention across runs:

Figure 1. T Cell Viability Pre- vs Post-Fill

Run	Pre-Fill Viability	Post-Fill Viability
A	97.1%	96.8%
B	95.4%	96.3%
C	96.3%	95.7%

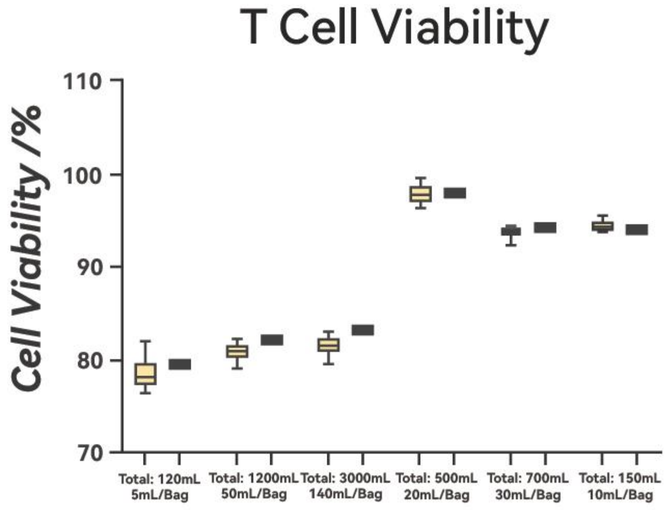
Average ΔViability: <1.2%

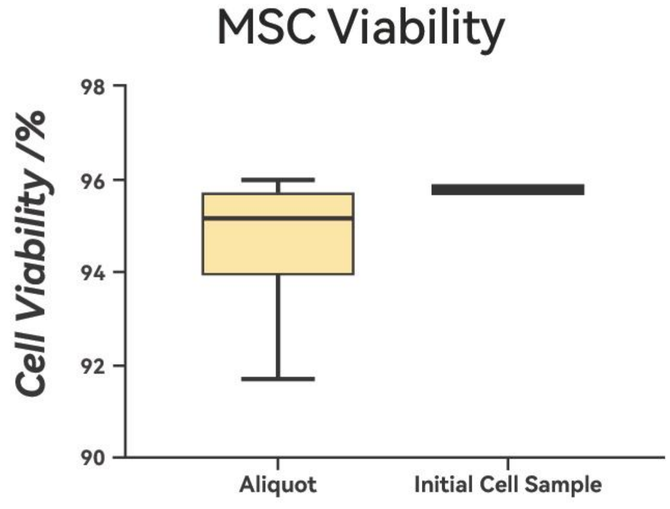
2. MSC Viability and Aliquot Uniformity

In a 20-bag MSC formulation (120 mL total volume, 5 mL per bag):

Pre-fill viability: 95.76%
Post-fill average: 94.71%

Gentle P-Pac demonstrates excellent cell protection during automated formulation.



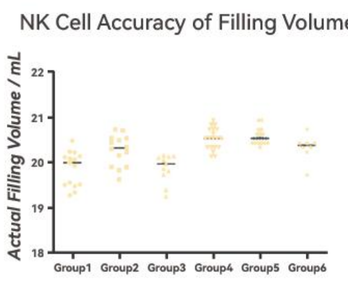


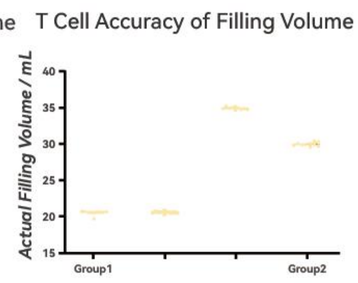
3. Dispensing Volume Accuracy

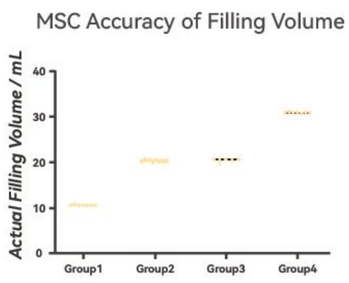
Gentle P-Pac's flow-sensor guided control ensures reliable dispensing precision across all cell and fill types.

