

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 >



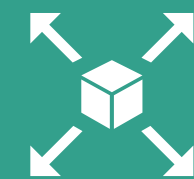
A helping hand >

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**

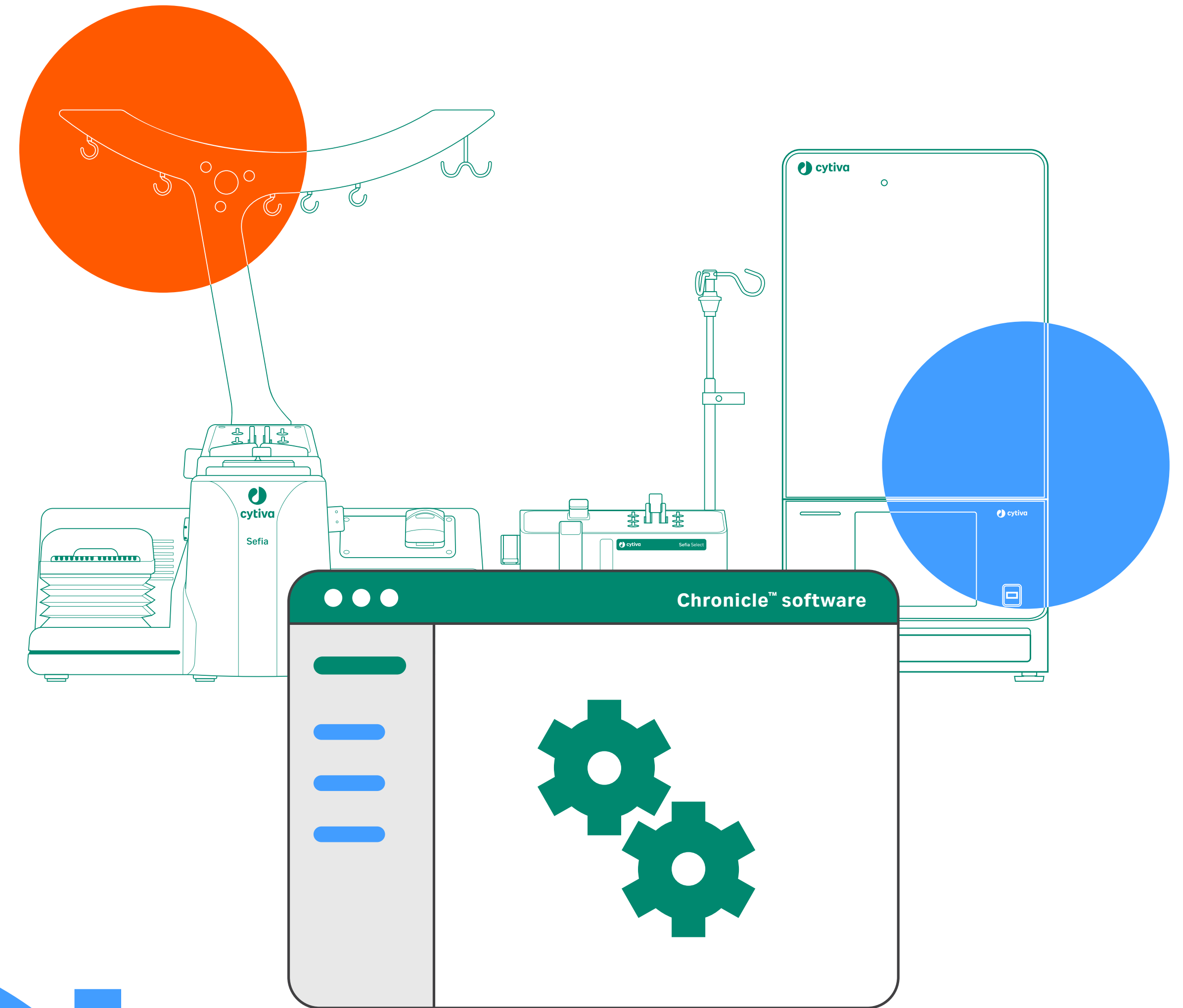


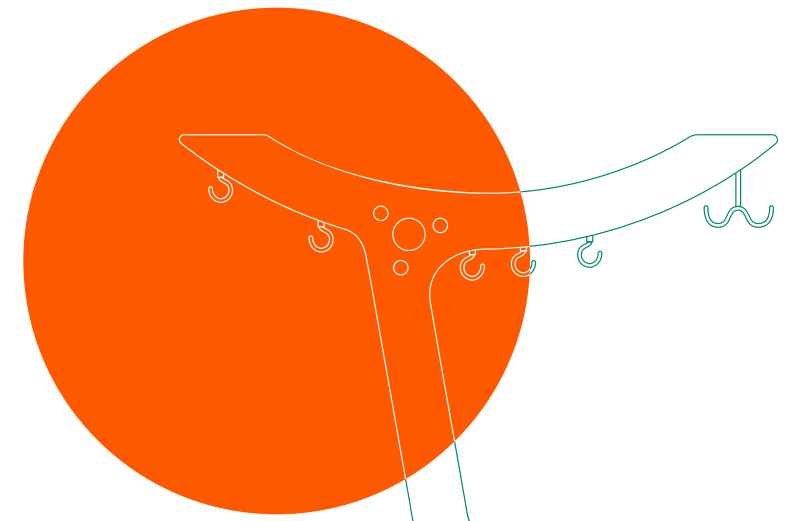
**Easy
integration**

Streamlined end-to-end manufacturing

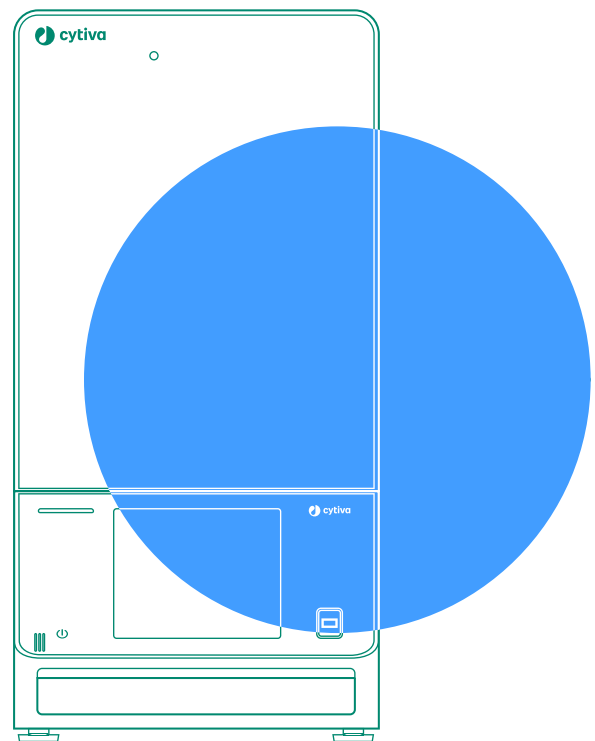
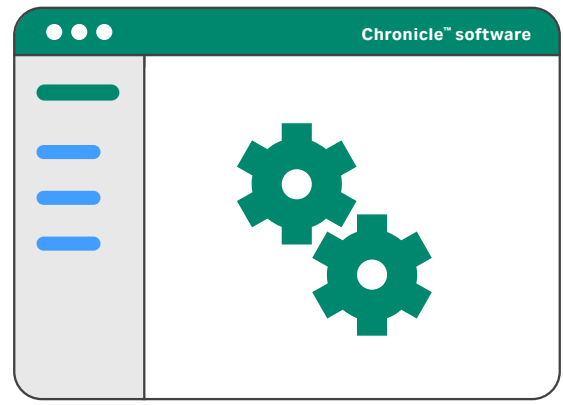
Automate manufacturing steps with the digitally integrated and functionally closed systems

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.

