

# Enhancing the Rapid Manufacturing of CAR-T Cell Therapy Products with the Novel Cost-Effective Solution – GoFast™

Huiyu Wang, Silin Sa and Liping Yu, Applied Cells, Inc. Santa Clara, CA, USA



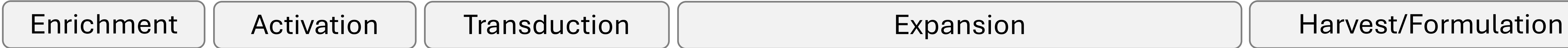
ISO 13485:2016



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Conventional Process: 1-2 weeks

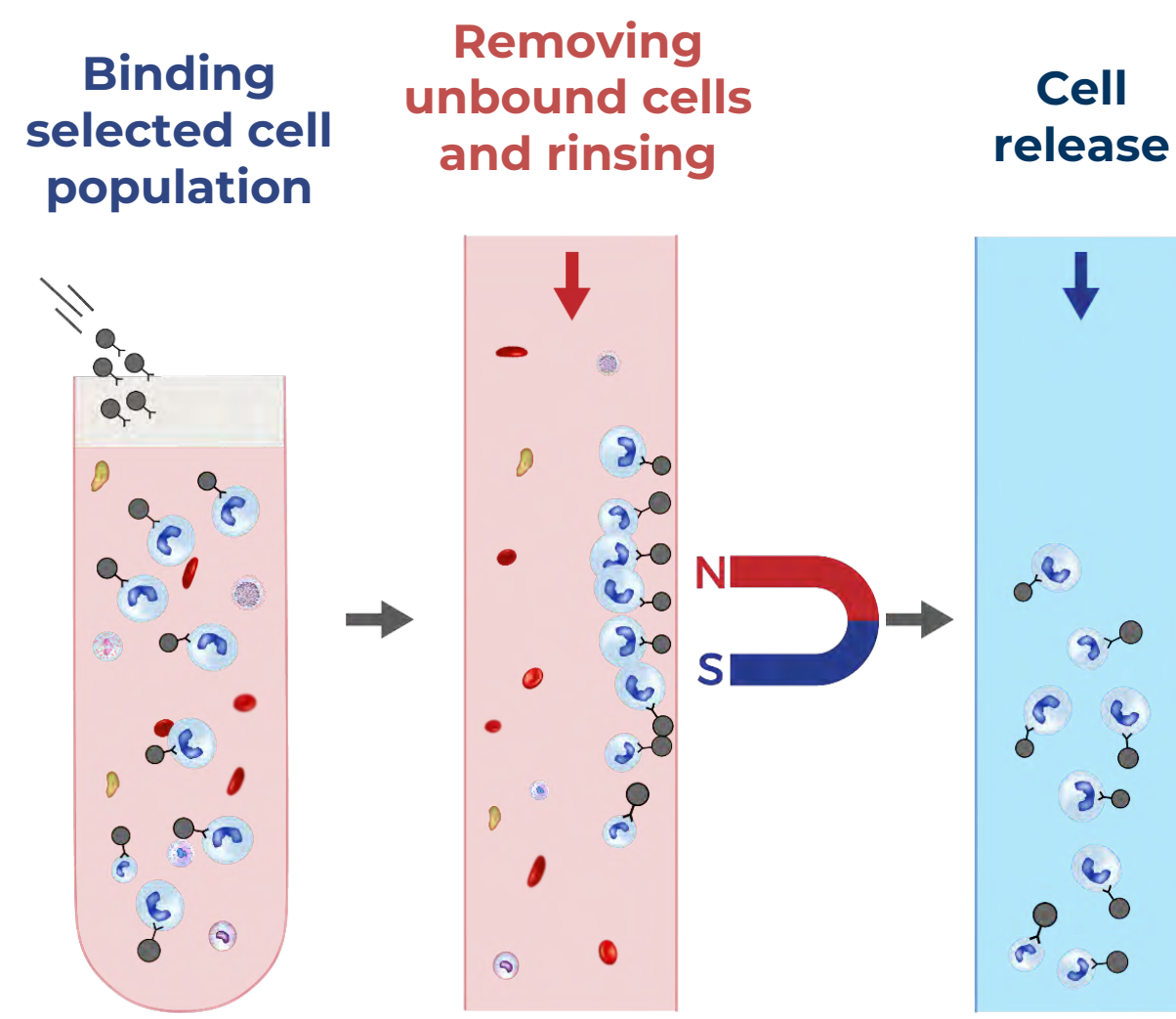


