



CASE STUDIES: TECHNOLOGY IN ACTION

Made Scientific & Streamline Bio

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RELIABLE BY DESIGN

How AI-Driven Robotics Is Redefining Cell Therapy Manufacturing

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Cell Therapy Manufacturing Has a Scale Problem

- \$500K+ per patient dose
- 30–40% batch failure rate
- 95% of eligible patients cannot access approved therapies
- Manual operation intensive

The CGT manufacturing market is projected to grow from \$5.2B (2023) to \$15B+ by 2030 — but only if the industry solves its reliance on manual, operator-dependent processes.

Today's workflows are labor-intensive, difficult to scale, and introduce variability at every touchpoint.

The result: prohibitive costs, inconsistent quality, and a fundamental barrier to equitable access — keeping life-saving therapies out of reach for most patients who need them.

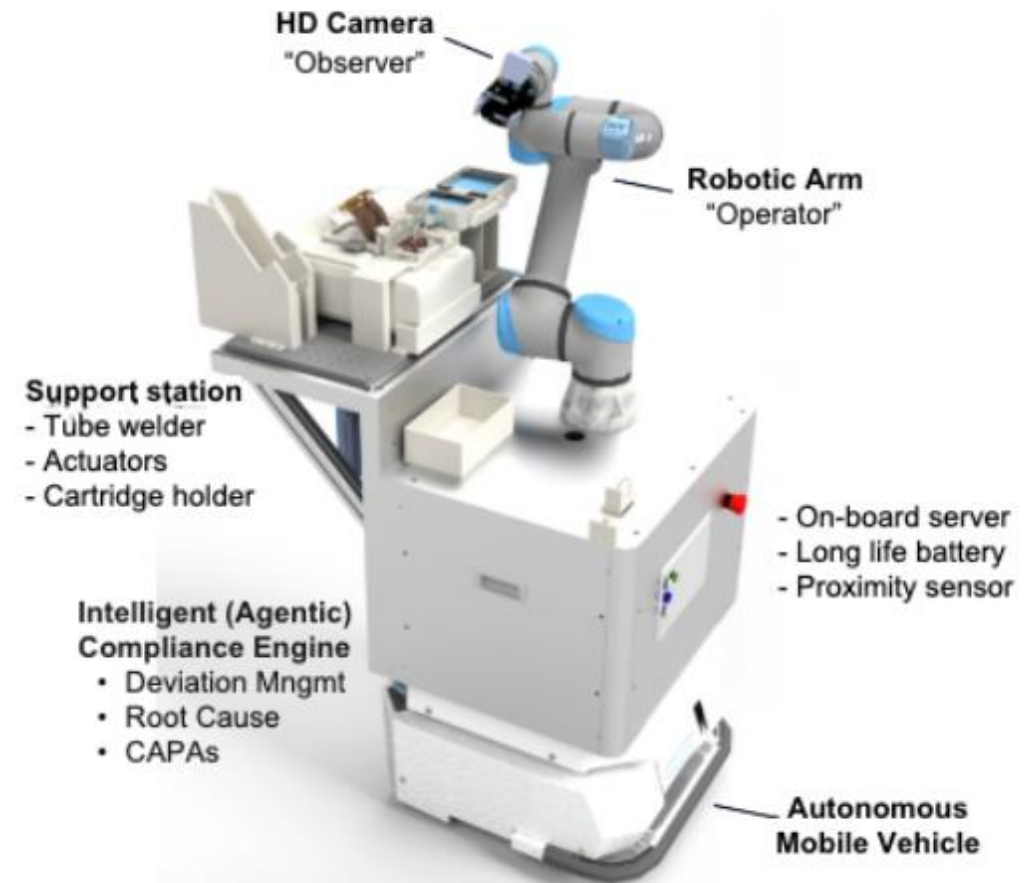
Why Current Manufacturing Falls Short

- Semi-automated processes with heavy manual touchpoints
- Operator-dependent variability reducing batch consistency
- High training burden and labor costs at every step
- Limited scalability in decentralized or resource-limited settings
- Regulatory complexity compounded by manual documentation
- High environmental monitoring burden due to operator capacity

Streamline AERO™: AI-Enabled Robotic Operator

A versatile, low-cost, autonomous robotic platform paired with an AI compliance engine — purpose-built to RELIABLY automate cell therapy manufacturing from clinical through commercial scale.

