Sefia™ cell therapy manufacturing platform

Helping you deliver what's next in CAR T manufacturing



cytiva



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 ›



Our services ›

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

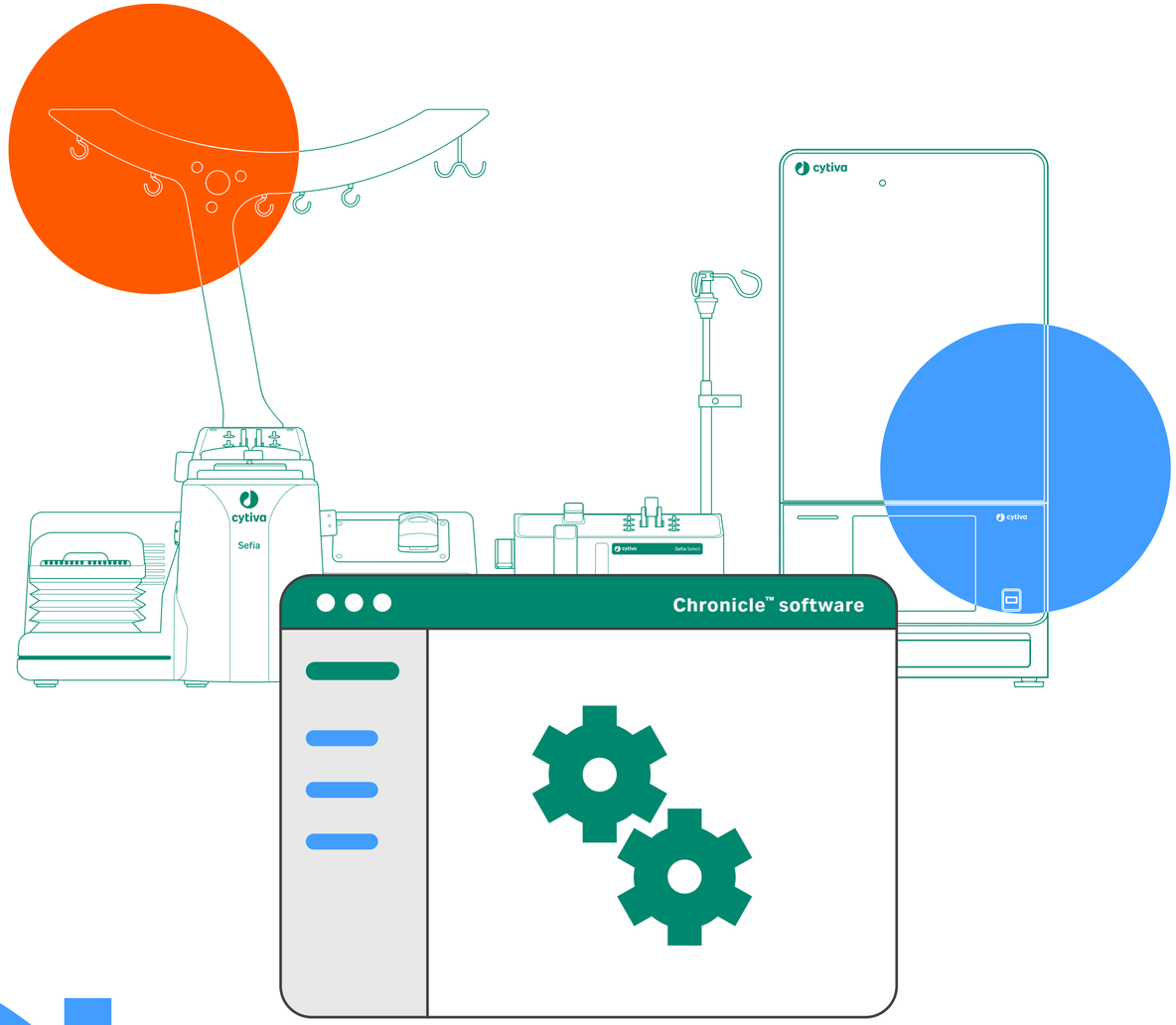
Features designed to reduce batch failure risk