Figure 2. Volume Deviation Across Batches

Cell Type	Target Vol.	Avg. Vol.	Deviation
CAR-T	20 mL	19.9 mL	±0.6 mL
NK	20 mL	20.3 mL	±0.8 mL
MSC	30 mL	29.7 mL	±0.9 mL



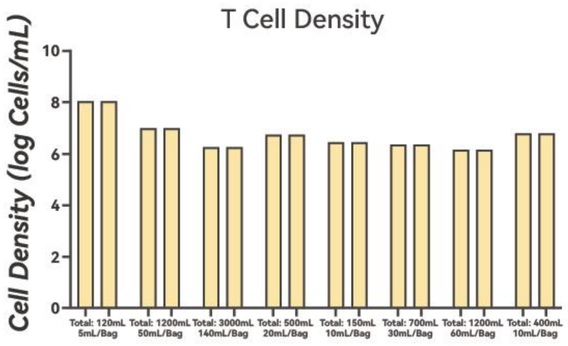


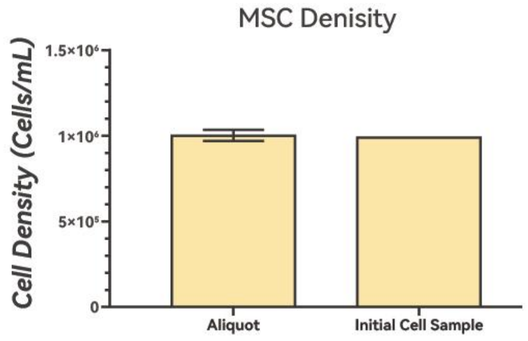


4. Cell Density Consistency

Post-formulation bag-to-bag density variation is critical for batch release. Data from clinical-grade runs show:

- **CAR-T Cells:** CV <5% across all bags
- **MSCs:** CV <10%, even at low fill volumes (5 mL)





Gentle P-Pac achieves this through adaptive mixing intensity based on residual volume, ensuring homogeneous cell suspensions.

Expanded Case Study:
VST Cell Aliquoting Using Gentle P-Pac

Background

Virus-specific T cells (VSTs) are used in adoptive immunotherapy, especially in post-transplant viral reactivation contexts. Because they are often administered at low volumes with high potency, formulation accuracy, cell integrity, and consistency across bags are crucial for therapeutic efficacy and regulatory compliance.

Objective

Demonstrate the Gentle P-Pac system's performance during the final formulation and aliquoting of a VST product across 30 cryobags, assessing key metrics such as:

- Cell viability pre- and post-dispense
- Density uniformity
- Volume fill precision
- Batch-wide reproducibility across time points

Batch Parameters

Metric	Value
Input Cell Product	VSTs
Pre-fill Volume	450 mL
Cryobag Type	50 mL cryopreservation bags
Fill Volume per Bag	10.5 mL
Total Bags	30
Dose per Bag	6.6×10^7 cells

Results

1.Cell Viability

- Pre-dispense viability: **96.2%**
- Average post-dispense viability: **95.3%**
- All 30 bags fell within a **<5% deviation** from baseline
- No time-dependent decline in viability during the 3-hour fill window

2.Cell Density Uniformity

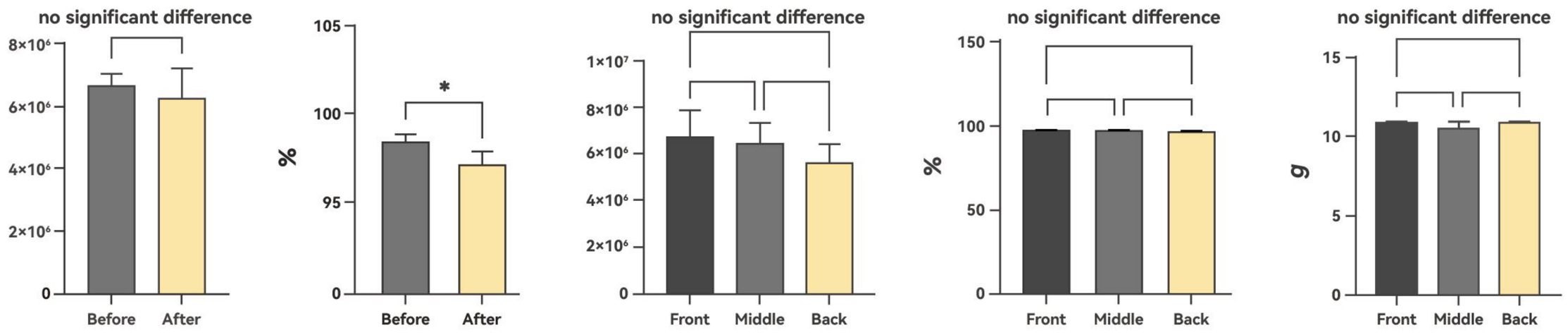
- Initial sample density: **6.3×10^6 cells/mL**
- Post-fill average: **6.28×10^6 cells/mL**
- Min/max range across bags: **$6.1–6.4 \times 10^6$**
- **cells/mL**
- Coefficient of Variation (CV): **<4%**
  No observable stratification, foam, or clumping

