

# Sefia™ cell therapy manufacturing platform

Helping you deliver what's next in CART manufacturing







# Transforming cell therapy manufacturing

## Designed to meet demand — Sefia™ cell therapy manufacturing platform

When it comes to cell therapy manufacturing, you're not just in production. You're crafting hope for millions awaiting these breakthrough treatments. And excelling on this path to commercial realization craves the support of a platform made specifically for cell therapy manufacturing. A platform that not only provides flexibility and easy integration, but also promotes productivity and automates key steps of your workflow.

Introducing Sefia™ cell therapy manufacturing platform — a modular, digitally integrated platform to automate cell therapy manufacturing steps. Sefia platform combines two functionally closed systems: Sefia Select™ system to automate cell isolation, harvest, and formulation steps, and Sefia™ expansion system to automate cell activation, transduction, and cell expansion steps.

Break away from asking "what if"... it's time to get after what's next.



# Cytiva and Kite collaboration

The Sefia™ platform has been developed as part of a collaboration with Kite, a Gilead Company, a global leader in autologous CAR T cell therapies.

“

In cell therapy manufacturing, innovation and flexibility are key to ensuring that all eligible patients are getting the therapies they need as quickly as possible. As the global leader in cell therapy, Kite is proud to be on the forefront of cell therapy automation and to be part of a collaboration with Cytiva that developed the Sefia platform. Implementation of the Sefia platform enables us to increase efficiencies and produce CAR T Cell therapies at a global scale.

*Chris McDonald, SVP, Global Head of Technical Operations, Kite*



# Explore Sefia platform

## An end-to-end cell therapy solution >

From starting sample to final doses



The  
benefits >



A helping  
hand >

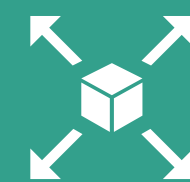


# Gain confidence in delivering your cell therapy to patients

Sefia platform helps take your cell therapy manufacturing to the next level



**Streamlined  
end-to-end  
manufacturing**



**Flexibility to  
meet your  
process needs**



**Increased  
productivity  
at commercial  
scale**



**Features  
designed to  
reduce batch  
failure risk**



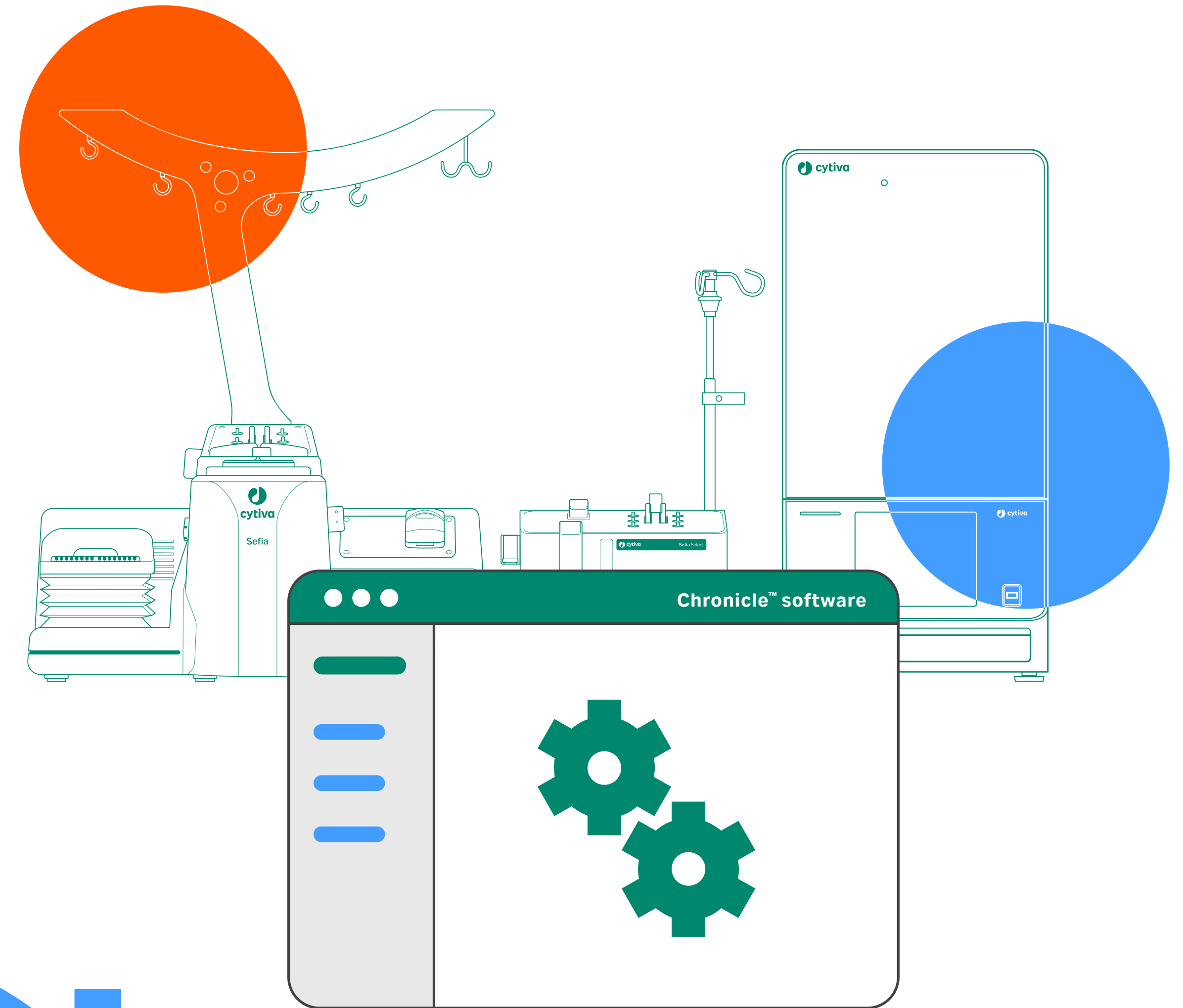
**Easy  
integration**



# Streamlined end-to-end manufacturing

## Automate manufacturing steps with the digitally integrated and functionally closed systems

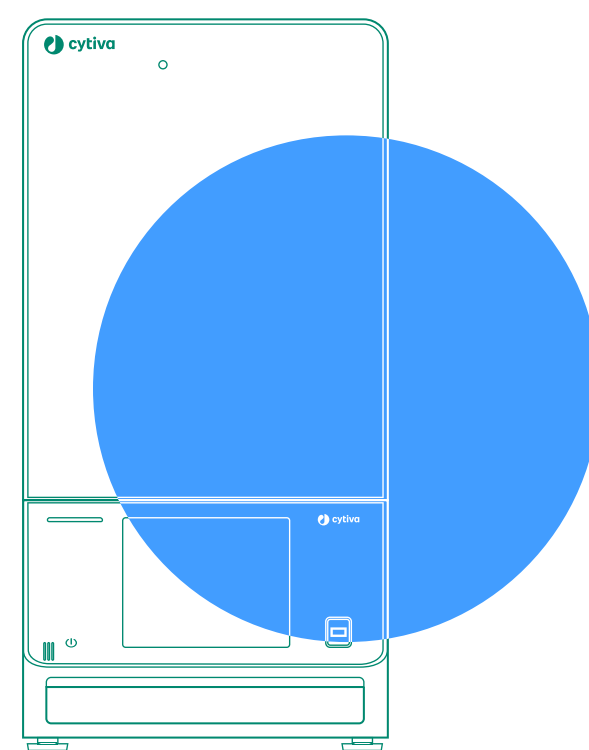
As part of your cell therapy manufacturing, Sefia Select system automates cell isolation, harvest, and formulation steps, while Sefia expansion system automates cell activation, transduction, and cell expansion steps.