Easy integration

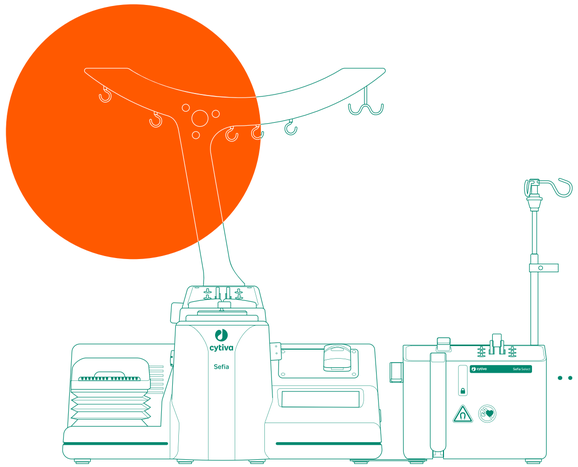
Streamlined end-to-end manufacturing

Automate manufacturing steps with the digitally integrated and functionally closed systems

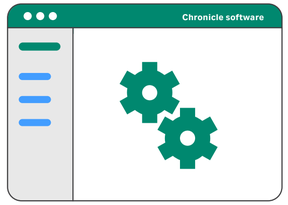
As part of your cell therapy manufacturing, Sefia Select system automates cell isolation, harvest, and formulation steps, while Sefia expansion system automates cell activation, transduction, and cell expansion steps.

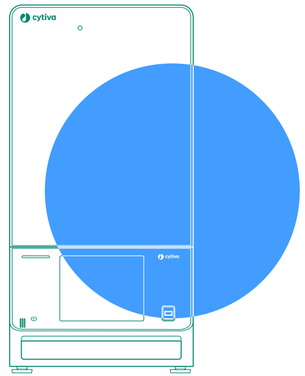


Deep dive



Sefia Select system





Sefia expansion system

Fresh or frozen apheresis

Doses/batch records

	TIME[1]	PERFORMANCE[1]
	2.5 to 3.3 h	**Average T cell purity = 90.0%**
	8 to 9 days	Average activation marker expression = 91.8%
		Average transduction efficiency = 55.3%
		Average daily fold expansion = 2.1 2.55 × 10^9 T cells (frozen) to 4.9 × 10^9 T cells (fresh)
	1.3 h	Washout efficiency above 99.9% and average cell recovery = 91.7%
	25 min	Up to 4 doses Average final volume accuracy +/- 5%

[1]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.