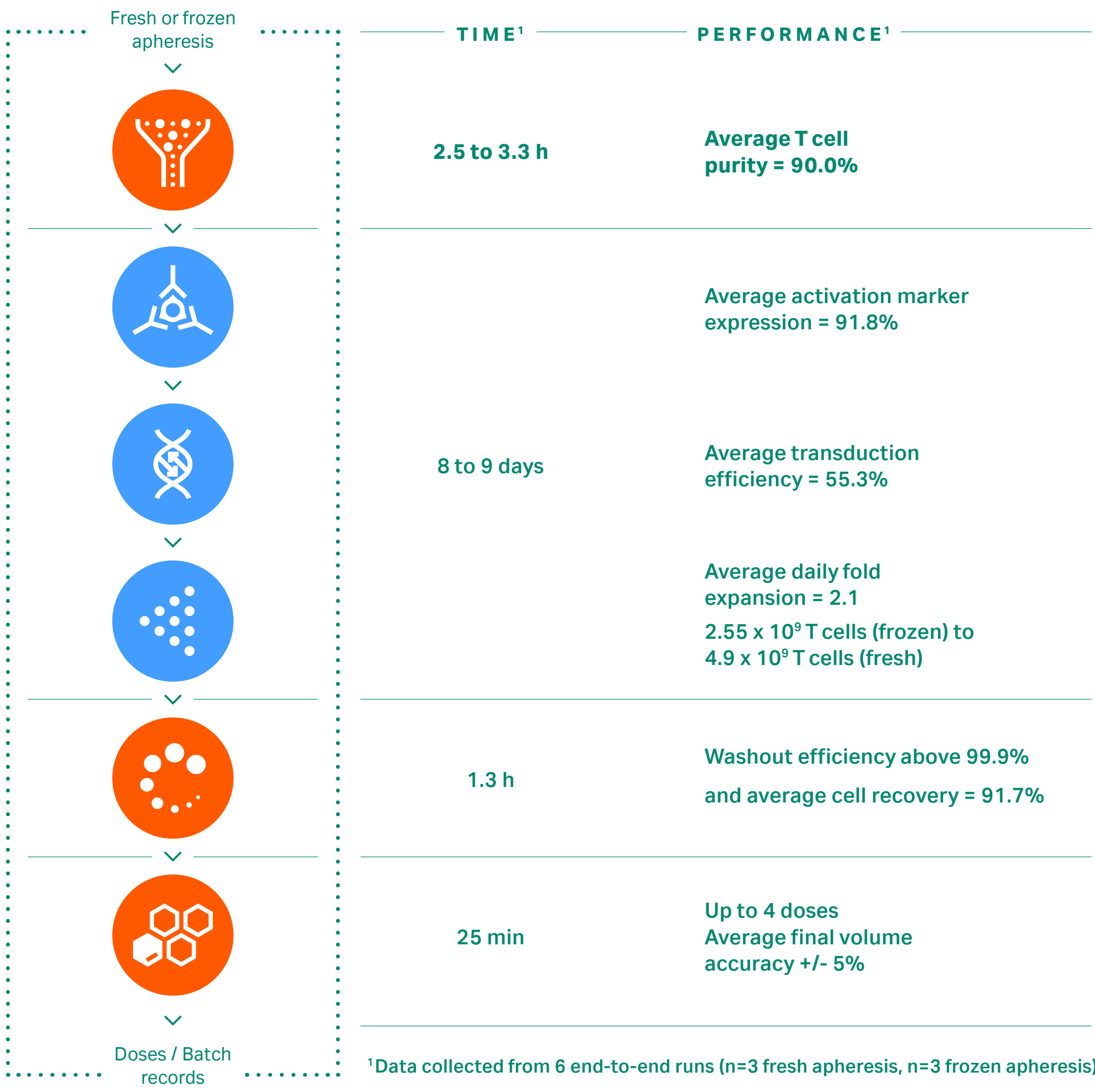




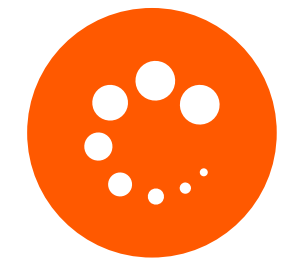
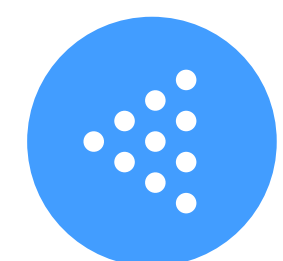
Sefia Select™ system



Sefia™ expansion system



Fresh or frozen apheresis



Doses / Batch records

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

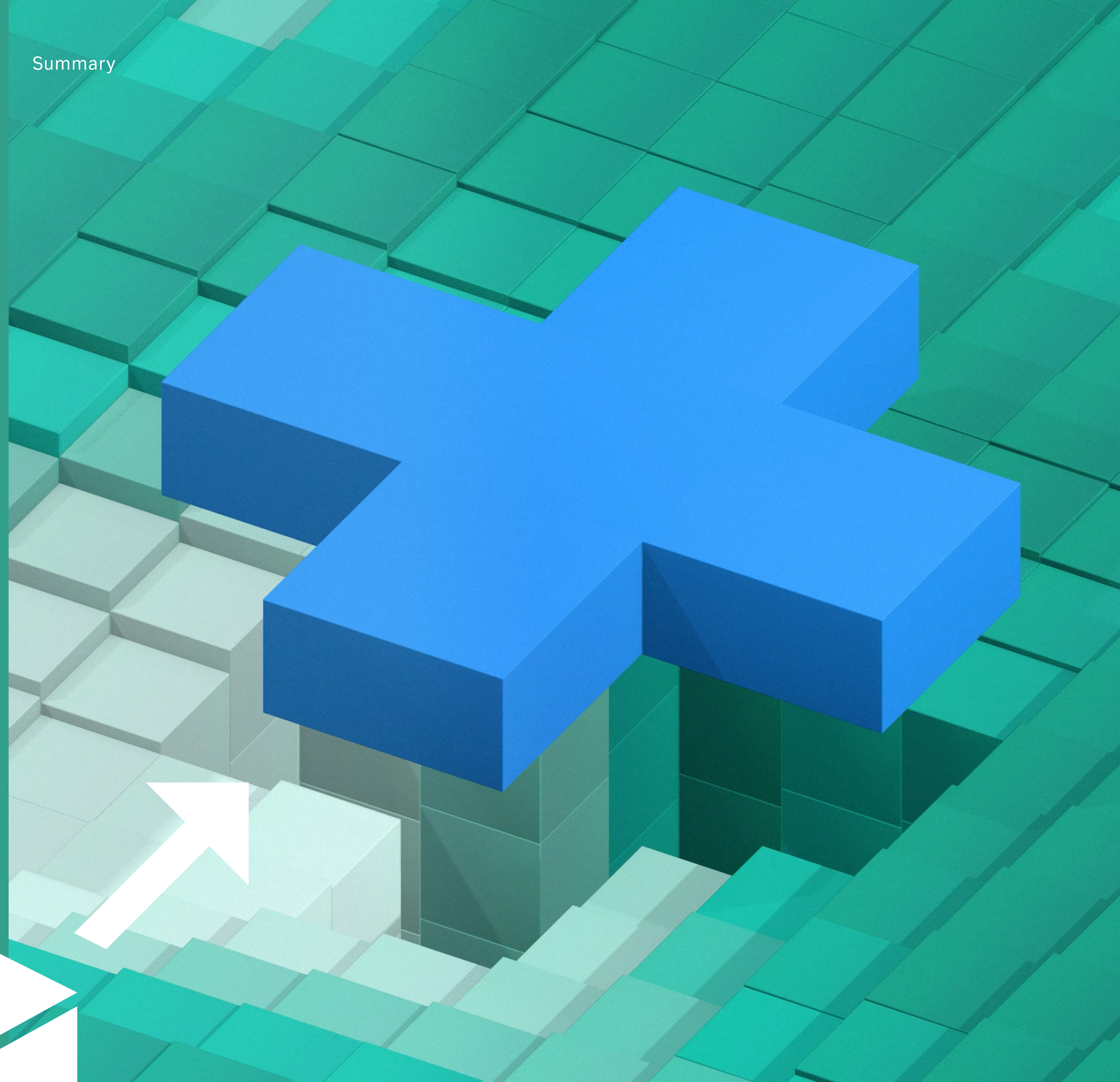
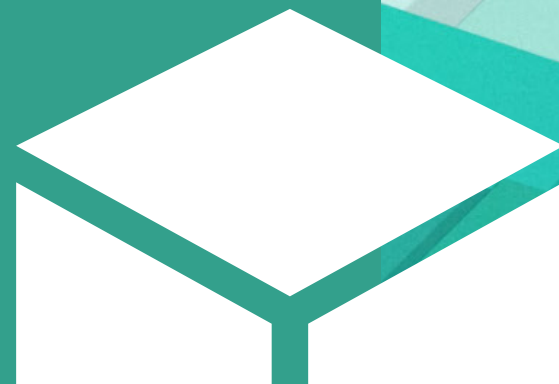
Flexible platform that meets your process needs

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.