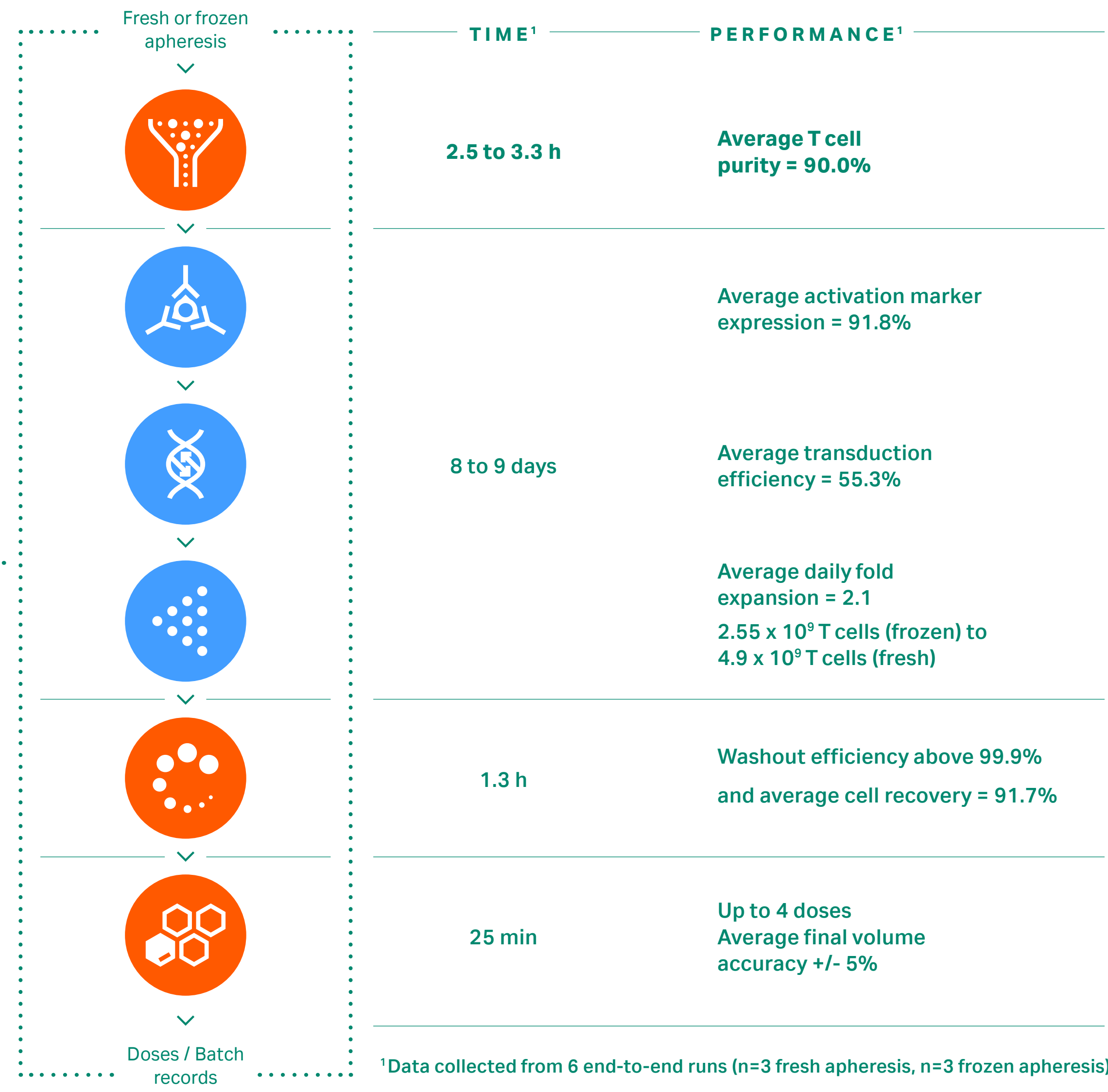
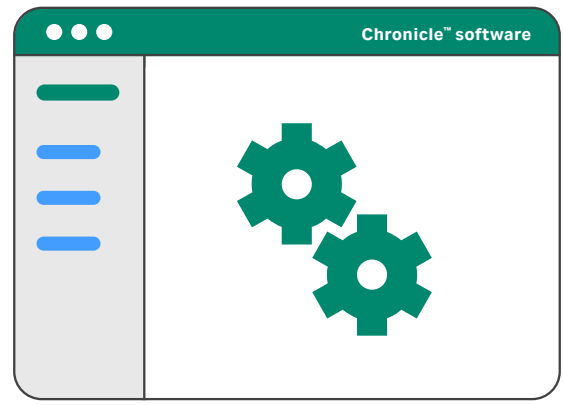




Sefia Select™ system



Sefia™ expansion system



<sup>1</sup>Data collected from 6 end-to-end runs (n=3 fresh apheresis, n=3 frozen apheresis)

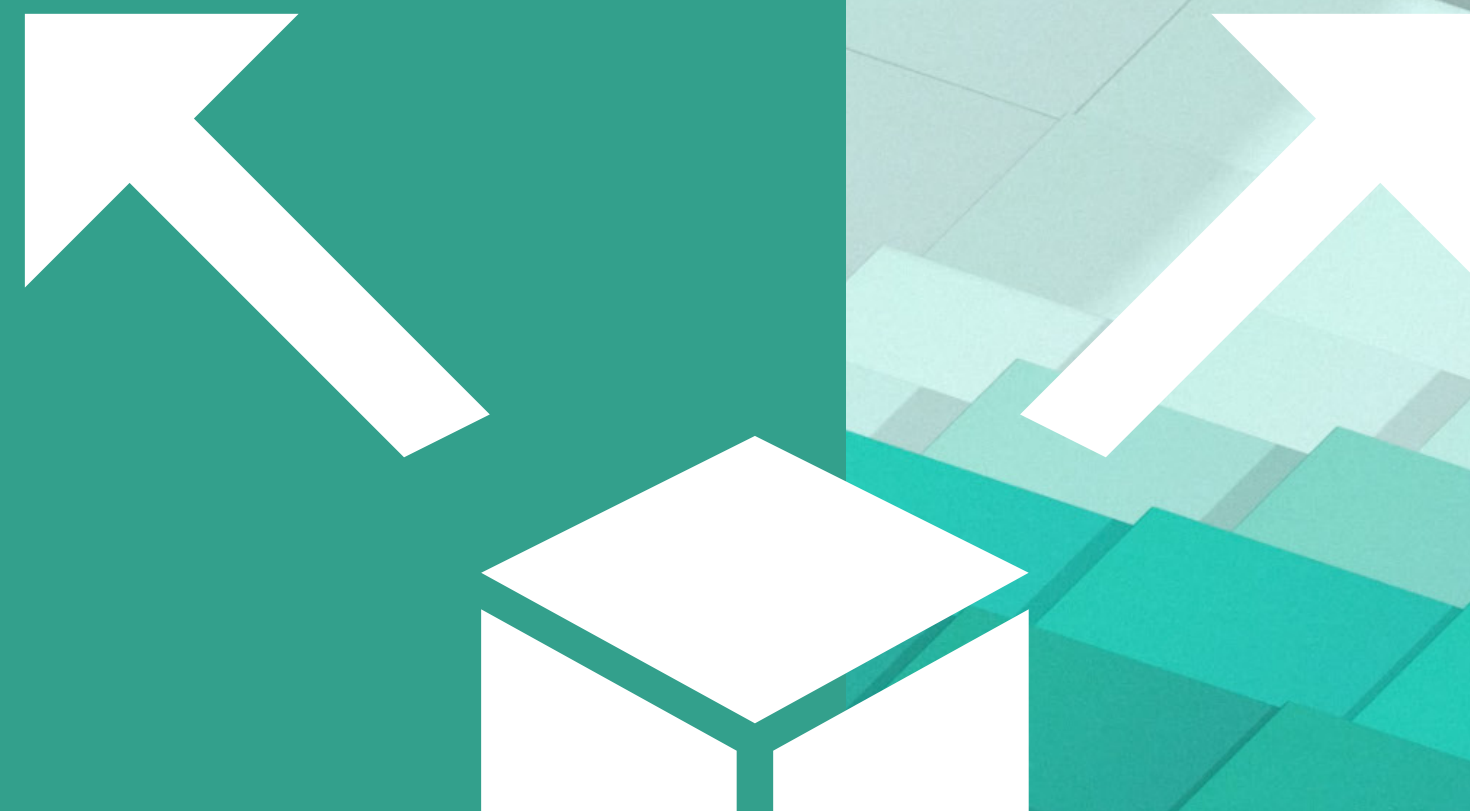




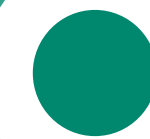
# Flexible platform that meets your process needs

## Leverage a platform that adapts to — and with — your process

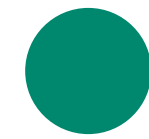
The flexibility provided by the consumables, different applications, and parameters permits Sefia platform to accommodate the variability of initial products as well as the specificity of your current process.



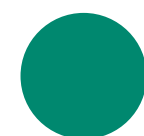




Versatile system with multiple applications to cover CAR T workflow key steps



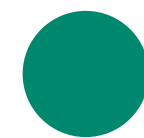
Configurable by the user with large parameter range setting for each application



Parameters are open and can easily be changed by the user, then locked based on user profile permissions



High reproducibility even with variable cell composition of input products



Compatibility with multiple culture media, activators and viral vectors (lentivirus and retrovirus)