Deep dive



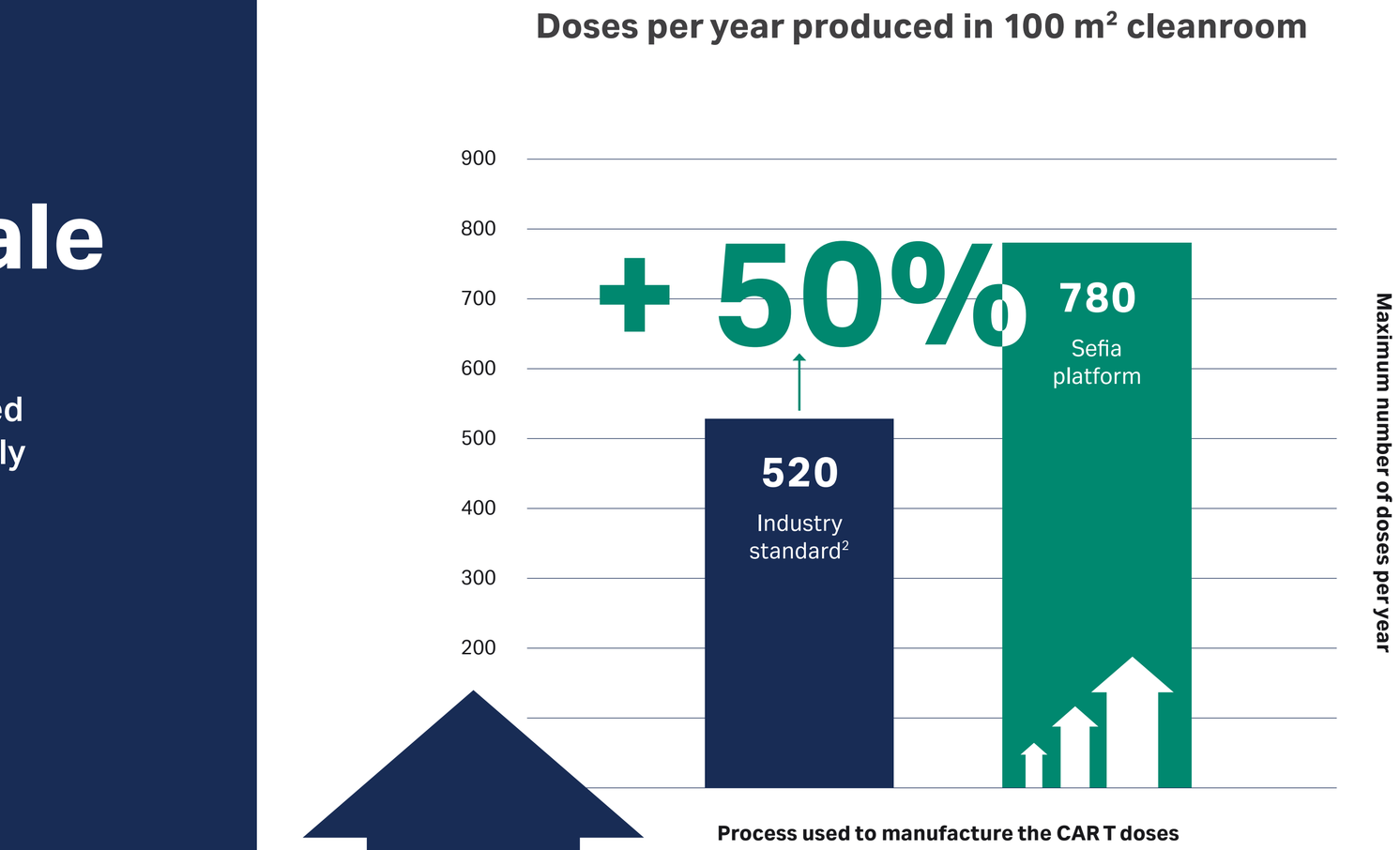


- Versatile system with multiple applications to cover CAR T workflow key steps
- Configurable by the user with large parameter range setting for each application
- Parameters are open and can easily be changed by the user, then locked based on user profile permissions
- High reproducibility even with variable cell composition of input products
- Compatibility with multiple culture media, activators, and viral vectors (lentivirus and retrovirus)

Increase productivity at commercial scale

Experience an up to 50% increase in manufactured doses per year as compared to industry-standard processes, ultimately driving a reduction in cost burden[2]

- 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



[2]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.

Deep dive

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 (m^2)