- **Drop-in ready** — integrates with existing processes, devices, and infrastructure with no facility redesign
- **Autonomous** — reduces human touchpoints while maintaining real-time data capture and compliance
- **Scalable** — cost-effective from Day 1, at less than 10% the cost of current static automation systems



Automating the Full CAR-T Workflow

Day 0: Cell Wash & Selection

Day 1: Activation

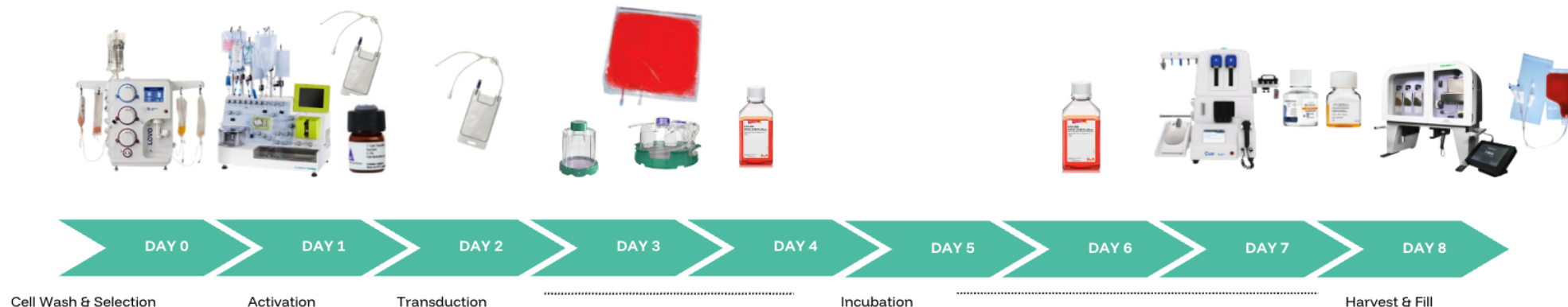
Day 2: Transduction

Days 3-6: Incubation / Expansion

Day 7: Harvest & Fill

Day 8: Disposition & Release Testing

AERO integrates at each unit operation step — reducing manual touchpoints, improving process consistency, enabling continuous analytics, and capturing data in real time throughout the workflow.



CAR-T manufacturing at Made Scientific

Automated CAR-T production in a CNC environment – no infrastructure changes



Equivalent Product Quality, Significantly Less Operator Time

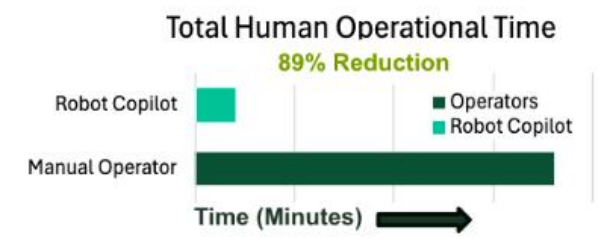
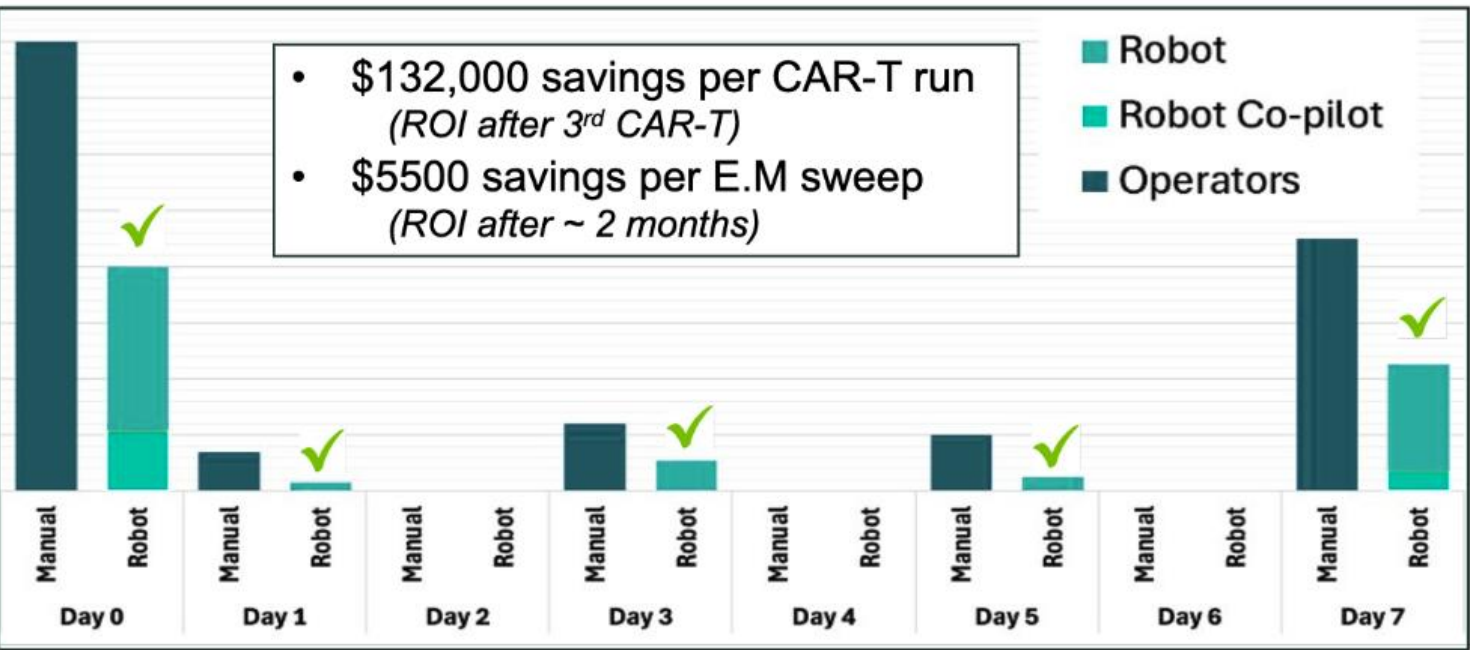
Potential to save >300 additional minutes in end-to-end automated CAR-T runs, with equivalent or improved product quality.