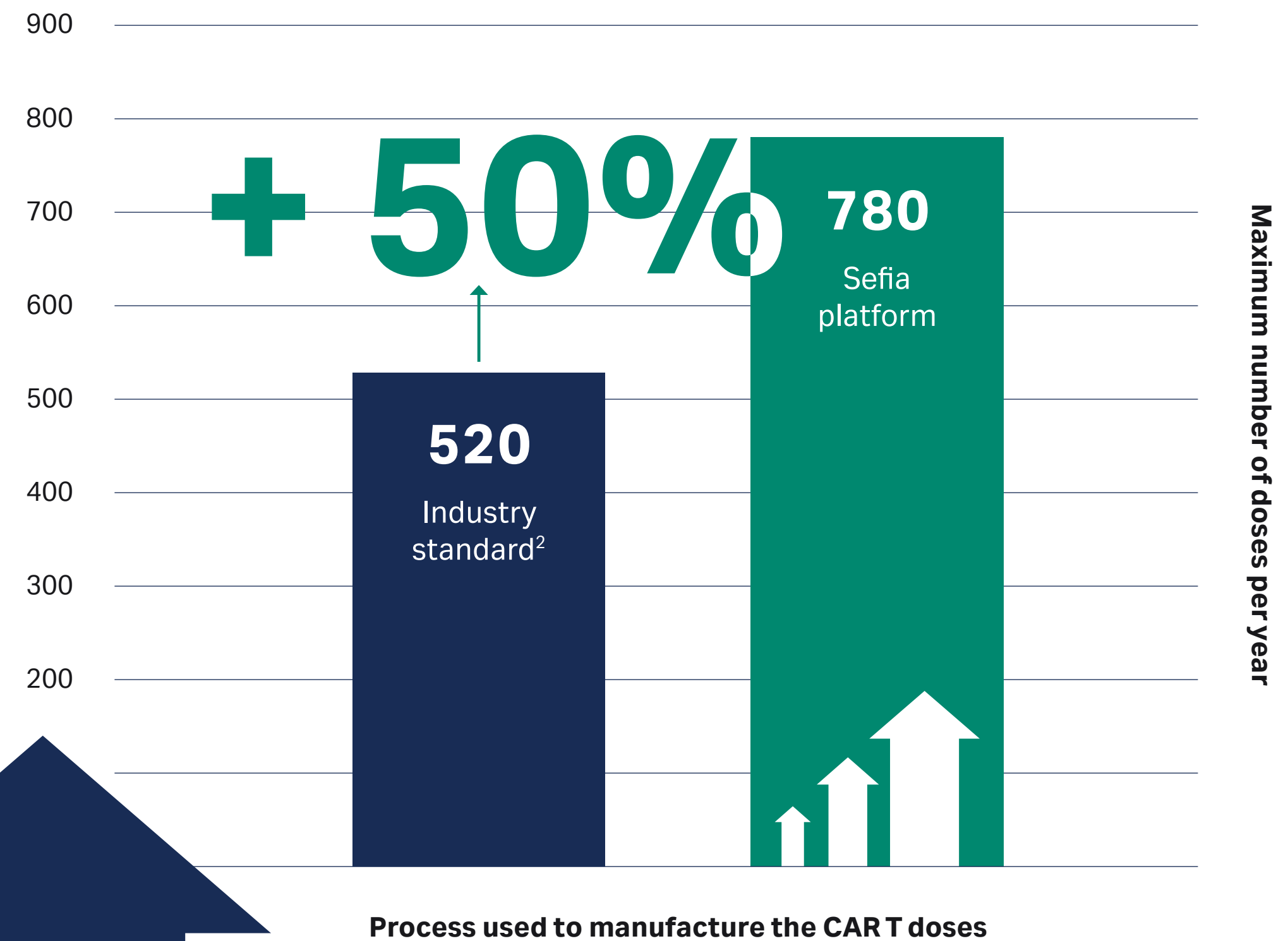


# Increase productivity at commercial scale

Experience up to a 50% increase in manufactured doses per year as compared to industry-standard processes, ultimately driving a reduction in cost burden<sup>2</sup>

- Optimize your equipment usage and facility space with a modular approach
- Leverage automation in your cell therapy manufacturing process to reduce labor costs when scaling out

## Doses per year produced in 100 m<sup>2</sup> cleanroom



<sup>2</sup>semi-automated process using multiple and disconnected systems to cover the full manufacturing workflow

All data referenced in this section regarding materials, equipment, media, process suite utilization, size requirements, operator productivity, and labor requirements has been determined using process economic modeling, public website information, vendor specifications, and insights provided by relevant subject matter experts and external consultation.



The following table shows that as you manufacture your cell therapy doses, Sefia platform can help optimize both facility size and the number of required operators as you scale out to commercial.



Facility size (m²)

Doses per year	250	1000	2500
Industry-standard process <sup>2</sup>	45	179	446
Sefia platform	30	119	297

Operators required

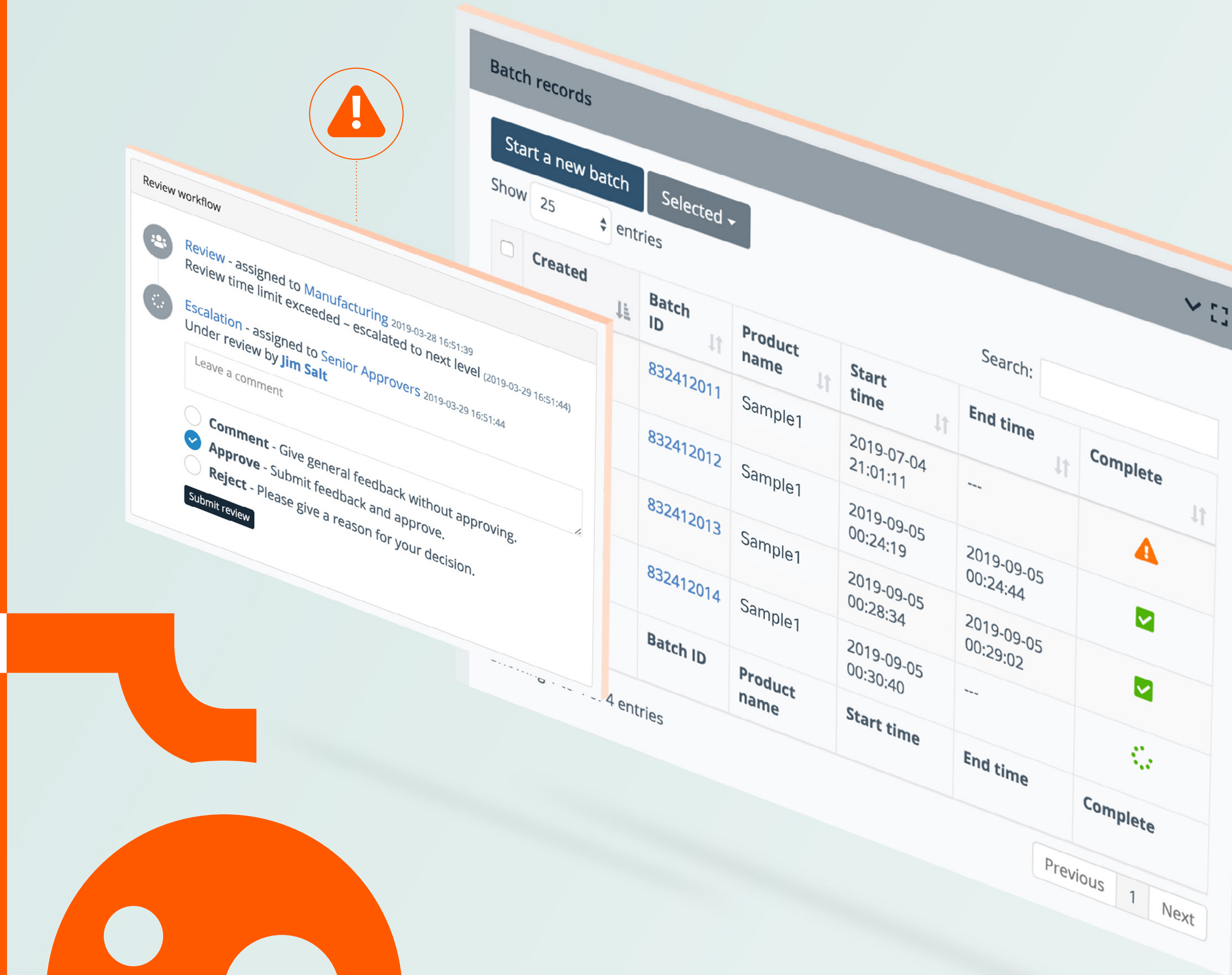
Doses per year	250	1000	2500
Manual process	34	136	338
Industry-standard process <sup>2</sup>	18	72	178
Sefia platform	12	42	102

<sup>2</sup>semi-automated process using multiple and disconnected systems to cover the full manufacturing workflow



# Features designed to reduce batch failure risk

Reduce operator-derived errors via the platform's functionally closed design and automated capabilities. Monitor system performance with device functionality pre-checks, alarm notifications, and comprehensive batch reports.





# Batch failure risks



Contamination

Product out of  
specification

Material failure

Equipment failure

Operator error



Functionally closed

Process monitoring

Automatic cell  
recovery

Diagnostic tool and  
kit integrity

eSOPs





# Easy integration

**Be supported in your move to GMP manufacturing with a regulatory document package for easy process changes. Plus, enjoy smooth platform integration with onboarding and training services.**



## ~~Task 24~~

Tap the arrow next to the parameter group name to proceed with the selected parameters


Sefia

S-Wash v102



← Applications

Parameters

Kit Installation

Traceability

Summary

Kit Test


Parameters

Default
Showing 12 of 20 parameters

Dilution volume	440	ml	Enable dilution temperature	No	
Dilution temperature	4	°C	Post-dilution manual mixing	No	
Dilution mix time	00:00	mm:ss	Dilution rate	17	ml/min
Initial line priming with product	20	°C	Enable process temperature	No	
Process temperature	No	°C	Enable input bag rinsing	No	
Input bag rinsing volume	50	ml	Input bag rinsing manual mix	No	

View all

Chronicle
 S-wash v102


SN 1234 5W v2.0.1

8/30/2023 11:51:30

## Complete

~~Task 25~~

Tap **Next** on each of the additional screens to proceed to the kit installation screen or **Back** to return to the **Parameters** screen




Parameters

Kit Installation

Traceability

Summary

Kit Test



Kit installation guidance (Page 1/2)

Ensure that you have closed all the clamps on the kit before connecting any bag. Perform the following actions:

1. Insert the separation chamber in the centrifuge tower and close the covers tightly.
2. Insert the chamber line in the left optical sensor.
3. Insert the cassette in the holder.
4. Tightly screw the air filter on the left air sensor.

Back

Next

Chronicle
S-wash v102

SN 1234 SW v2.0.1

8/30/2023 11:51:30 AM

## Complete

### ~~Task 26~~

Before opening the blister pack, check the following points:

- Verify the integrity of the packaging.
- Verify the kit reference on the label.

If the kit reference is not passed.

• If the Tyvek® cover is green and the text is visible.

• If the kit is sterilized by exposure to EtO. If the sterility indicator is not green, contact Cytiva.

**cytiva** **Sefia™** Cell Processing Kit

For use with Sefia Platform on

**REF** 29656477

**CT-200.1**

**LOT** CT20012301A01

**SN** 1234567

204-07-01

STERILE FLOW

⚠️ ⚠️ ⚠️ ⚠️ ⚠️ ⚠️

## Complete





# Adopting a new technology requires time, resources and money

Sefia platform support includes: the changes to the process, on-boarding the operators, the regulatory compliance and change to the facility.