Deep
dive





- **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 burden²

- 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 m² cleanroom



Process used to manufacture the CART doses

²semi-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 ²	45	179	446
Sefia platform	30	119	297

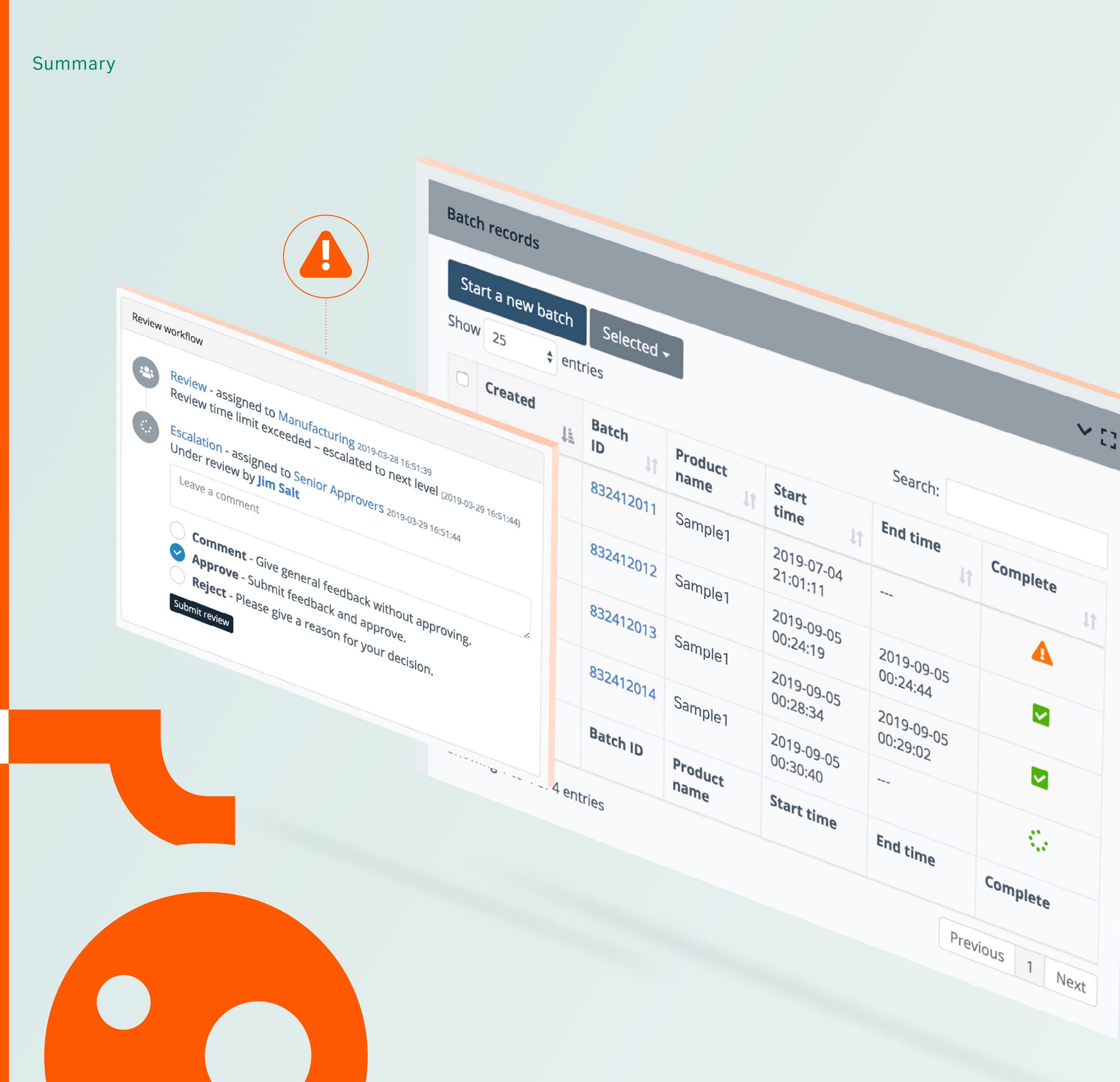
Operators required

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

²semi-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



Functionally closed

Product out of specification



Process monitoring

Material failure



Automatic cell recovery

Equipment failure



Diagnostic tool and kit integrity

Operator error



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.



Deep dive



Task 24

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

Parameters		S-Wash v102	
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	No	Enable process temperature	No
Process temperature	20 °C	Enable input bag rinsing	No
Input bag rinsing volume	50 ml	Input bag rinsing manual mix	No

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

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.

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.
- Verify the lot number on the Tyvek® cover is green and the text is visible.
- Verify the sterilization indicator on the Tyvek® cover is green. If the sterility indicator is not green, contact Cytiva.

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 reproductibility 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.