GoFast™ Process: less than 3 days



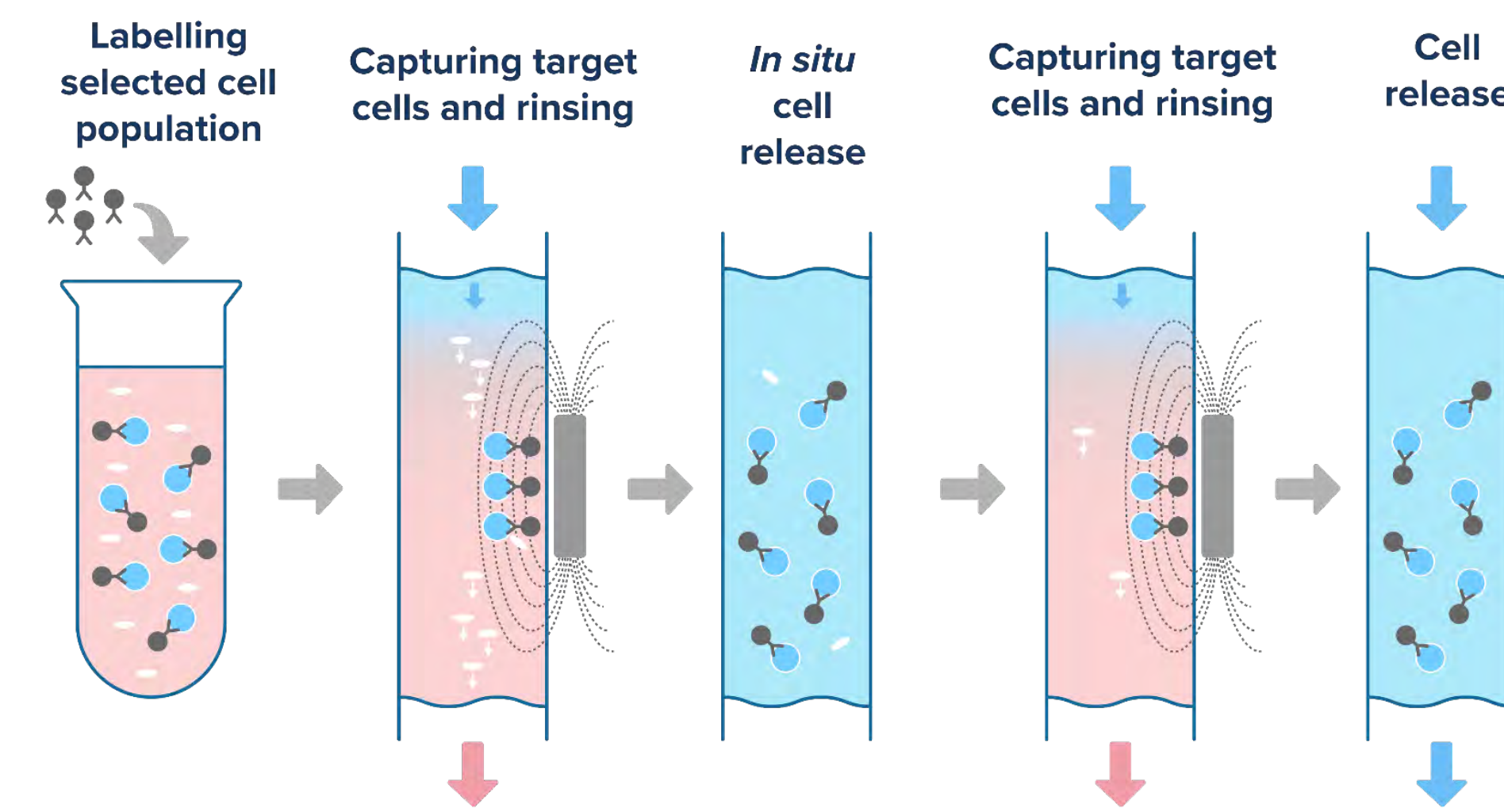
## TECHNOLOGIES

### Column-Free Magnetic Cell Separation



- COLUMN-FREE**  
Paired with 50nm GMP magbeads; closed single-use sterile fluidic tubing set
- AUTOMATED**  
Automated separation and release
- HIGH CAPACITY**  
No theoretical upper limit of maximum cell number
- FAST**  