## Process

Our field application specialists (FAS) are here **to support you throughout your integration** of the Sefia platform and beyond.

With Fast Trak™ process development, Cytiva can develop a **robust, scalable process and improve productivity** by optimizing a single-unit operation or the entire process.



## Operators

Save operator time and increase reproducibility thanks to **eSOPs on Chronicle software**.

**User-friendly design**– with color-coded single-use kits and kit installation guidance.



## Regulatory

Compliance with quality requirements such as **ISO 9001, CE, GAMP 5 and FDA 21 CFR Part 11**.

Product documentation on **regulatory support portal**.

**OptiRun™** service solution supporting product's life cycle.



## Facility

Centralized creation and deployment of parameter groups and eSOPs over sites

Process design service to determine size of facilities and define required resources.



# Sefia™ platform

A modular solution to cell therapy



Apheresis



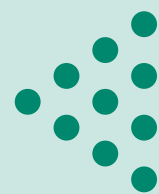
Isolation



Activation



Gene transfer



Expansion



Harvest



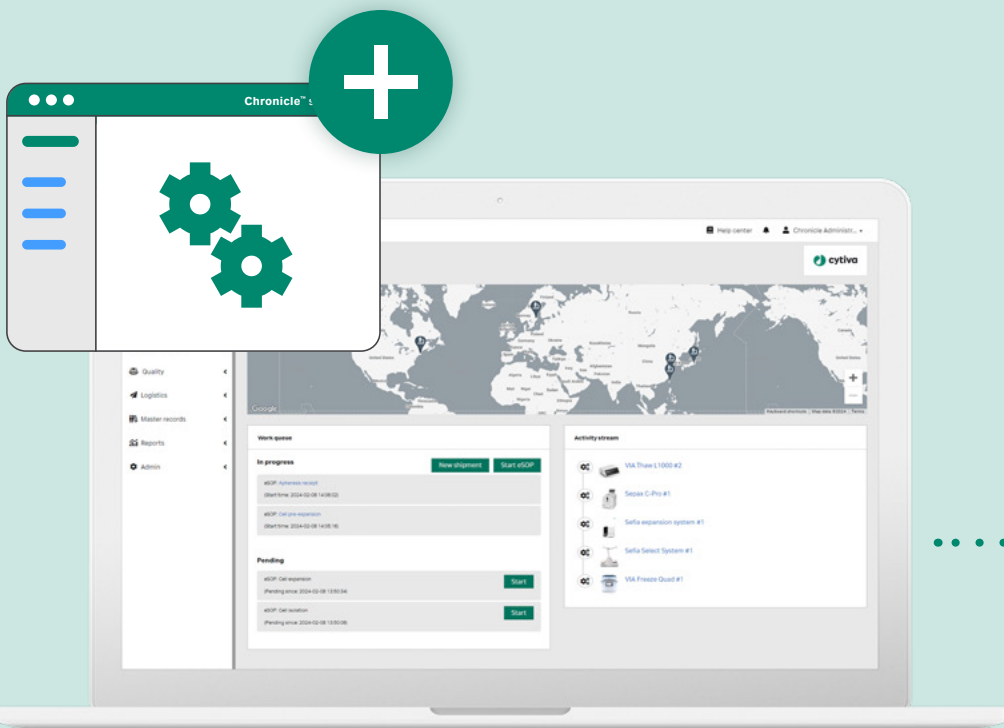
Formulation



Cryopreservation



Final doses



Chronicle™ software >



Sefia Select™ system >



Sefia™ expansion system >



# Sefia™ platform

A modular solution  
to cell therapy



Apheresis



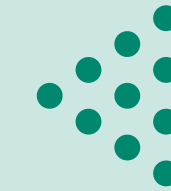
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Gene transfer



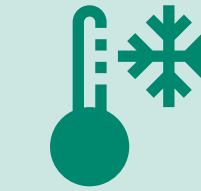
Expansion



Harvest



Formulation



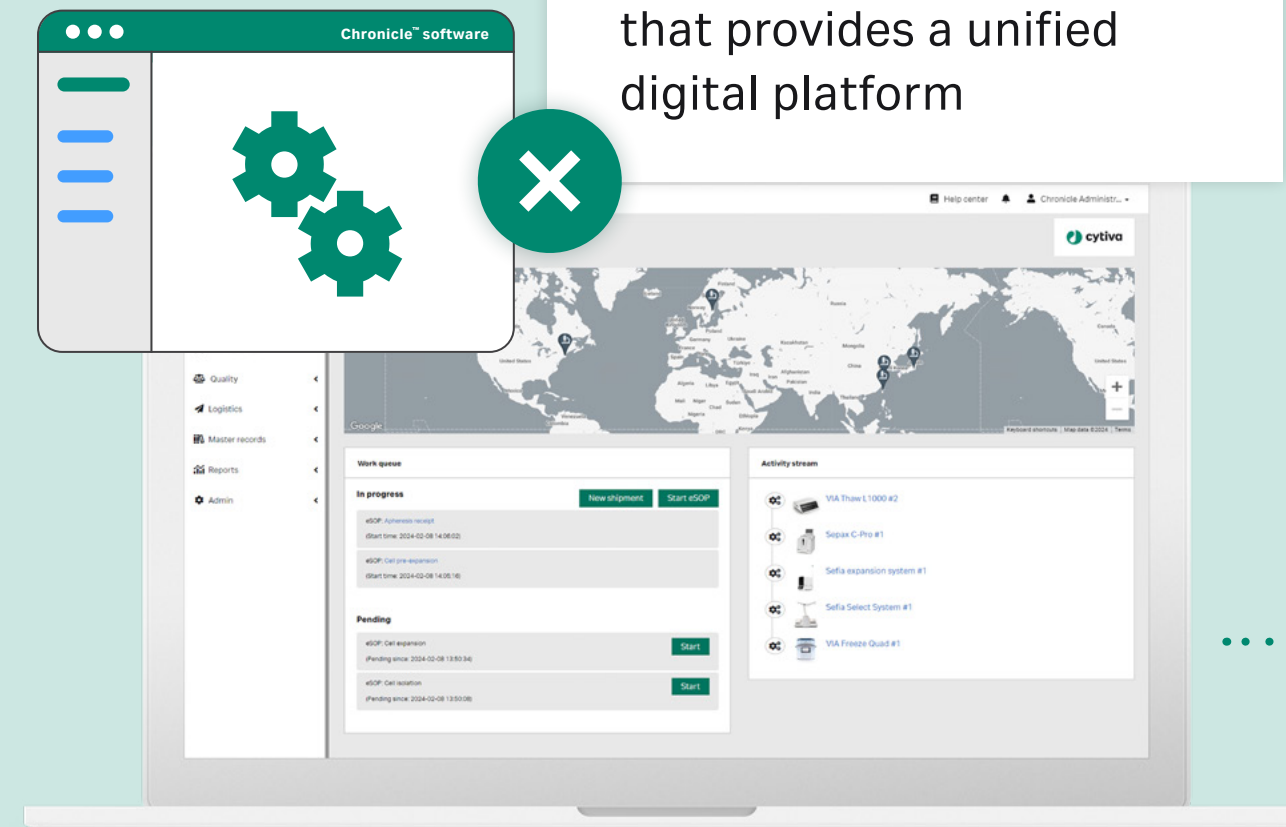
Cryopreservation



Final doses

## Chronicle software

Monitor your facility's  
manufacturing operations  
and supply chain logistics  
with automation software  
that provides a unified  
digital platform