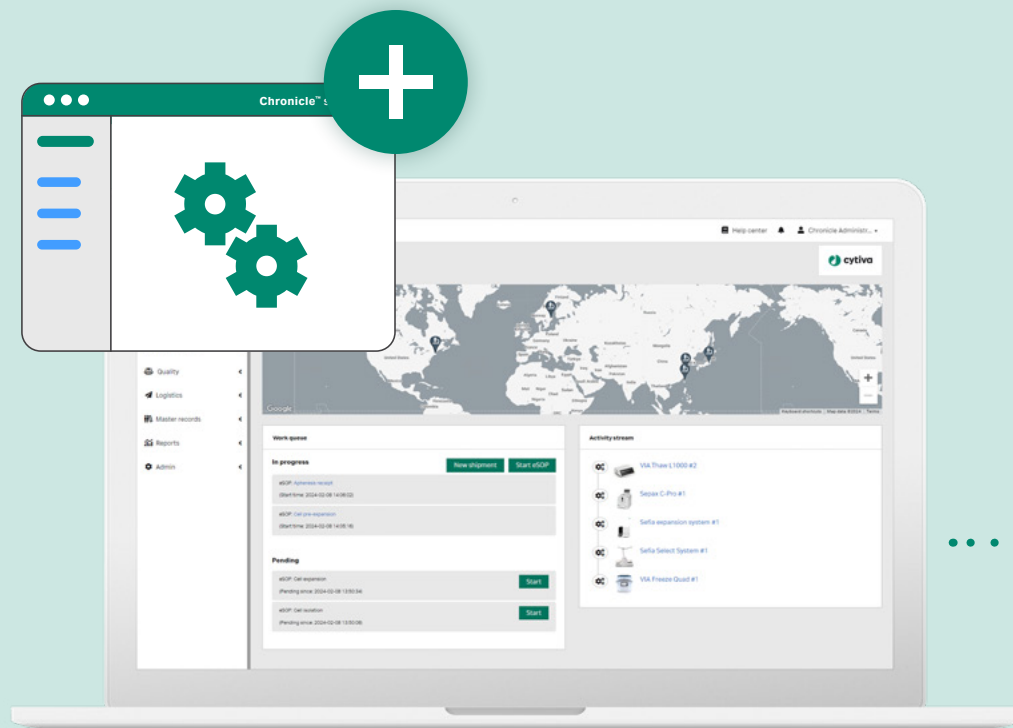
Facility

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



Chronicle™ software >



Sefia Select™ system >



Sefia™ expansion system >

Sefia™ platform

A modular solution to cell therapy



Apheresis



Isolation



Activation



Gene transfer



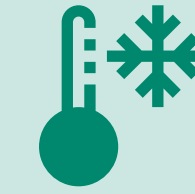
Expansion



Harvest



Formulation



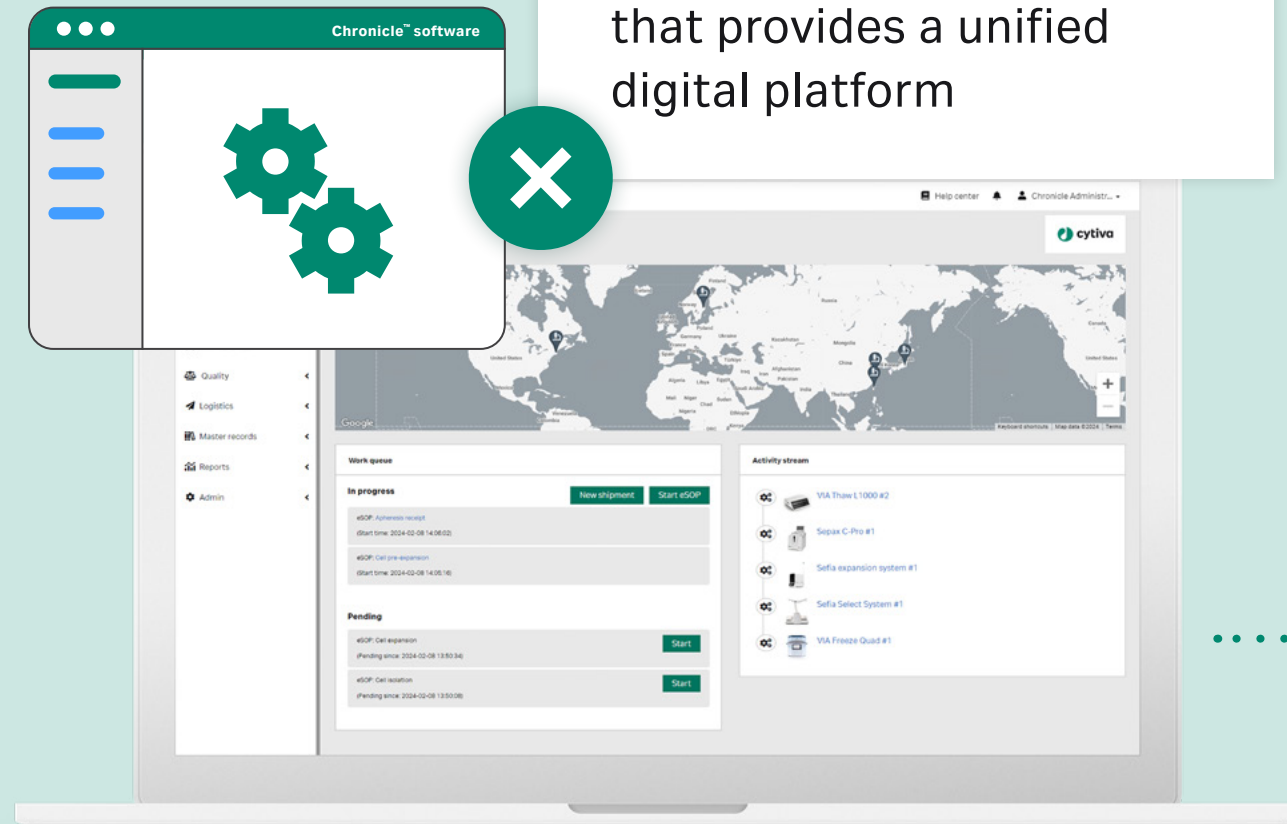
Cryopreservation



Final doses

Chronicle software

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



Chronicle™ software >



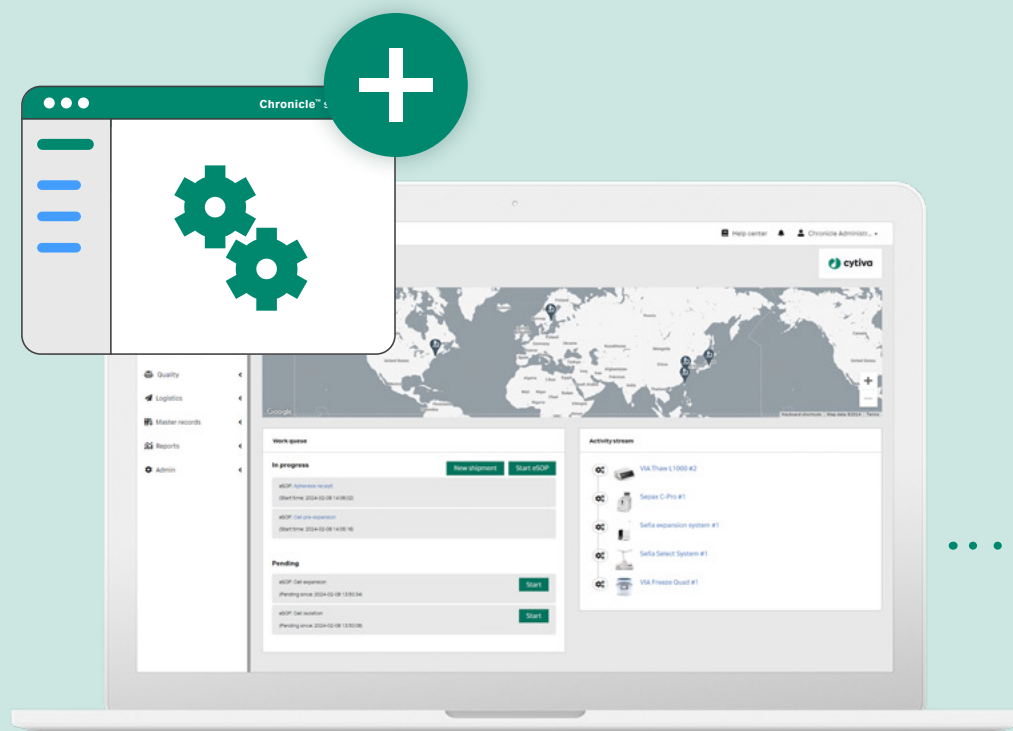
Sefia Select™ system >



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



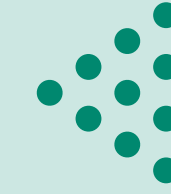
Isolation



Activation



Gene transfer



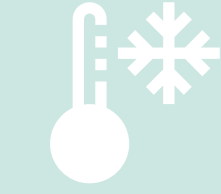
Expansion



Harvest



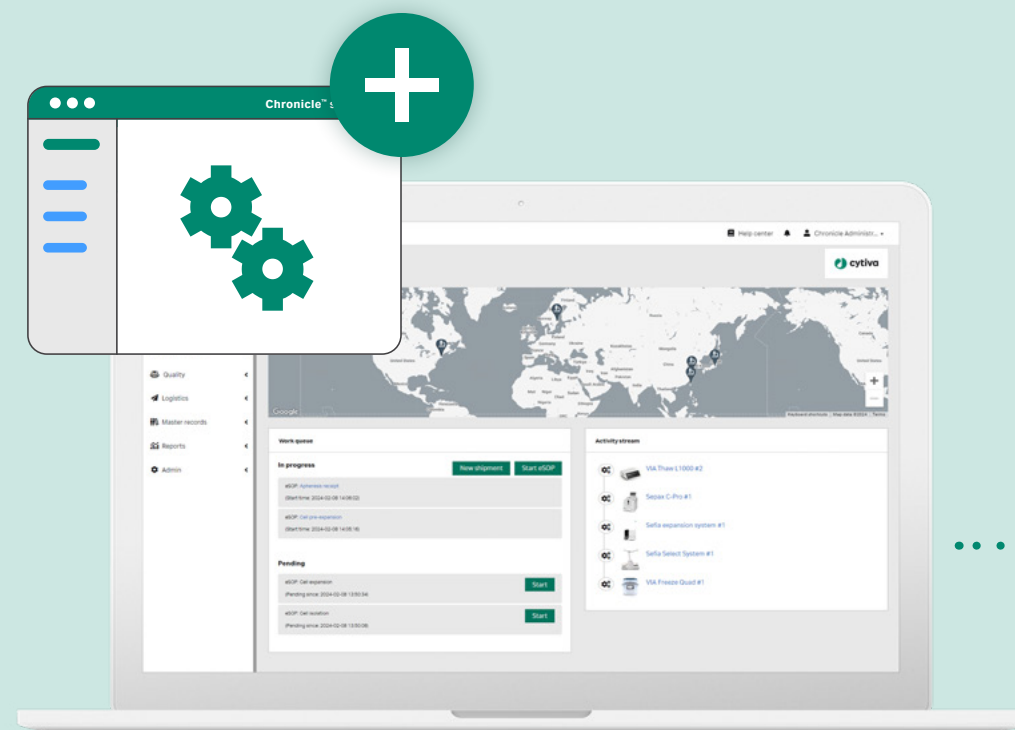
Formulation



Cryopreservation



Final doses



Chronicle™ software >



Sefia Select™ system >



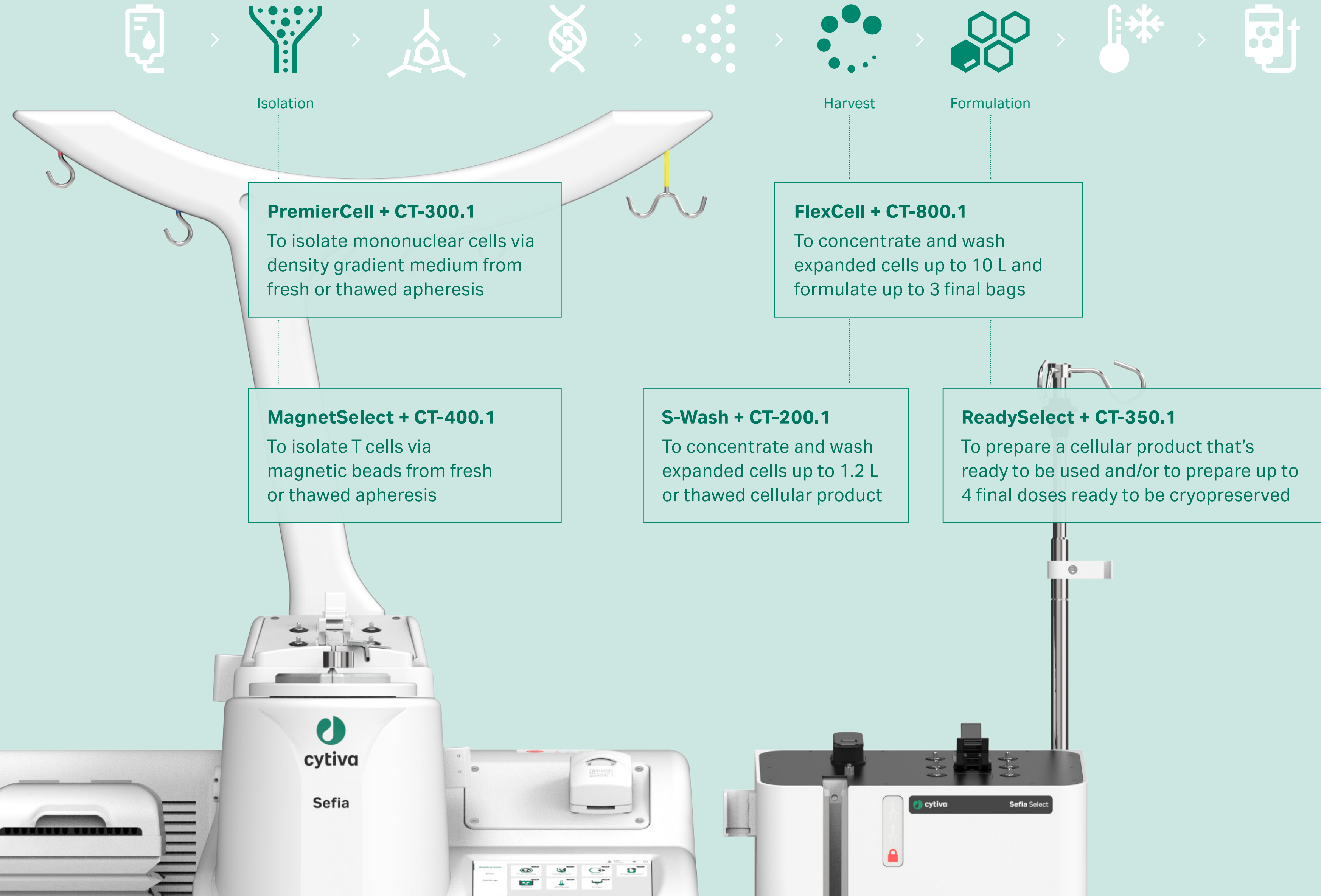
Sefia expansion system

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.