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

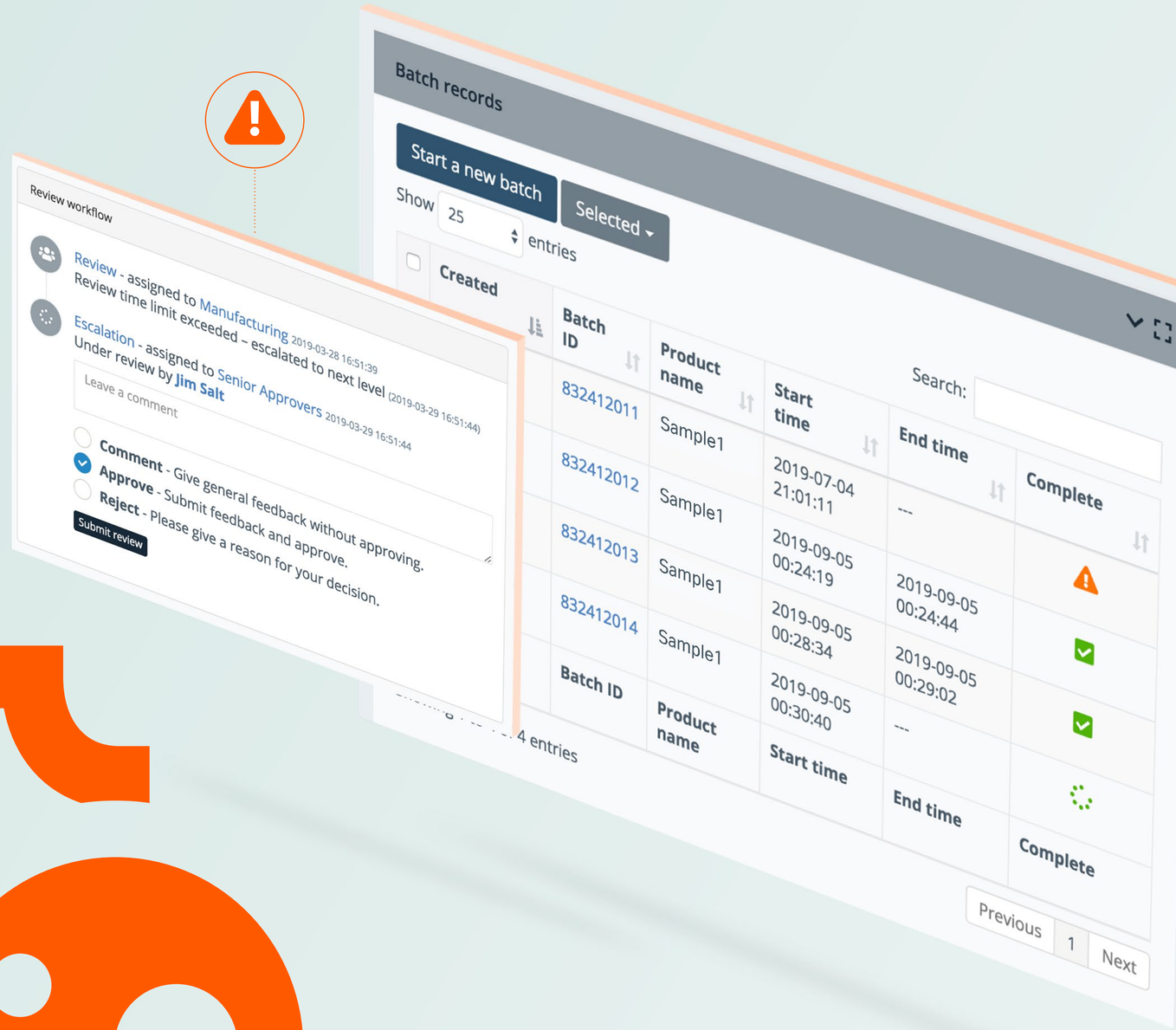
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Features designed to reduce batch failure risk

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.