Full LP (washed) finish in ~90min
- FLEXIBLE**  
Customizable to workflows to save time and cost, both positive and negative selections

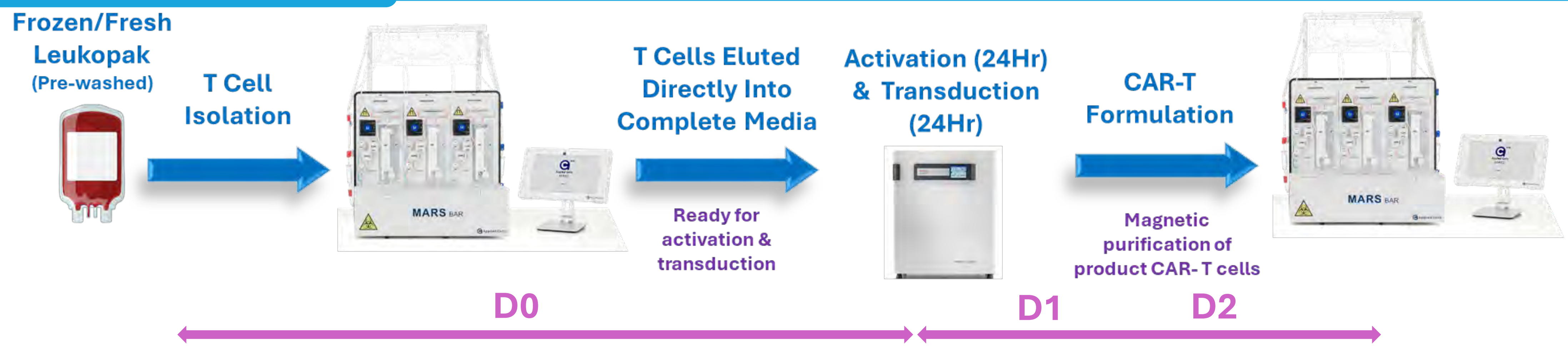
### MARS® In-Situ Rinse for even higher purity



- NO RE-RUNS**  
Single pass process for rare cells
- HIGH PURITY**  
Reliably achieving high 90%
- LOW RESIDUE**  
Effective B cell and viral vector removal