3.Volume Accuracy

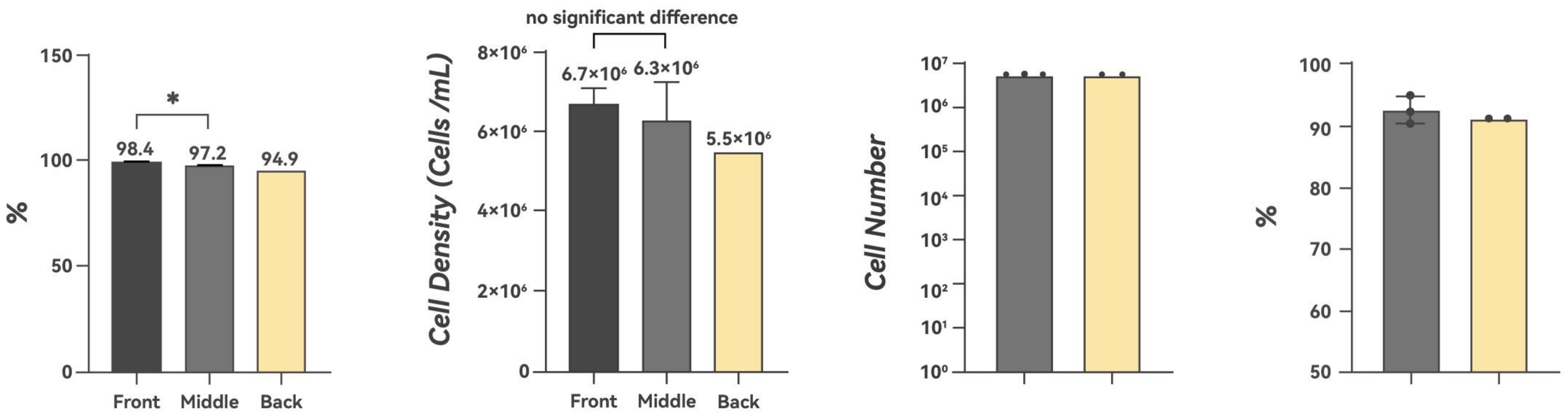
- Target fill: **10.5 mL/bag**
- Gravimetric testing across early/mid/late bags: **±0.6 mL**
- No operator adjustment or recalibration required

4.Process Stability

- Inline air removal ensured bubble-free fills
- No fill sensor anomalies observed
- Uniform visual clarity and sealing quality confirmed post-process



Cell Viability Before Canning VS. After Resuscitation



Study Conclusion

This VST fill batch demonstrates Gentle P-Pac’s ability to maintain viability, ensure volume and density precision, and operate with high consistency throughout the full runtime. The reproducibility observed between the first and last bag reinforces the platform's suitability for regulated fill-finish processes where dose reliability is critical. The results validate its use in high-potency, low-volume cell therapies such as VSTs and other autologous products.

Conclusion

The Gentle P-Pac system enables precise, high-throughput, and biologically safe fill and finish operations for advanced cell therapies. It achieves:

- Viability retention above 95%
- Consistent dosing volumes (±2%)
- Excellent density uniformity
- Built-in temperature control and air removal

These capabilities make it an optimal solution for both clinical and commercial cell therapy manufacturing environments.

Whether you’re manufacturing autologous therapies like CAR-T or scaling allogeneic platforms using NK, MSC, or iPSC-derived products, the **Gentle P-Pac system** offers the precision, consistency, and process control required for today’s demanding clinical and commercial pipelines.

With proven performance across diverse cell types and validated in clinical-grade settings, Gentle P-Pac enables:

- Streamlined fill and finish workflows
- Viability and volume precision backed by real-world data
- Closed-system operation for GMP-compliant manufacturing

CONTACT US

To learn how **Gentle P-Pac** can integrate into your process—or to request a demo using your specific cell product—contact our technical team at:

E-mail info@cellbri.com

Website www.cellbri.com/

Let us help you simplify the most sensitive step in cell therapy production—without compromising precision or viability.