**Chronicle™ software** >



**Sefia Select™ system** >

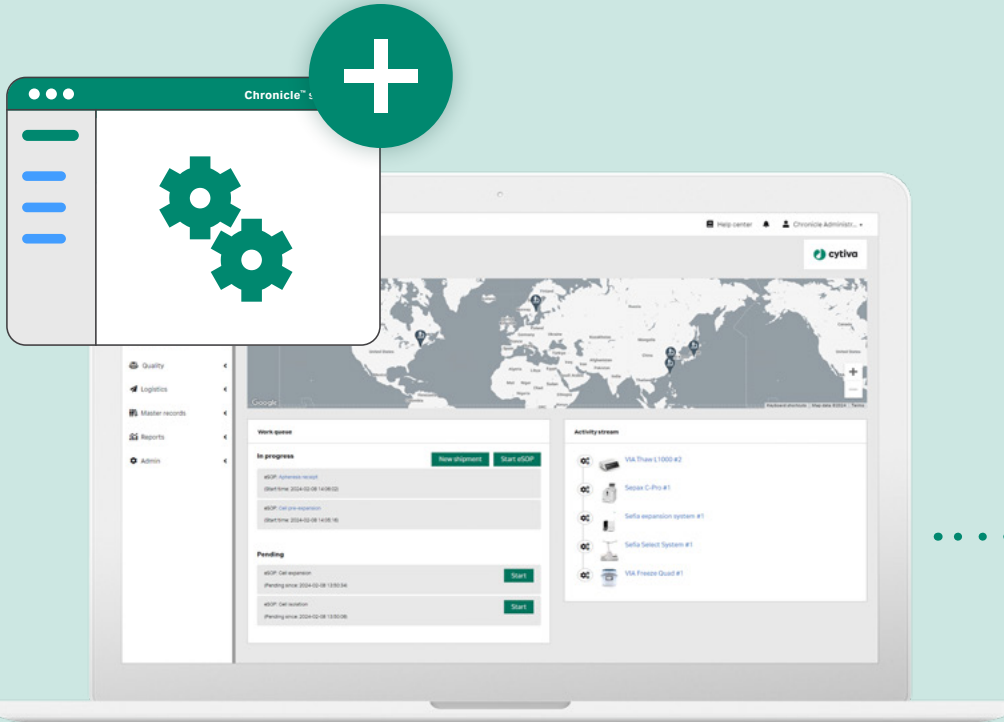


**Sefia™ expansion system** >



# Sefia™ platform

A modular solution to cell therapy



Chronicle™ software >



Sefia Select™ system >



Sefia™ expansion system >



# Sefia™ platform

A modular solution to cell therapy



Apheresis



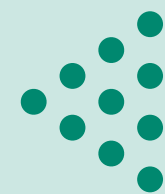
Isolation



Activation



Gene transfer



Expansion



Harvest



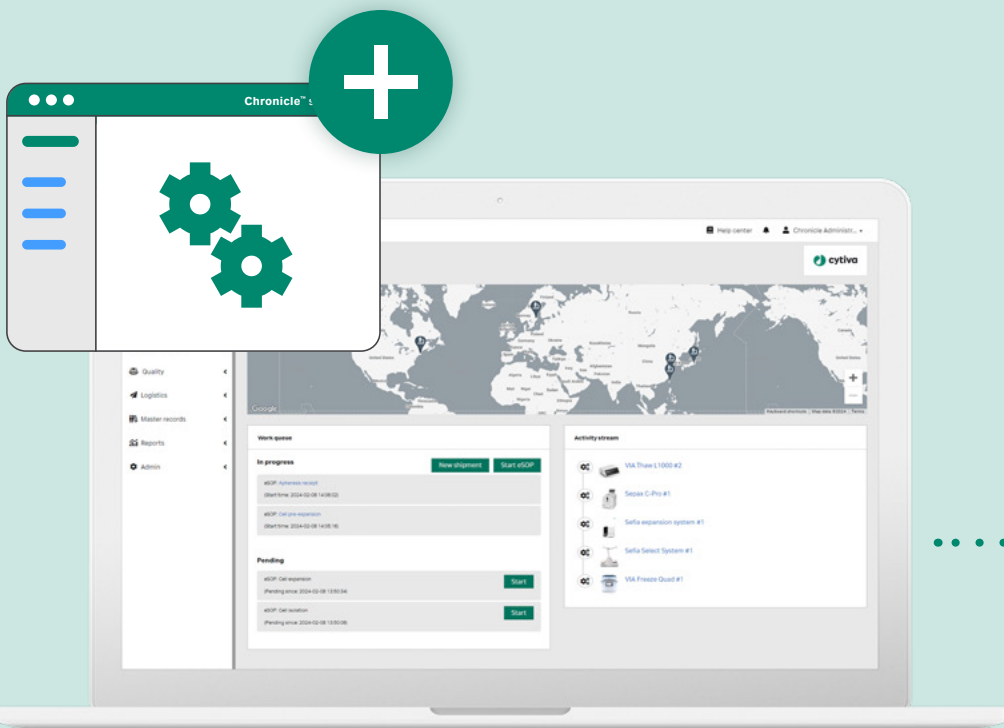
Formulation



Cryopreservation



Final doses



Chronicle™ software >



Sefia Select™ system >



### Sefia expansion system

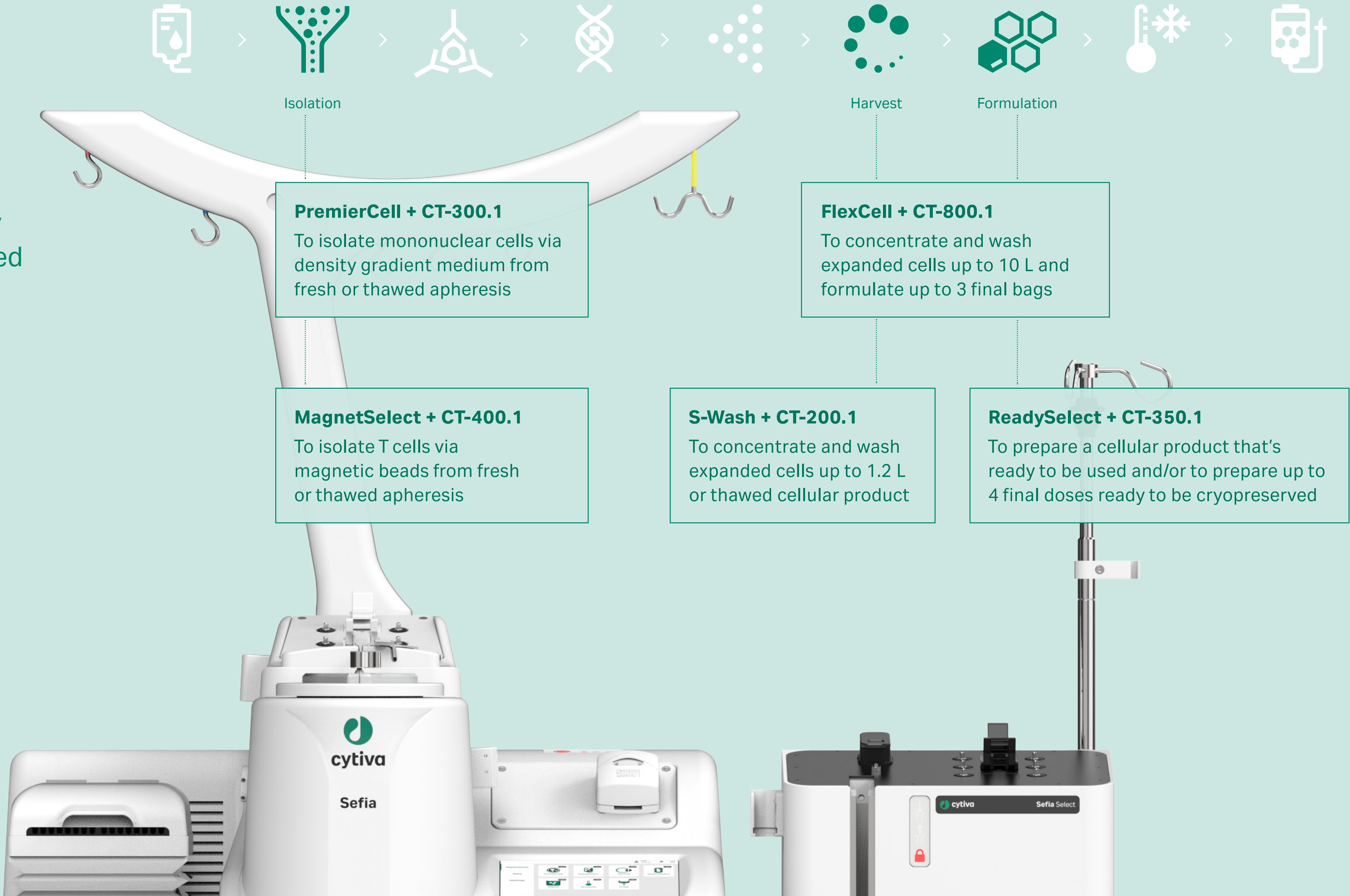
Optimize resources by combining three consecutive steps of your workflow — cell activation, transduction, and cell expansion — in a single procedure with this system

Sefia™ expansion system >



# Sefia Select system

Automated and functionally closed system with dedicated applications and single-use kits for greater flexibility, efficiency, and security.





# Performances<sup>4</sup>

MagnetSelect	Fresh healthy donor	Fresh Patient model	Frozen healthy donor
Initial total white blood cells	14 × 10 <sup>9</sup>	30 × 10 <sup>9</sup>	5 × 10 <sup>9</sup>
Initial percentage of T cells	56%	2.5%	61%
Initial percentage of B cells	12%	95%	13%
Typical processing time	2.5 h	3.5 h	3 h
Average T cell recovery	76%	72%	63%
Average T cell purity	90%	89%	92%
Average cell viability drop	1%	1%	3%
Average platelet depletion	99%	n/a	n/a
Average red blood cell depletion	94%	n/a	n/a
Standard deviation for final volume	± 3.2 mL	± 3.2 mL	± 3.2 mL

FlexCell	Values
Typical processing time	2 h
Average cell recovery	80%
Average cell viability loss	3%
Standard deviation for final volume	± 3.2 mL

<sup>4</sup>Indication only as performances depend on user and cellular product configuration



PremierCell	Values
Typical processing time	2 h
Average cell recovery — Lymphocytes — Monocytes	55% 55%
Average platelet depletion	92%
Average red blood cell depletion	86%
Average cell viability loss	7%
Standard deviation for final volume	± 4.3 mL