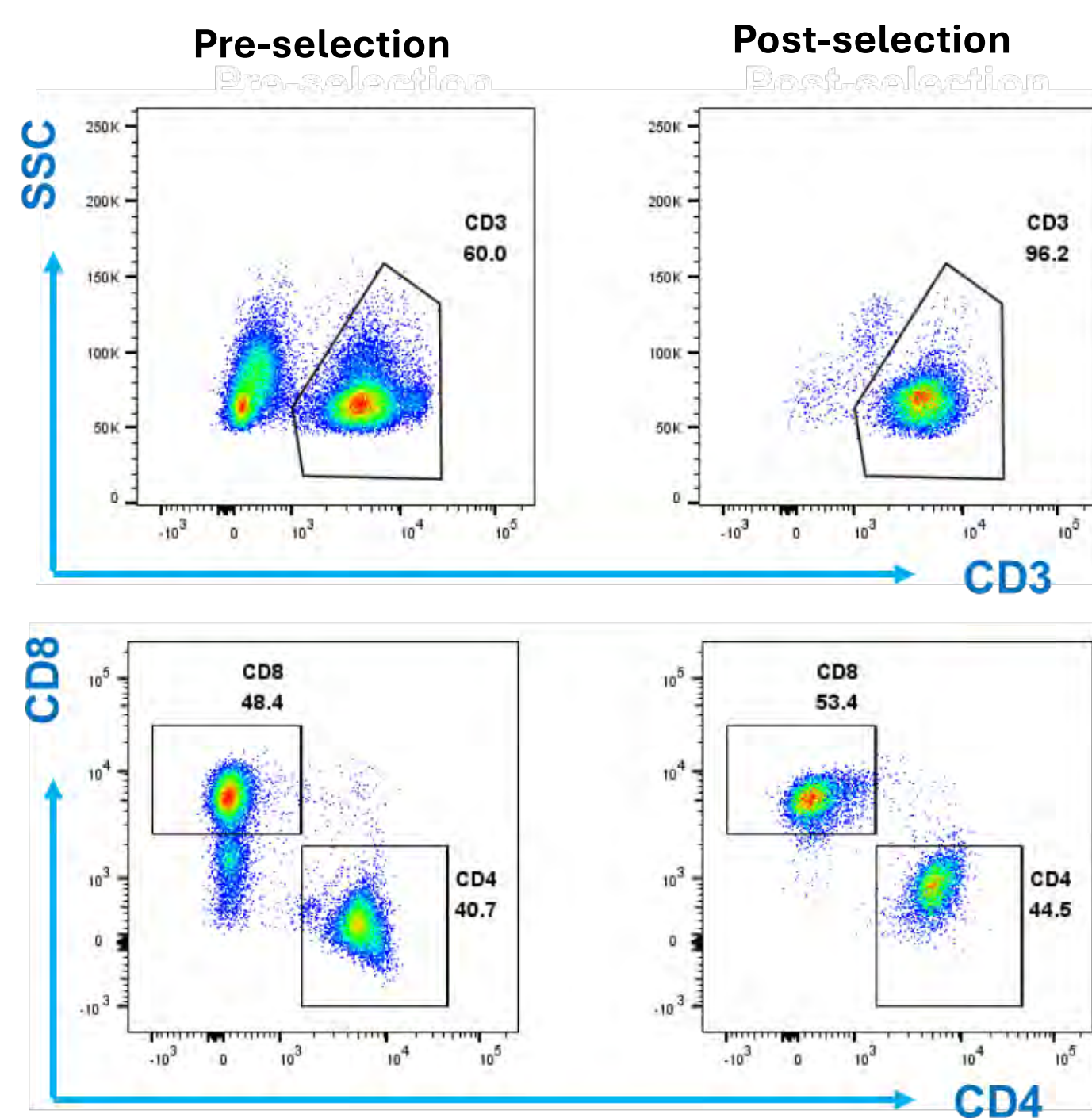
## GoFast™ PROCESS ON MARS® BAR

MARS® Bar enabling simplified GoFast™ CAR-T process: Only requires MARS® Bar and a bioreactor i.e., Grex