Parameter	Manual	AERO
Cell viability (start)	> 95%	> 95%
Expansion (viability)	~55-fold (96%)	~60-fold (97%)
End product (viability)	$1.7\text{--}3.6 \times 10^9$ (>92%)	$1.5\text{--}4.0 \times 10^9$ (>94%)
% CAR-T+ cells (Day 7)	~46%	~50.1%

Data from N=3 runs. Validated on Miltenyi Prodigy workflows.

Cleanroom Operation Time: Manual vs AERO System

Equivalent CAR-T products + significant reductions in total operator time = cost savings + increase capacity without added EM burden



Potential to save > 300 additional minutes in end-to-end automated CAR-T runs

Built Different: What Sets AERO Apart

Fully-autonomous & modular Operates independently in existing cleanroom layouts — no facility redesign required

Real-time compliance Agentic AI captures analytics, documentation, and process data continuously — reducing regulatory burden

Platform-agnostic validation with AI machine vision for defect detection

- Miltenyi CliniMACS Prodigy[®]
- Fresenius Kabi LOVO[®]
- ScaleReady G-Rex[®]
- Sterile welding and seal
- More new unit operations coming up with AI-driven adaptability



Integration Roadmap to Full GMP Deployment

Phased approach de-risks the path from development to commercial-scale.

- **Q2 2025:** Semi-automated solution (Prodigy-based workflow)
- **Q1 2026:** Fully-automated solution (Prodigy-based workflow)
- **Q4 2026:** Automation of G-Rex bioreactor, incubators, and cell counting
- **Q3 2027:** Initial GMP deployment

Each milestone builds validated evidence toward full cleanroom integration and regulatory readiness for commercial manufacturing.

Made Scientific + Streamline Bio

AI-Driven Robotic Automation, Delivered in a GMP-Ready CDMO Environment

Made Scientific

- Fully integrated U.S.-based cell therapy CDMO, backed by GC Corporation
- GMP-ready execution, integration planning, and tech transfer
- 60,000 sq. ft. development & manufacturing facility — Princeton, NJ
- Commercial expansion underway
- Structured documentation practices aligned with GMP expectations

Streamline Bio

- AI-driven autonomous, modular robotics purpose-built for cell therapy
- Designed to integrate with existing equipment (CliniMACS Prodigy, G-Rex, LOVO)
- Validated in a live manufacturing setting at Made Scientific
- Progressing toward full GMP cleanroom integration

Together, deep CDMO manufacturing expertise paired with purpose-built AI robotics — with an Early Adopter Program now open for therapeutic developers advancing CAR-T programs from early to late phase.

Impact: Expanding CGT Manufacturing Capacity

Reduce Labor Burden

- Autonomous operation frees skilled personnel for higher-value tasks
- Training costs reduced by >80%

Remove Environmental Control Limitation

- Fewer operators in the room, with increased process capacity

Improve Manufacturing Reproducibility

- Consistent processes independent of operator variability
- Real-time data capture enhances batch-to-batch quality

Expand Access

- >50% cost reduction enables broader patient access
- Modular design supports decentralized manufacturing models

Learn More About the Early Adopter Program

Modular robotics are designed to integrate into existing infrastructure and support diverse equipment and protocols with minimal disruption.

- Standardize labor-intensive steps to reduce execution variability
- Improve traceability to support deviations, investigations, and comparability
- Enable repeatable workflows designed for scale-up and multi-suite deployment

Scan QR code to explore further:



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THANK YOU!