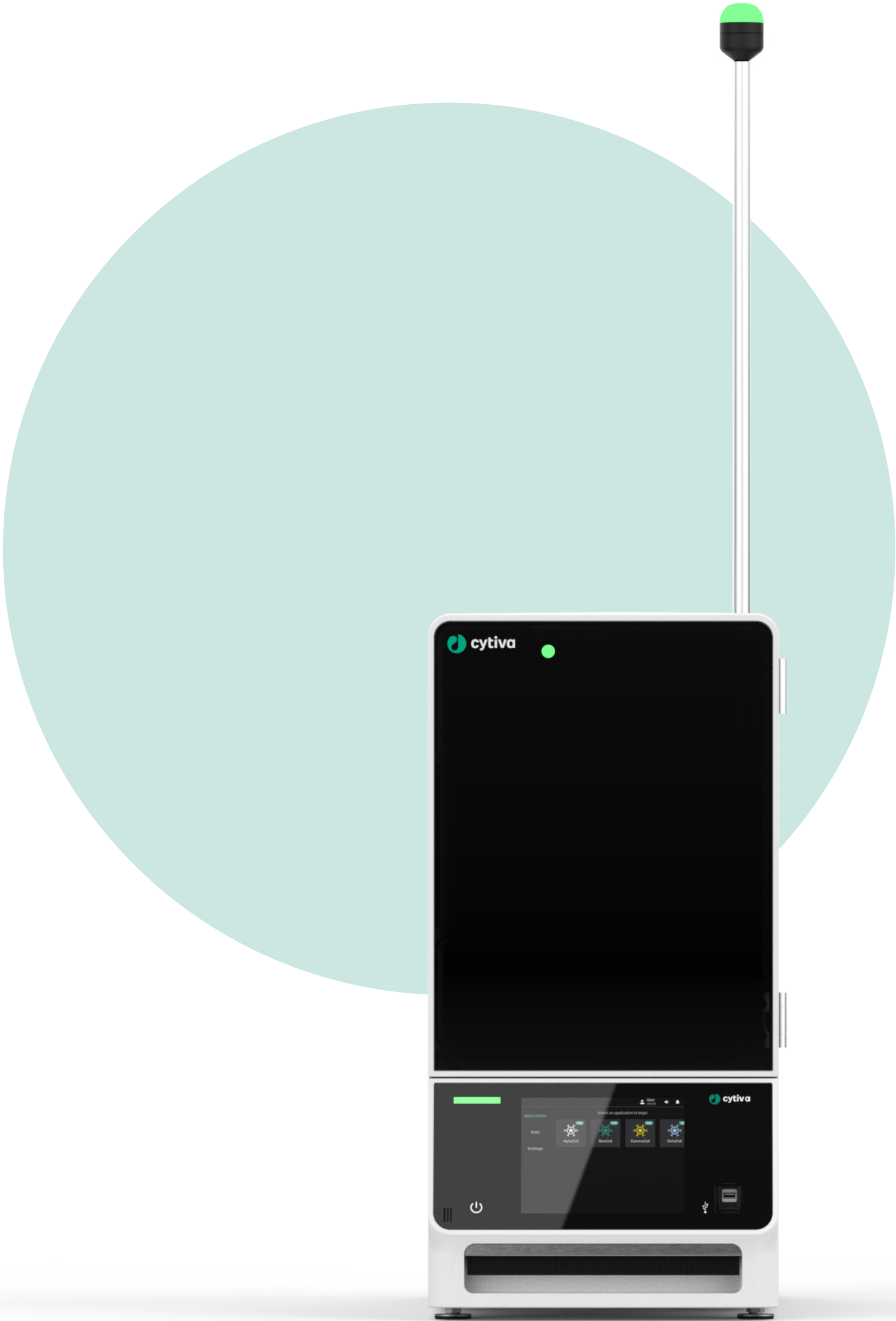
S-Wash	Values
Typical processing time	1.5 h
Washout efficiency	4 log
Average cell recovery for expanded cells	98%
Average cell recovery for thawed cells	87%
Average cell viability loss	3%
Standard deviation for final volume	± 3.6 mL

ReadySelect	Values
Average final volume accuracy	98%
Average cell repartition accuracy	96%
Average cell recovery	96%
Average cell viability loss	2%





CLICK TO  
VIEW ANGLES



# Sefia expansion system

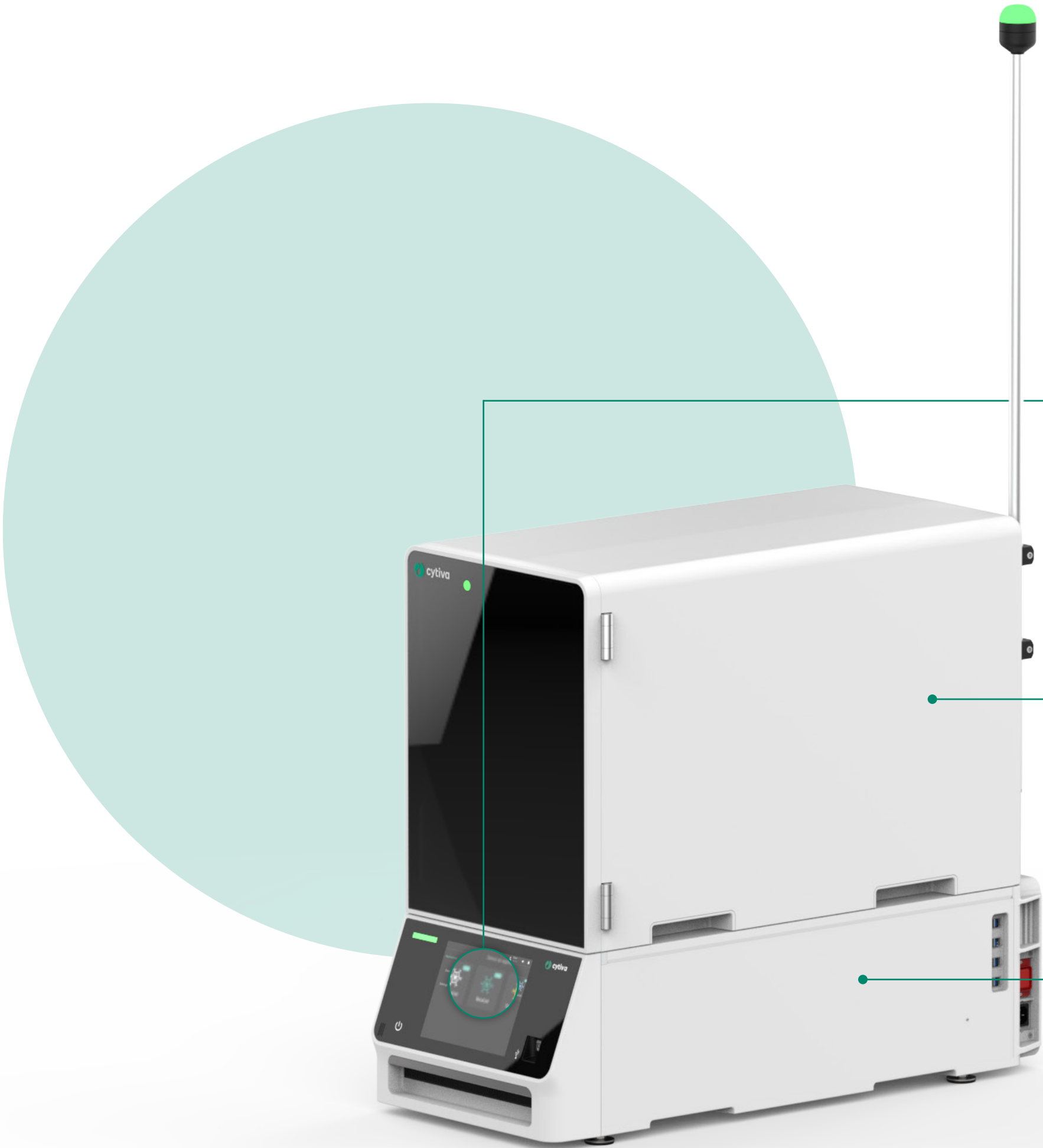
An automated system that covers cell activation, transduction, and expansion in autologous cell therapy manufacturing for regulatory compliance, reproducibility, and cost-efficiency.







CLICK TO  
VIEW ANGLES



Universal application offers high flexibility **with customizable parameters** that allow operators to optimize activation, transduction, and expansion steps

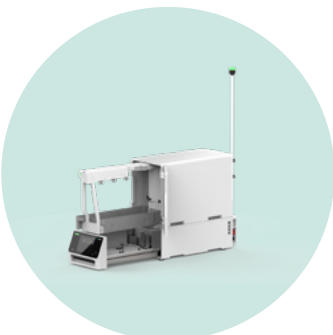
Sefia expansion system can be used with your **current reagents and media** as well as various types of viruses (lentivirus or retrovirus)

Two culture vessels with fluorinated ethylene propylene (FEP) or silicone membrane to fit your needs



While the Sefia expansion system is a leading cell therapy solution with broad capabilities, Cytiva has not validated and verified all workflows or use cases.