## RESULTS

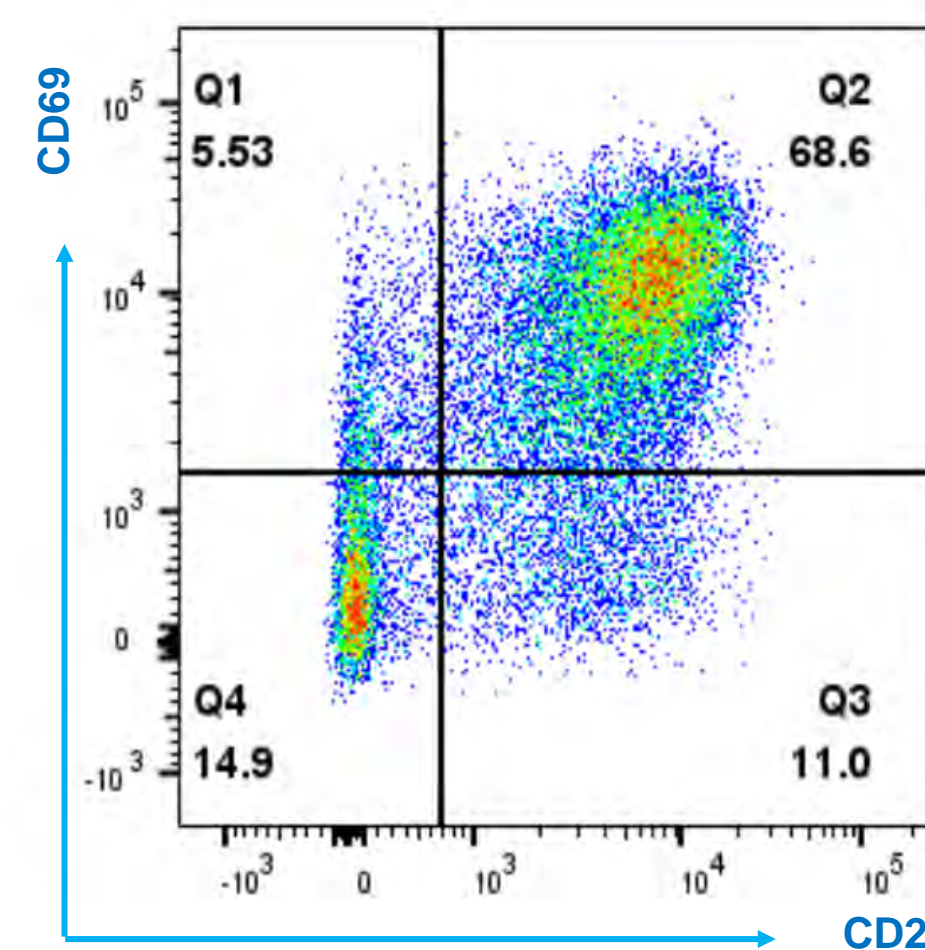
(Day 0) T cell selection from fresh leukopak using GMP CD4/CD8 nanobeads



### T Cell Isolation Time on MARS® Bar

Specifications	Full LP	½ LP	¼ LP
Pre-Label Volume	50 mL	25 mL	25 mL
Label Incubation Time	30 min		
Pre-MARS Volume	130 mL	65 mL	35 mL
<b>T Cell Selection Time</b>	<b>81 min</b>	<b>43 min</b>	<b>24 min</b>
Total MARS Time	92 min	54 min	35 min