Deep dive



Batch failure risks

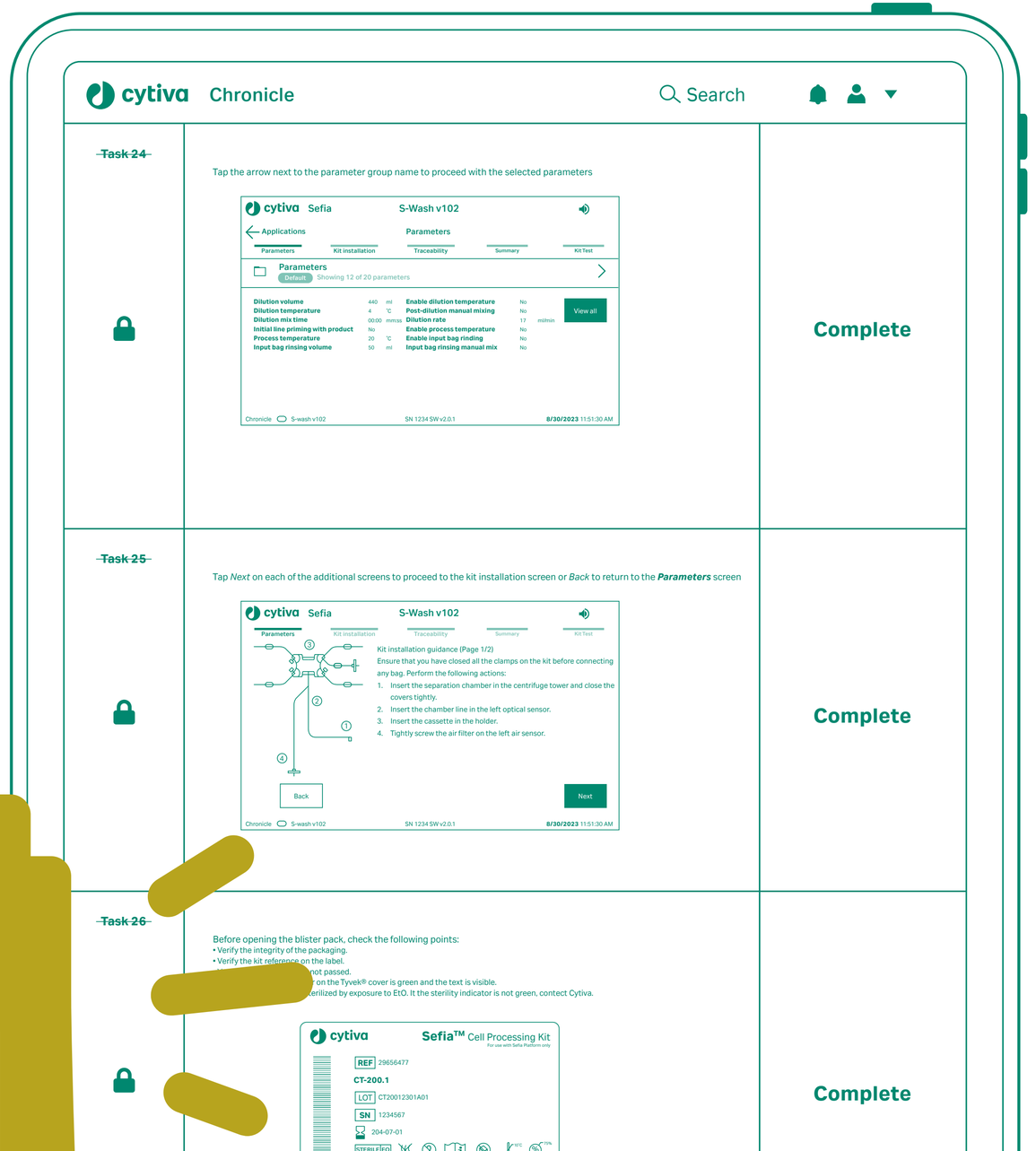


Contamination	→	Functionally closed
Product out of specification	→	Process monitoring
Material failure	→	Automatic cell recovery
Equipment failure	→	Diagnostic tool and kit integrity
Operator error	→	eSOPs

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



Adopting a new technology requires time, resources, and money

Sefia platform support includes: the changes to the process, on-boarding the operators, 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.**

Equipment service solutions supporting product's life cycle.