CLICK TO  
VIEW ANGLES



Harvest bag  
up to 1.2 L

Initial cellular product  
between 5 to 250 mL

Sampling lines to collect  
samples during the run

Static culture supported by batch,  
fed-batch, and perfusion methods

Temperature and CO<sub>2</sub> control and  
monitoring

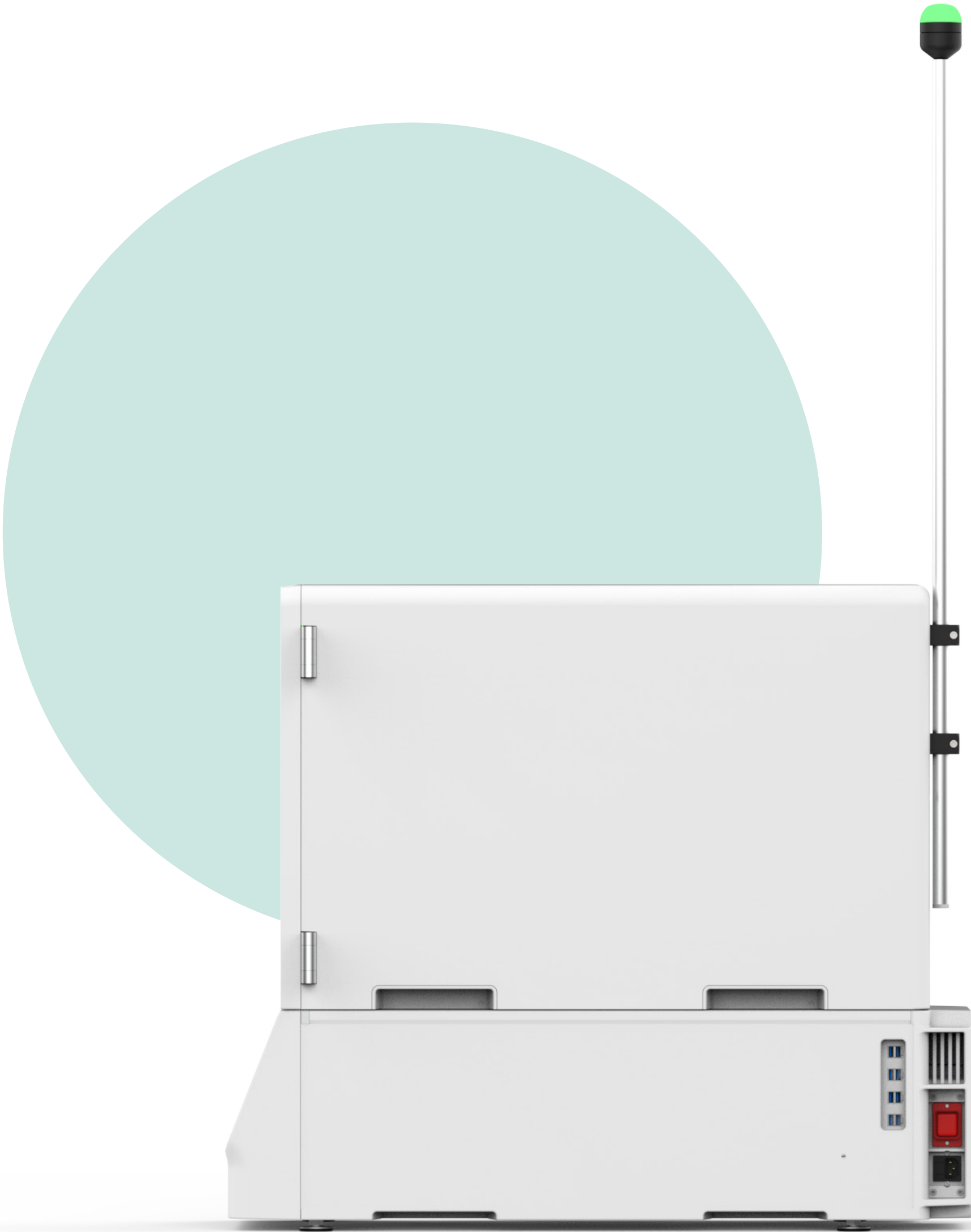
Typical processing duration: 5 to 12 days



While the Sefia expansion system is a leading cell therapy solution with broad capabilities, Cytiva has not validated and verified all workflows or use cases.



CLICK TO  
VIEW ANGLES



# Sefia expansion system

An automated system that covers cell activation, transduction, and expansion in autologous cell therapy manufacturing for regulatory compliance, reproducibility, and cost-efficiency.





Performances<sup>5</sup>

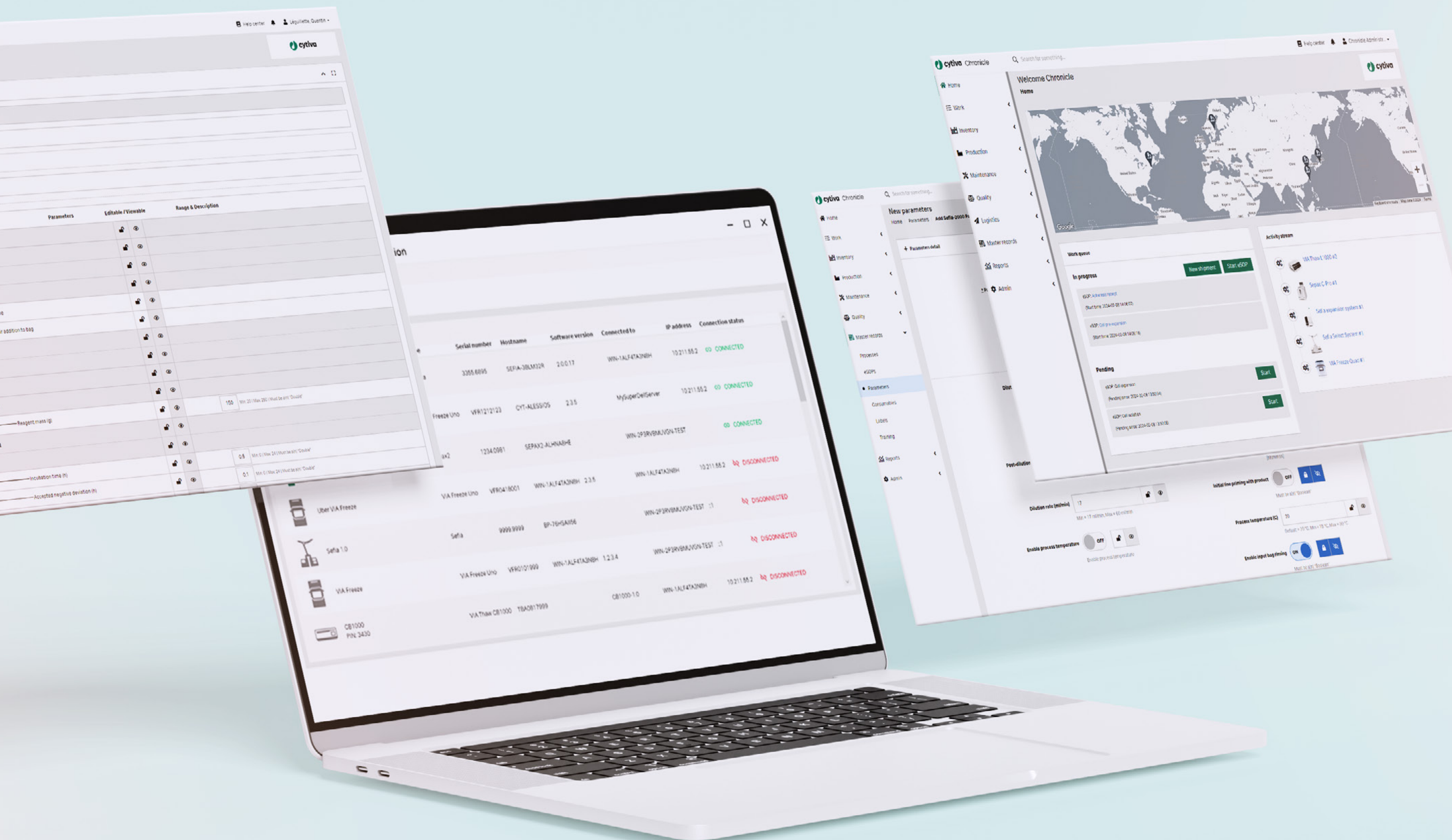
×

Step	Description	Fresh healthy donor (n=3)	Frozen healthy donor (n=3)
Activation	Initial cellular product	Isolated T-cells enriched	Isolated T-cells enriched
	Activator	T Cell TransAct	T Cell TransAct
	Total viable cell seeding number for activation	100 × 10 <sup>6</sup> T cells in 150 mL	100 × 10 <sup>6</sup> T cells in 150 mL
	Activation marker expression post activation	99.3%	84.2%
	Cell viability post-activation (day 5)	96.7%	95.2%
Transduction	Transduction efficiency at harvest	58.3%	52.2%
	Cell viability post-transduction	96.7%	95.2%
Expansion / General	Cell culture medium	Akron ImmunoCell Growth medium (serum free)	Akron ImmunoCell Growth medium (serum free)
	Average daily fold expansion	2.26	1.84
	Cell viability at harvest	98.1%	96.3%
	Cell recovery of cells from the culture vessel at time of harvest	96.0%	94.8%
	Number of cells at the end of the workflow	4.9x10 <sup>9</sup> T cells (day 8)	2.55 x10 <sup>9</sup> T cells (day 9)

<sup>5</sup>These performances are given for information as performance depends on parameter setting, used reagents and media as well as initial cellular product. The workflow can also be used for other types of viruses, activators and cell culture media.

# Chronicle software

## A complete, connected solution



### Improve your manufacturing experience

Real-time instrument data monitoring with instant alarm notifications

- Electronic standard operating procedures (eSOPs) and electronic batch manufacturing records (eBMRs)
- Centralized creation, approval, and deployment of parameter groups onto the connected Sefia instruments
- Batch scheduling, including consumables, products, instruments, and operator bookings