(Day 0/1) T cell activation with CD3/CD28 nanobeads for 24hr

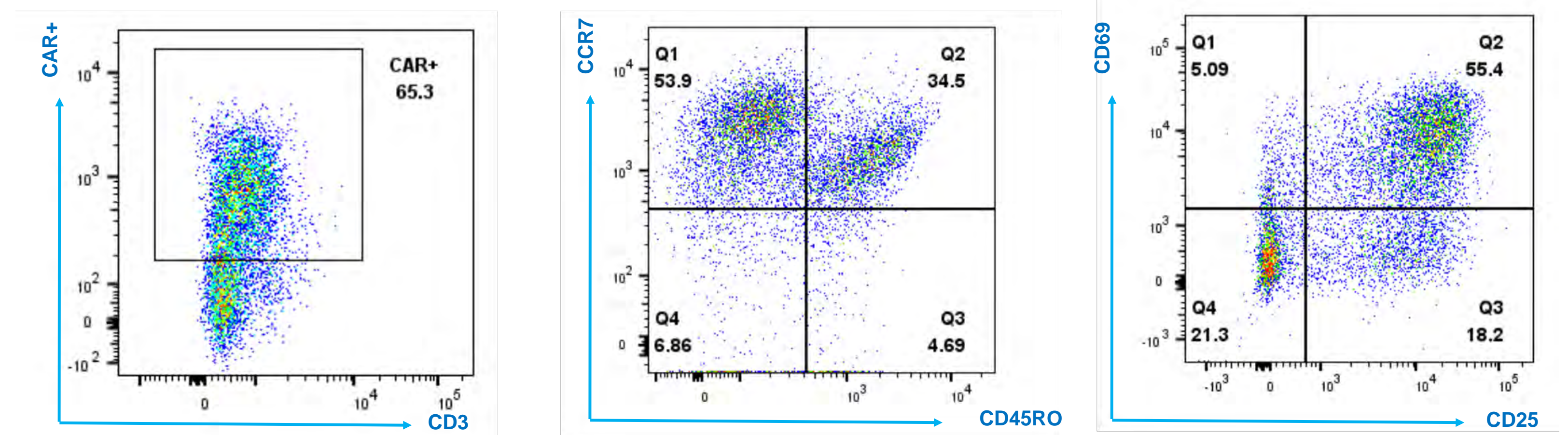


T cells show sufficient activation after 24hr

### Summary of the Results

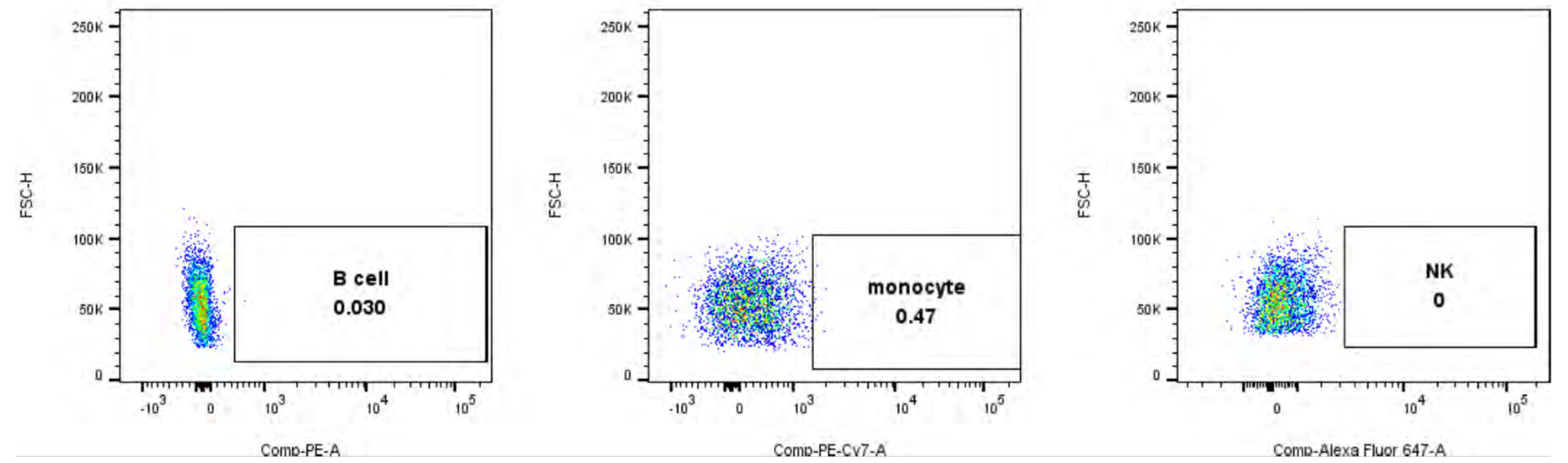
- Starting from 9.3E8 total cells (1/10 leukopak) isolated 2.1E8 T cells with 96% purity
- After 24 hour activation followed by 24 hour transduction, 65.3% T cells were CAR+
- Harvest process resulted T cell recovery >90%, virus residue < 1% and controlled elution volume

(Day 1/2) T cell transduction with CD19-CAR lentivirus for 24hr & CAR-T harvested



Phenotype Analysis of CAR T cells when harvested: CAR+ T cells ~ 65.3% and Naïve T cell or stem cell memory T cells ~ 88%