Facility

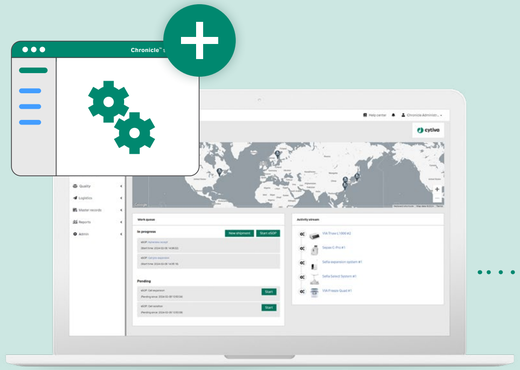
Centralized creation and deployment of parameter groups and eSOPs over sites

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 ›

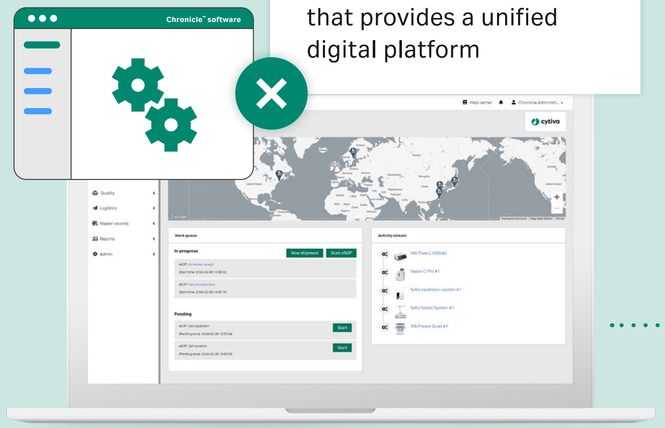
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A modular solution to cell therapy

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 ›

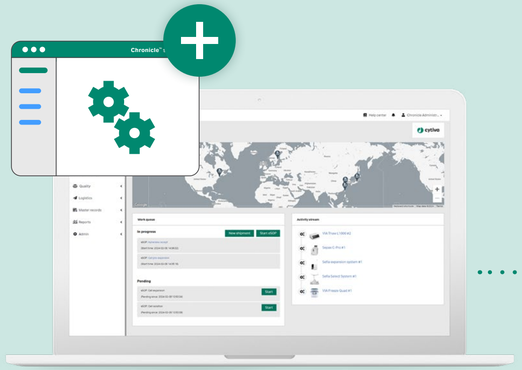
Sefia Select system ›

Sefia expansion system ›

Sefia platform

A modular solution to cell therapy

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Sefia Select system

Optimize resources by using the same system for three short yet influential steps of your workflow: cell isolation, harvest, and formulation



Chronicle software ›

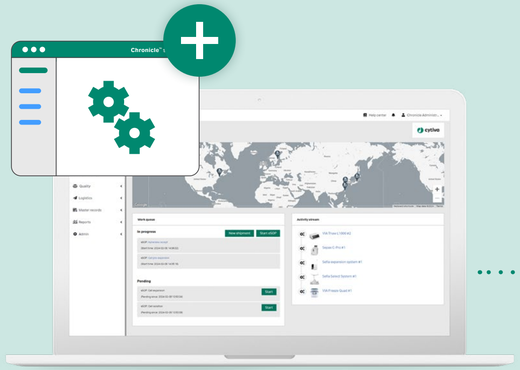
Sefia Select system ›

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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.