### Enable technical compatibility with ISPE GAMP 5, FDA 21 CFR Part 11, and EU GMP Annex 11 compliance

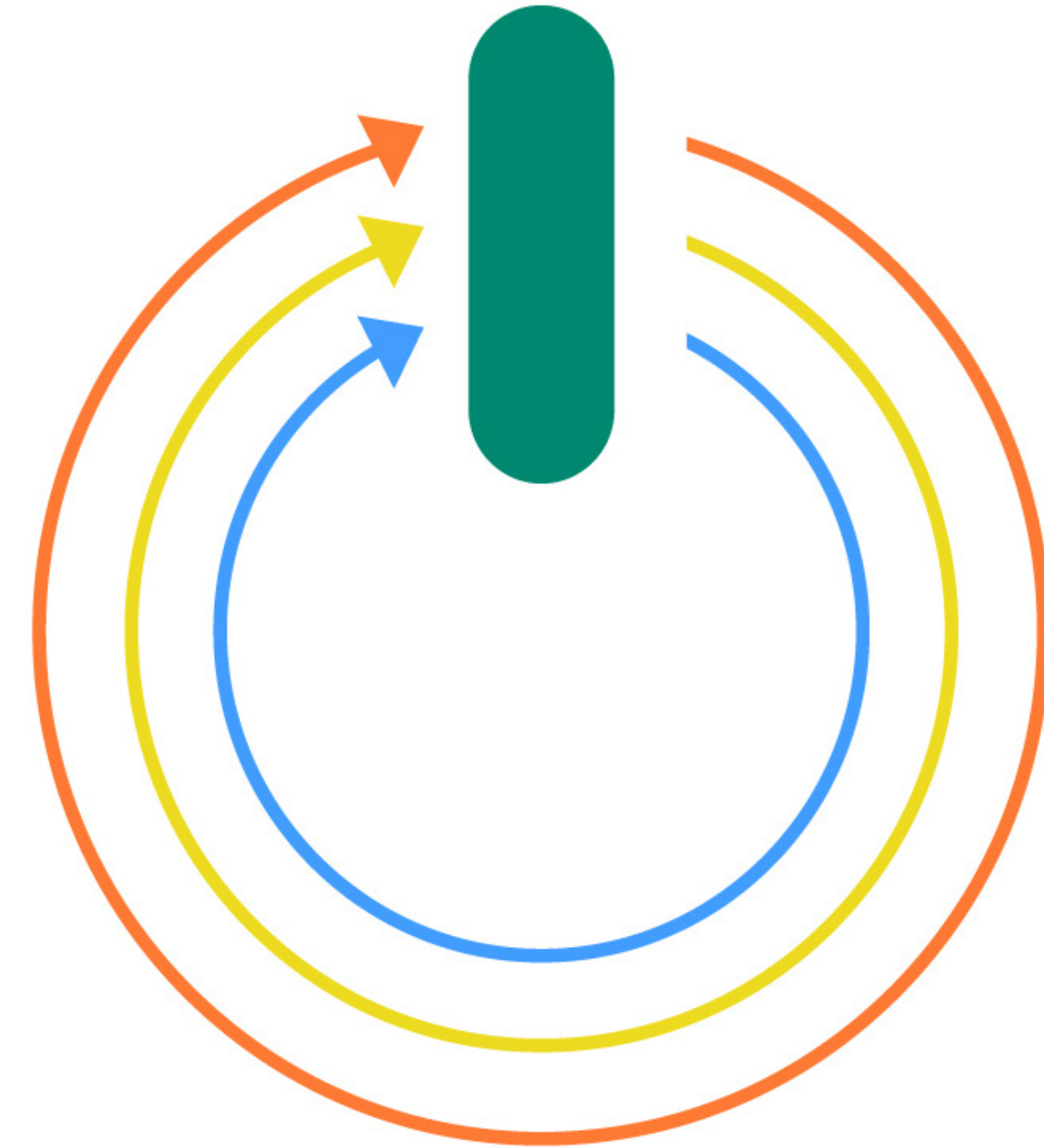
- Audit trails for GxP records
- Deviation and reviews
- Documents management
- Training records



# Maximize your uptime

## Configure your service plan to match your needs and timeline

To help optimize your operations, we offer tailored service solutions that support your manufacturing processes and facility operations. Support plans from OptiRun™ service solutions are customizable based on your instrument usage, operator expertise, budget, and more. Check with your representative for available options in your area.



## Incident Prevention

- Preventive maintenance
- Software alerts
- Customized training

## Reduced downtime

- Remote support with knowledgeable engineers and advanced technology
- Accelerated field engineer response
- Spare parts advisory



# Fast Trak™ services

Make a smooth transition to the Sefia platform with our process development team. Our experienced and dedicated scientists can help you transition from any technology, scale, or phase. Whether you're looking to optimize your entire process or single-unit operation, we can develop eSOPs and help with a smooth tech transfer. You'll be involved throughout the project because with Fast Trak services, our goal isn't just to solve your manufacturing challenges, it's to empower you to solve them too.

## Need to train your staff?

We got you covered. Our theoretical and practical trainings including basic knowledge of cell therapy processes and cell manufacturing. And you can deepen your knowledge on using the Sefia platform with **three in-person** courses:

01 isolation



02 activation, gene transfer, and expansion



03 harvest and formulation



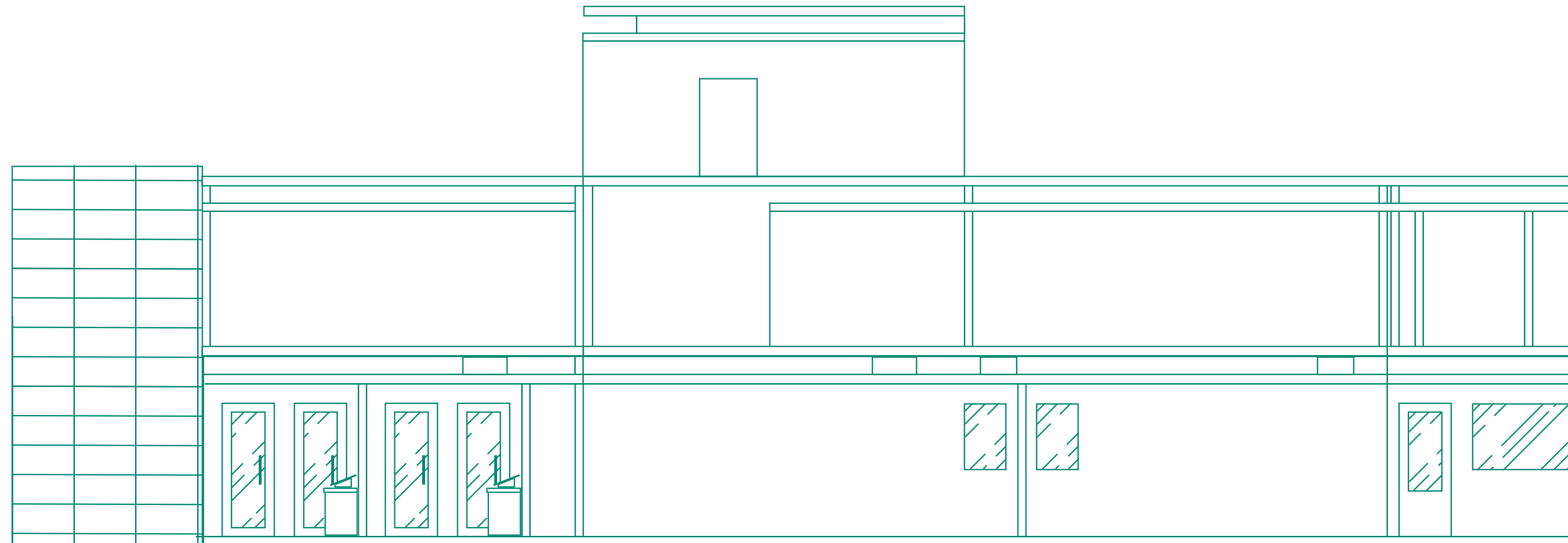
We also provide customized training based on your needs.





# FlexFactory™ platform

A comprehensive and configurable solution that enables you to prepare for GMP manufacturing. By tailoring a solution to fit your needs, you can scale at the pace of your business.



## Process design

Our engineers identify process and equipment requirements and assist in your process layout to help achieve an optimized workflow and GMP cleanroom compliancy.

## Instrumentation

Scale up or out with our flexible end-to-end manufacturing equipment — with the option to add third-party equipment.

## Project team

A dedicated team keeps your project on time and on budget with coordinated ordering, site preparation, deliveries, installations, and qualifications for smooth implementation at your site.

## Qualification documentation

Our qualification services team have spent 1000+ hours developing essential commissioning and qualification documents to help you meet global regulatory requirements.

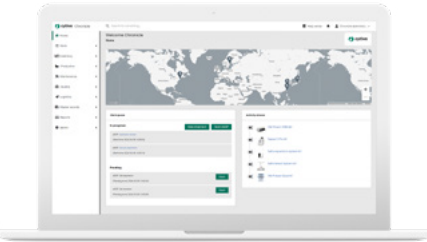
## GMP manufacturing automation software

Chronicle software allows for real-monitoring, and usage of eSOPs and eBMRs. Chronicle software also enables you to stay compliant with documentation management, audit trails, deviations, reviews, and training records.

## Training


Prepare your team for success in cGMP environments with our customizable FlexFactory platform training, all part of our Fast Trak services.

# Smart, flexible cell therapy solutions for your manufacturing needs




Chronicle™ software

- Thawing
- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
- Cryopreservation




Sefia Select™ system

- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
-




Sefia™ expansion system

- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
-




VIA Thaw™ instrument

- Thawing
- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
-




Sepax™ C-Pro system

- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
-




Xuri™ W25 system

- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
-



VIA Freeze™ range

- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
- Cryopreservation



Media and reagents

- Isolation
- Activation
- Gene transfer
- Expansion
- Harvest
- Formulation
-



# Sefia cell therapy manufacturing platform

## Gain confidence in your manufacturing process

Scaling up cell therapy manufacturing can be a challenge. We understand the complexities of the journey — the setbacks, like batch failures or delays, not only pose a significant financial burden, but they deeply affect patients as well.

But with Sefia platform, you can feel confident that our end-to-end solution will produce at scale. It's designed to reduce batch failures and easily integrate to increase your productivity while ensuring product safety.

Discover how Sefia platform can provide value to your manufacturing process, promote smooth operations, and automate key steps of your workflow. Because on your path toward commercialization and bringing life-saving therapies to patients, you need to break away from the “what ifs” and have confidence in delivering what's next.



Discover how to  
deliver what's next

# 9 out of 11

commercialized CAR T therapies\* utilize  
our technology, services, and expertise

With Cytiva, you're in good hands.



\*current as of December 2024



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