PremierCell + CT-300.1

To isolate mononuclear cells via density gradient medium from fresh or thawed apheresis

MagnetSelect + CT-400.1

To isolate T cells via magnetic beads from fresh or thawed apheresis

S-Wash + CT-200.1

To concentrate and wash expanded cells up to 1.2 L or thawed cellular product

FlexCell + CT-800.1

To concentrate and wash expanded cells up to 10 L and formulate up to 3 final bags

ReadySelect + CT-350.1

To prepare a cellular product that's ready to be used and/or to prepare up to 4 final doses ready to be cryopreserved



Sefia

Sefia Select

Performances⁴



MagnetSelect	Fresh healthy donor	Fresh Patient model	Frozen healthy donor
Initial total white blood cells	14 × 10 ⁹	30 × 10 ⁹	5 × 10 ⁹
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

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

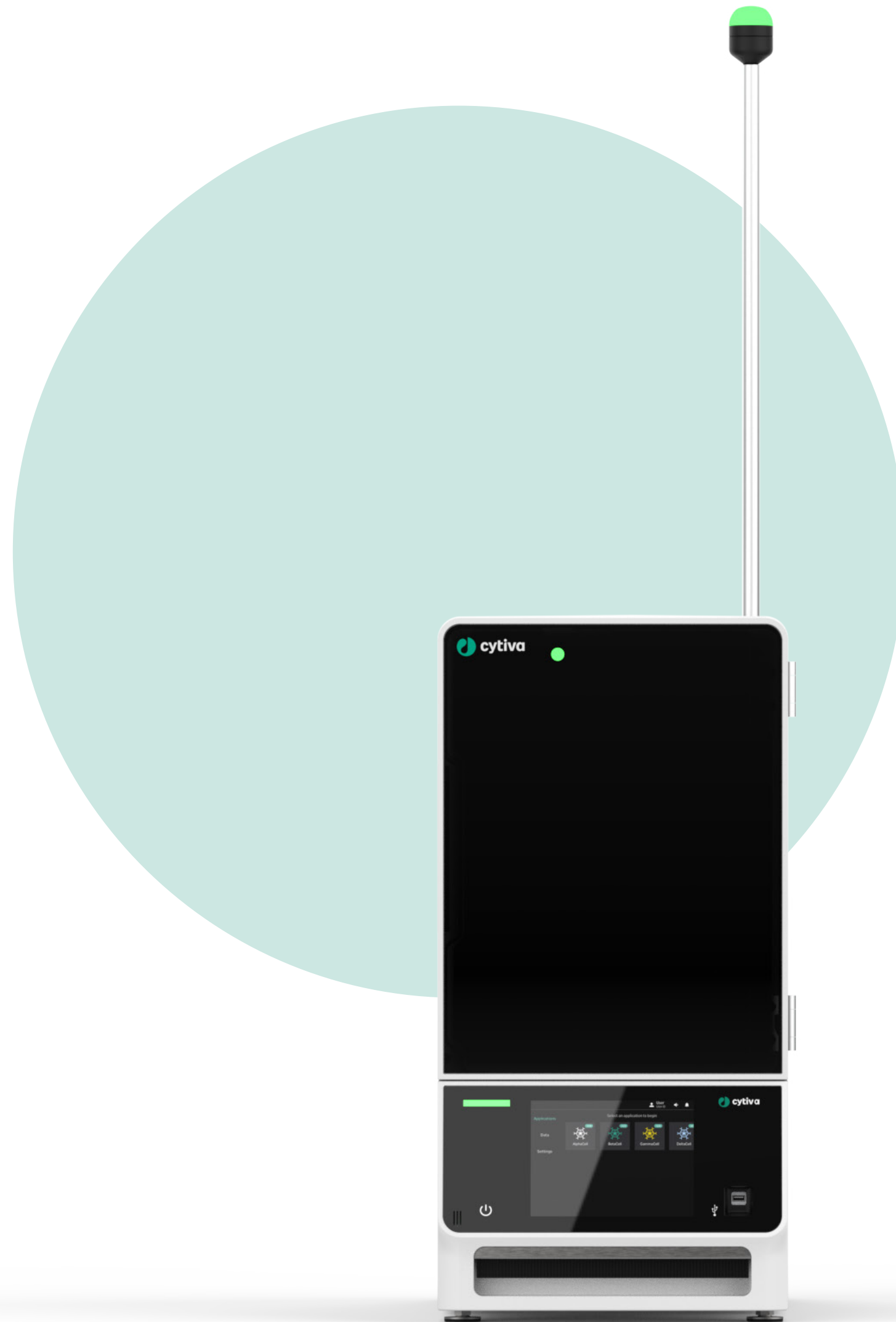
S-Wash	Values
Typical processing time	1.5 h
Washout efficiency	4 log
Average cell recovery for expanded cells	98%
Average cell recovery for thawed cells	87%
Average cell viability loss	3%
Standard deviation for final volume	± 3.6 mL