### More QC Results at Harvest – minimum contamination from other cell types



## DISCUSSIONS – BENEFITS OF MARS® Bar GoFast™ PROCESS

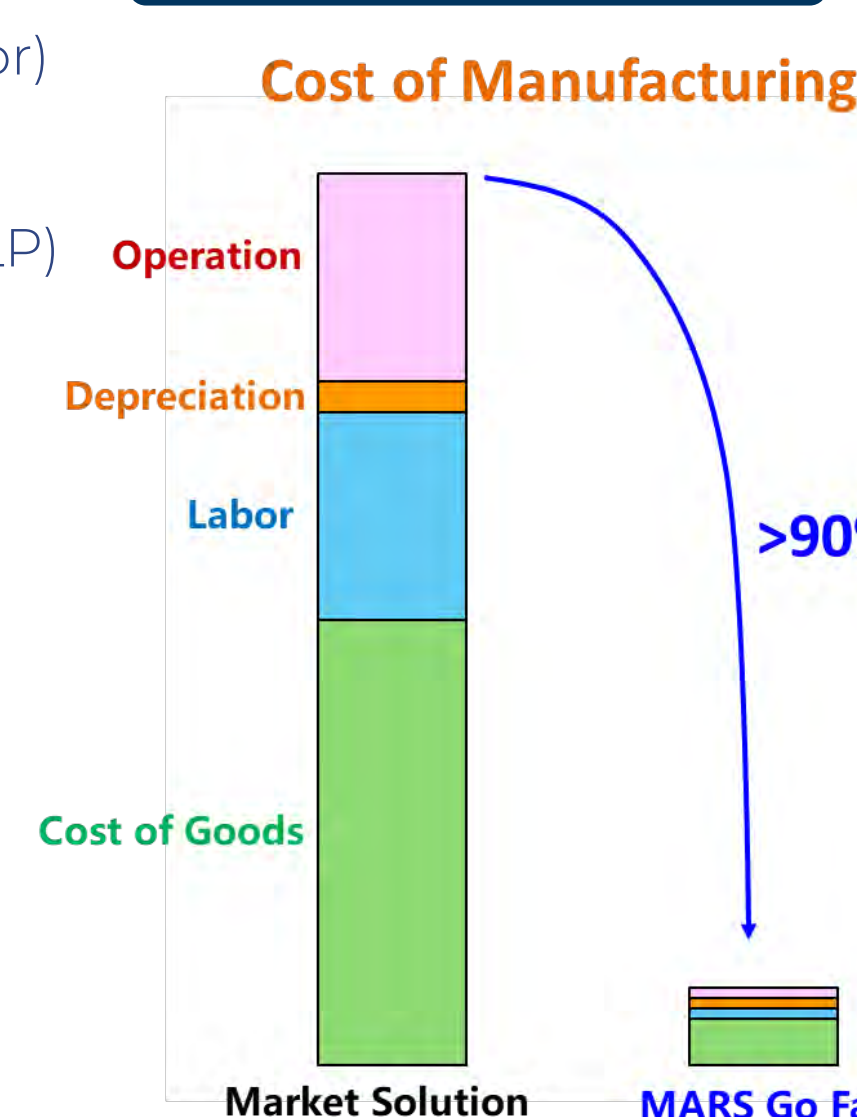
### Throughput

- Simpler workflow with minimal number of tools (MARS Bar → Bio-Reactor → Incubator)
- No occupation of cell selection platform
- Increased throughput : 4-5 full LP / MARS Bar / day (More if starting from ½ LP or ¼ LP)

### GMP Compliant

- 21CFR Part 11 with Audit Trail
- Sterile fluidics
- GMP Reagents (Low Cost)
- CE, UL, RoHS, REACH

### Cost Reduction



Visit ScaleReady booth to learn more of MARS® Bar

## OUR MARS® INTEGRATED SOLUTION FOR GoFast™ PROCESS



**MARS Atlas®**  
for Point-of-Care  
End-to-End  
GoFast™ CAR-T  
Manufacture

JOIN EARLY ACCESS PROGRAM

Learn more at  
[www.appliedcells.com](http://www.appliedcells.com)