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

⁴Indication only as performances depend on user and cellular product configuration



[CLICK TO
VIEW ANGLES](#)



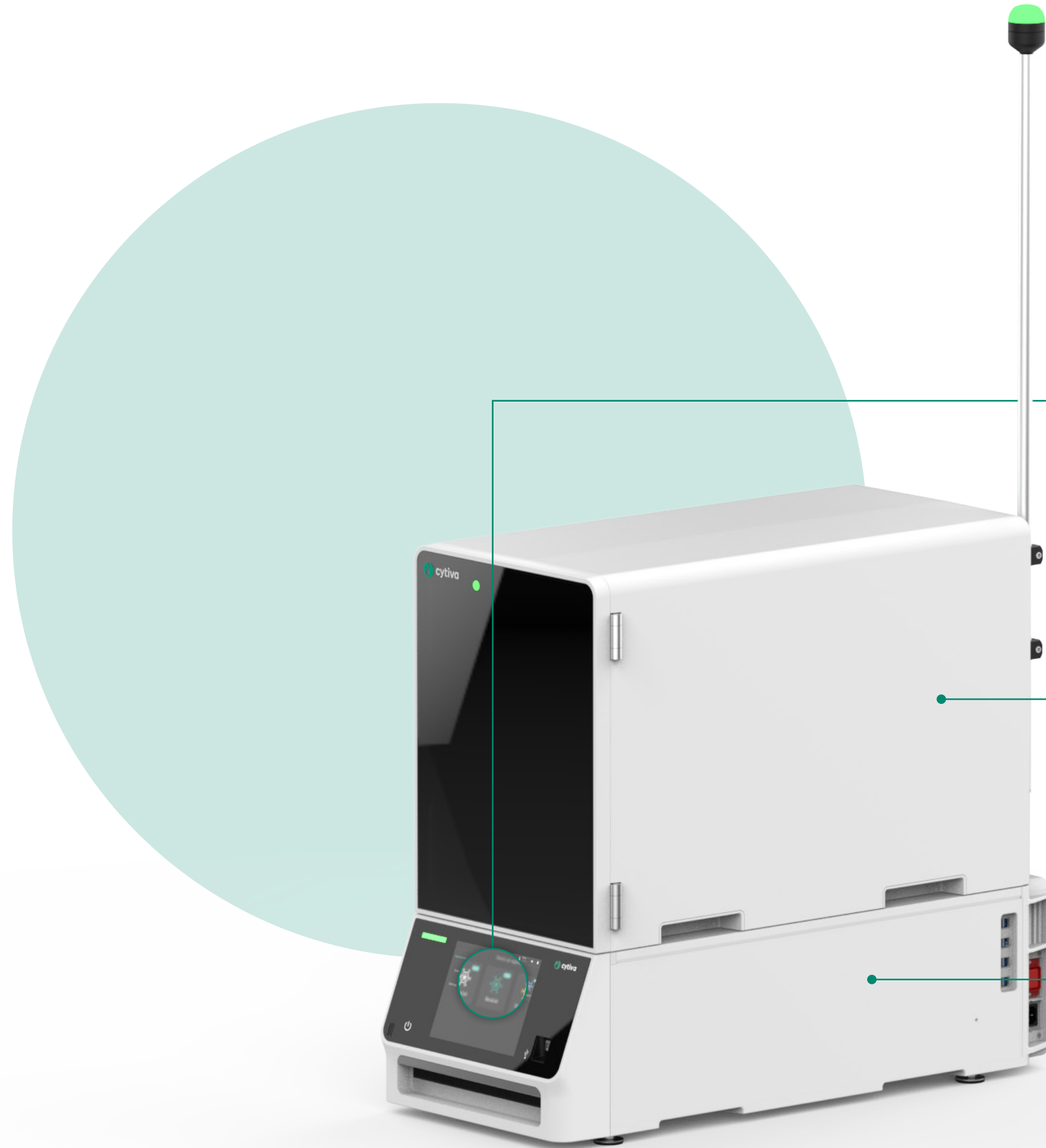
Sefia expansion system

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

Deep
dive 



CLICK TO
VIEW ANGLES



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

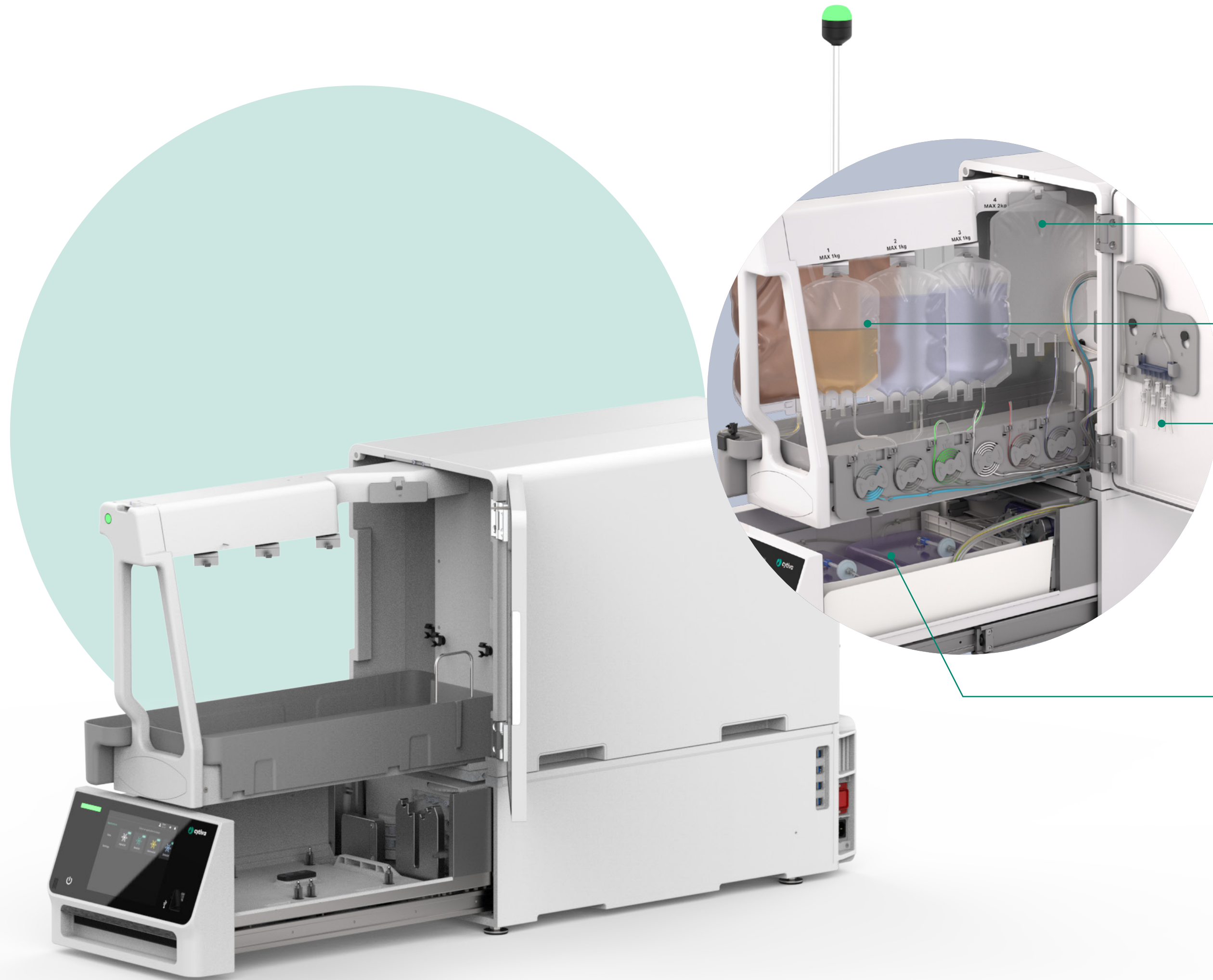
Sefia expansion system can be used with your **current reagents and media** as well as various types of viruses (lentivirus or retrovirus)

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





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

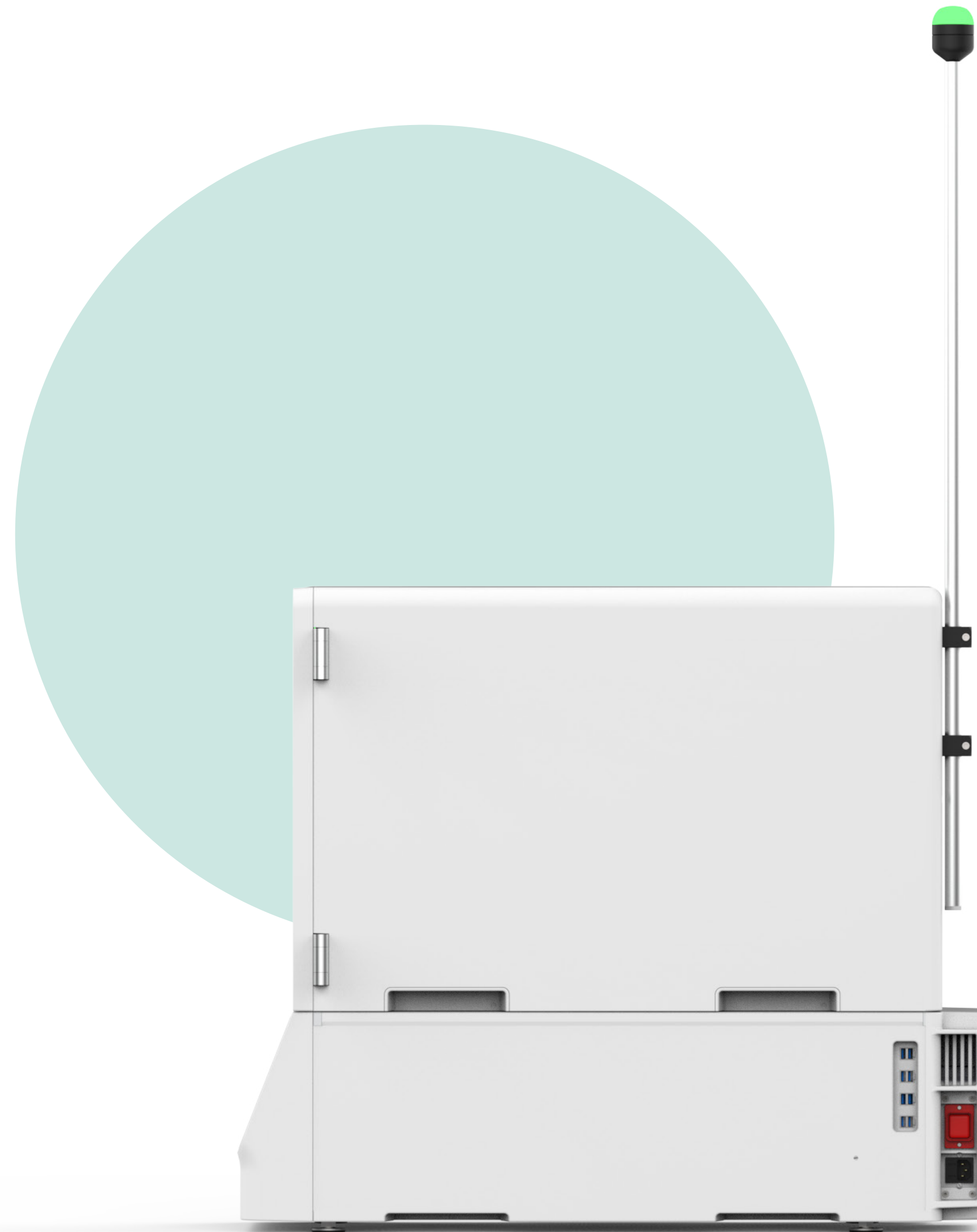
Temperature and CO₂ control and
monitoring

Typical processing duration: 5 to 12 days





[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.

Deep
dive

Performances⁵

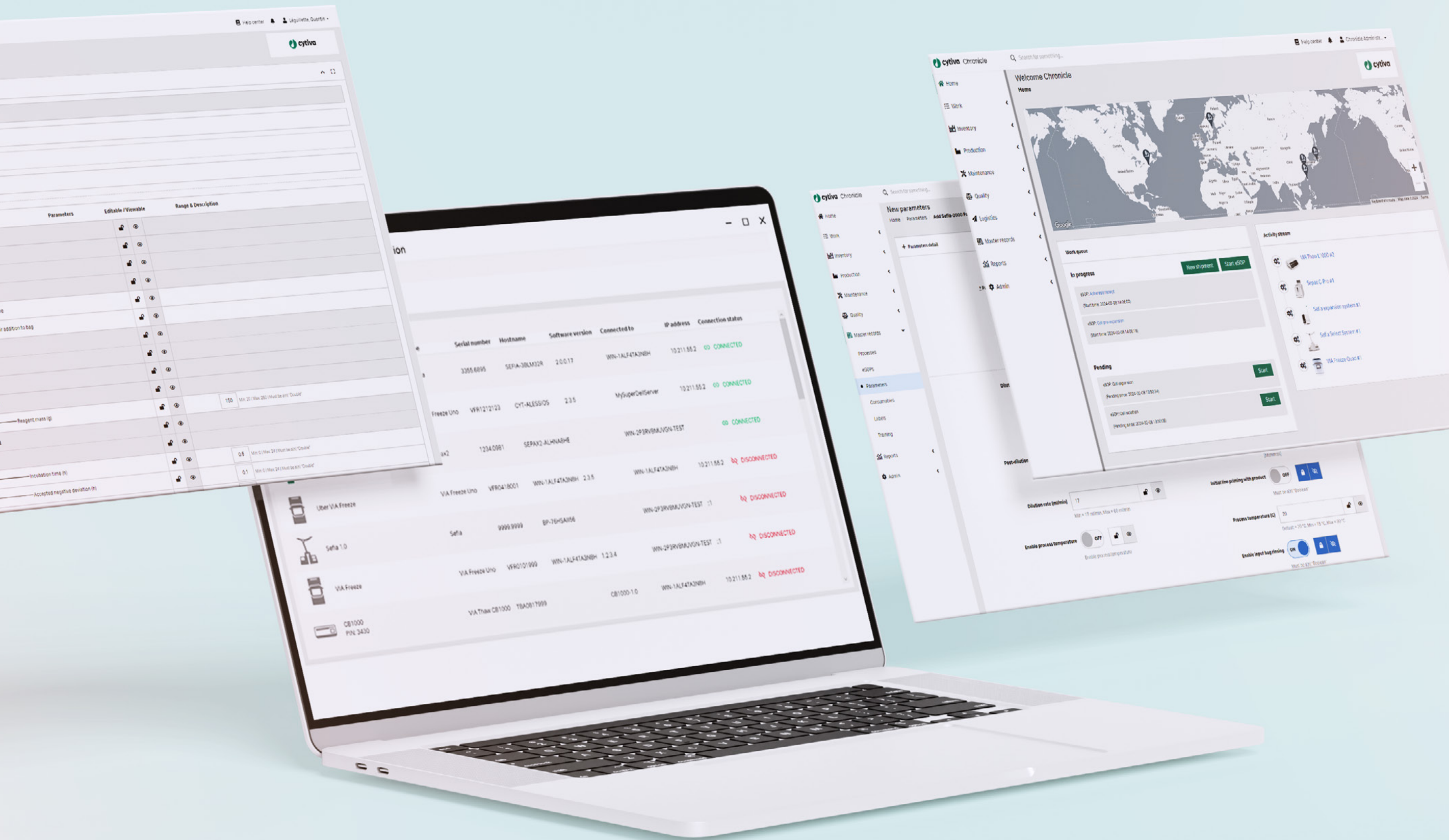


Step	Description	Fresh healthy donor (n=3)	Frozen healthy donor (n=3)
Activation	Initial cellular product	Isolated T-cells enriched	Isolated T-cells enriched
	Activator	T Cell TransAct	T Cell TransAct
	Total viable cell seeding number for activation	100 × 10 ⁶ T cells in 150 mL	100 × 10 ⁶ T cells in 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 ⁹ T cells (day 8)	2.55 x10 ⁹ T cells (day 9)

⁵These 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



Serial number	Hostname	Software version	Connected to	IP address	Connection status
3385 6095	SEFIA-20LX122R	2.0.0.17	WIN-1AJL47A2NH	10.21.18.2	CONNECTED
Freeze UP	VFR1212123	CVI-ALESSIOS	MySuperCellServer	10.21.18.2	CONNECTED
12345678	SEFACV-ALMNAHSE		WIN-2P3R9BA2VGN TEST		CONNECTED
VIA Freeze UP	VFR041001	WIN-1AJL47A2NH	2.3.5	10.21.18.2	DISCONNECTED
Sefia	9999 9999	EP-705A106	WIN-2P3R9BA2VGN TEST		DISCONNECTED
VIA Freeze UP	VFR021099	WIN-1AJL47A2NH	1.2.3.4	WIN-2P3R9BA2VGN TEST	DISCONNECTED
VIA Thaw CB1000	TBACH1999	CB1000 1.0	WIN-1AJL47A2NH	10.21.18.2	DISCONNECTED

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

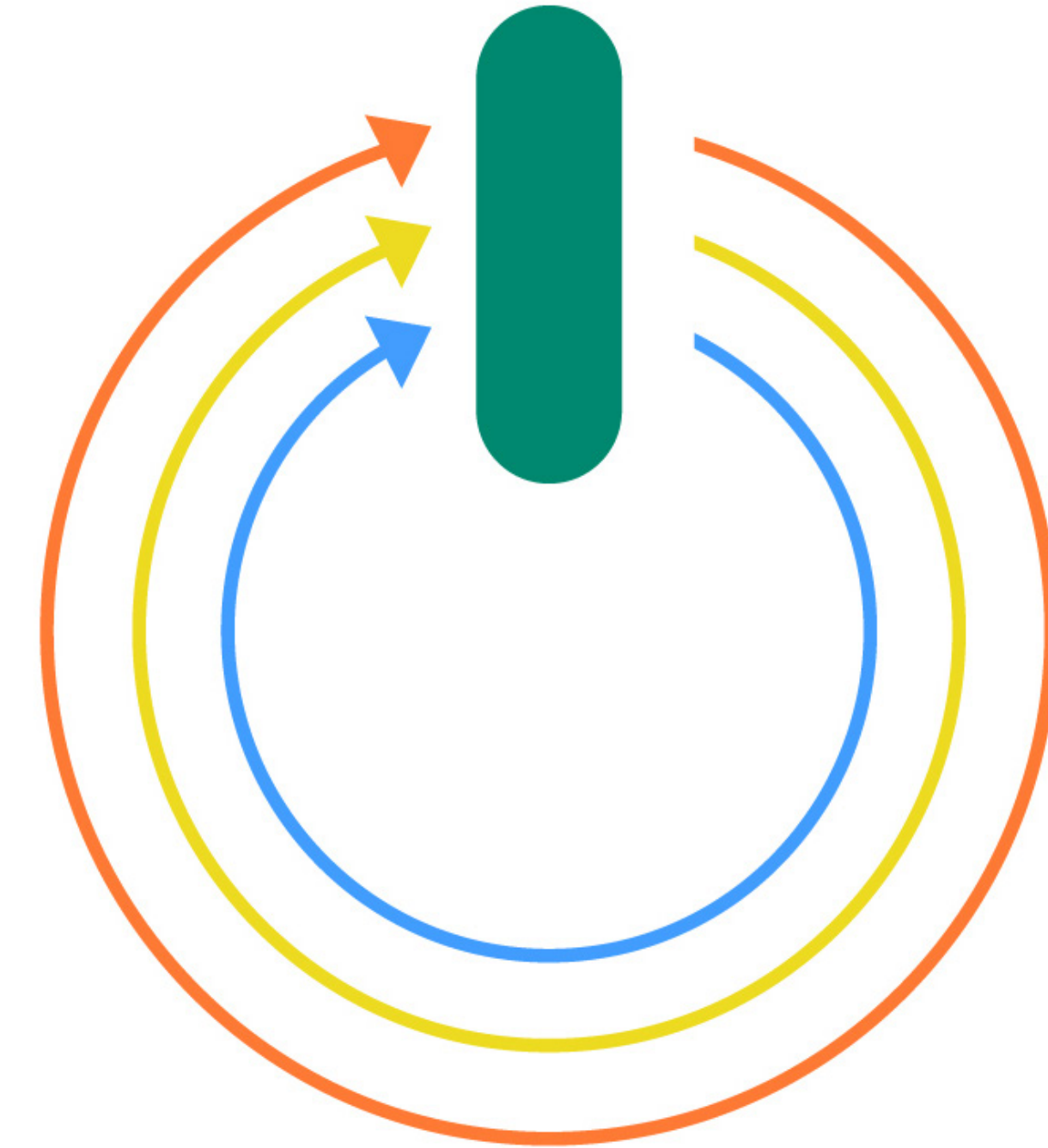
Enable technical compatibility with ISPE GAMP 5, FDA 21 CFR Part 11, and EU GMP Annex 11 compliance

- 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

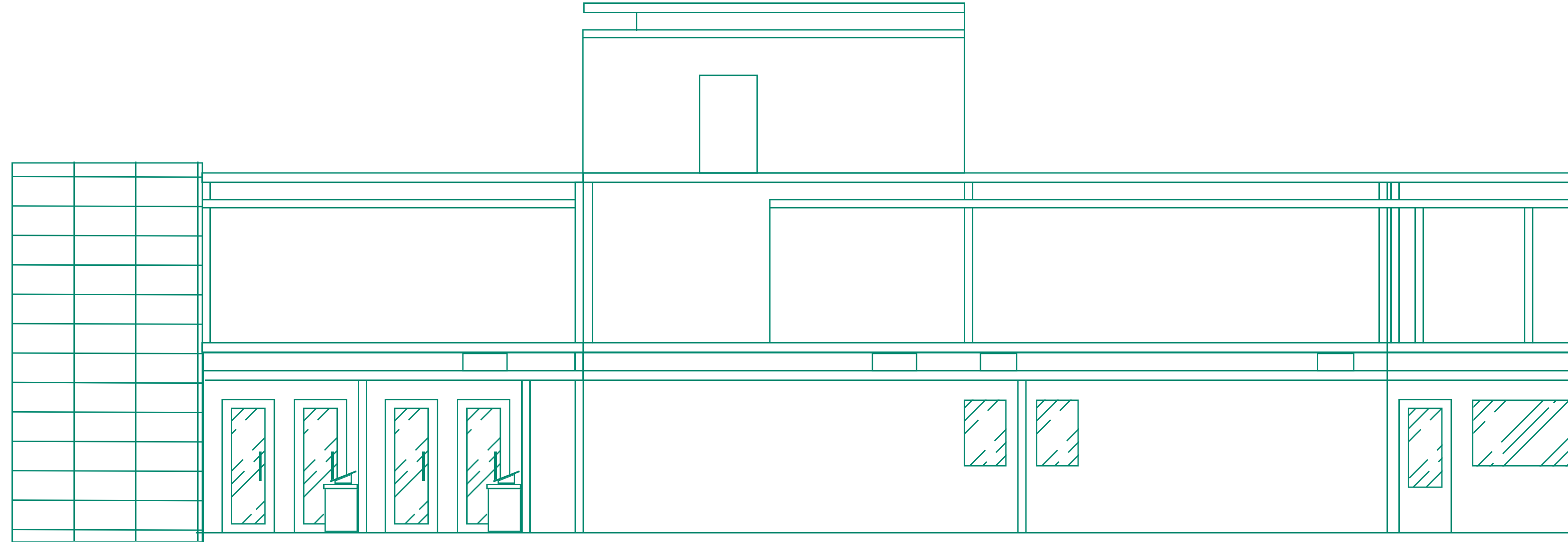


We also provide customized training based on your needs.



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

Sefia Select™ system

Sefia™ expansion system

VIA Thaw™ instrument

Sepax™ C-Pro system

Xuri™ W25 system

VIA Freeze™ range

Media and reagents

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

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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 CART therapies* utilize
our technology, services, and expertise

With Cytiva, you're in good hands.



*current as of December 2024

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