Deep dive

Isolation

Harvest

Formulation

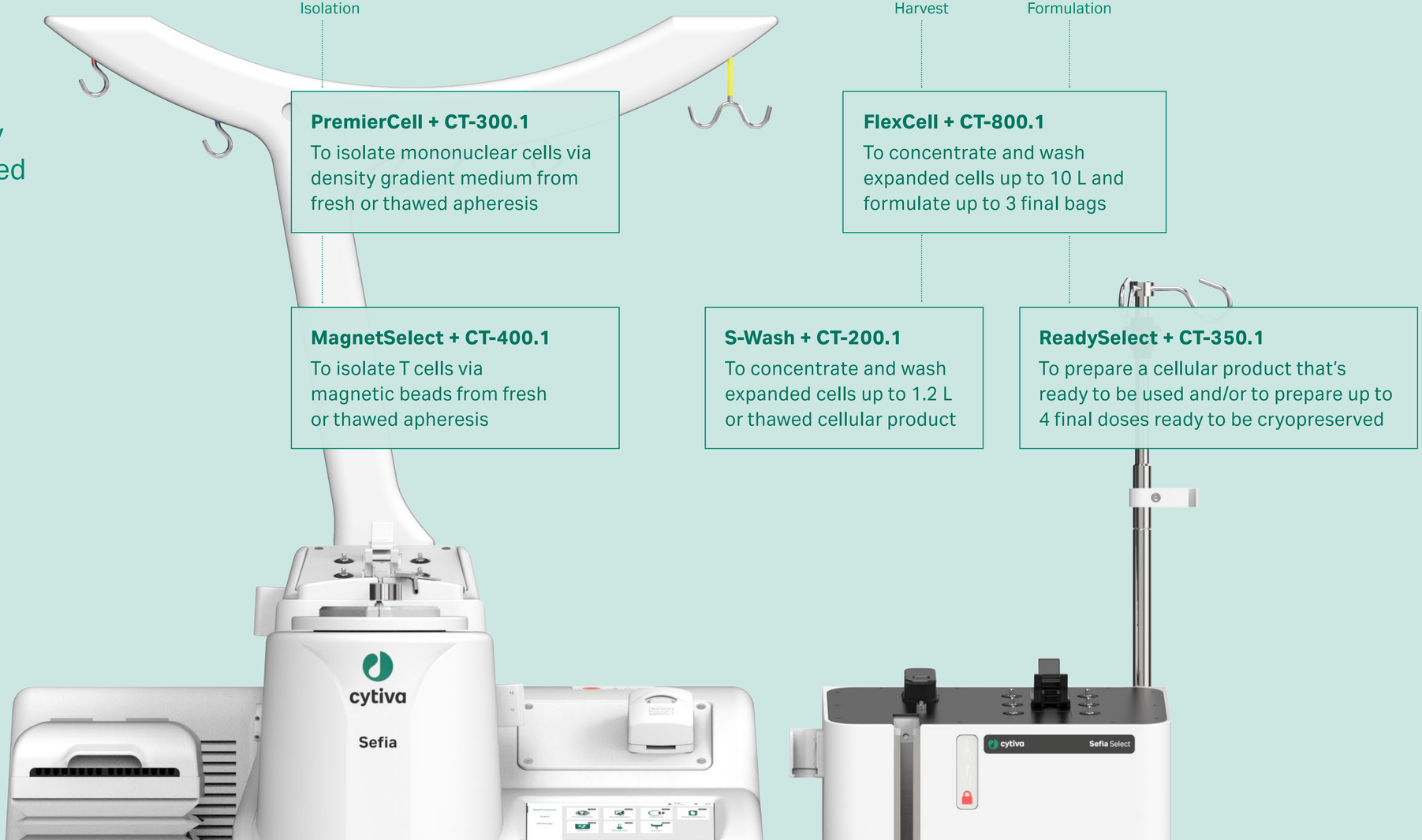
PremierCell + CT-300.1
To isolate mononuclear cells via density gradient medium from fresh or thawed apheresis

MagnetSelect + CT-400.1
To isolate T cells via magnetic beads from fresh or thawed apheresis

FlexCell + CT-800.1
To concentrate and wash expanded cells up to 10 L and formulate up to 3 final bags

S-Wash + CT-200.1
To concentrate and wash expanded cells up to 1.2 L or thawed cellular product

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



Performances[4]

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%

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

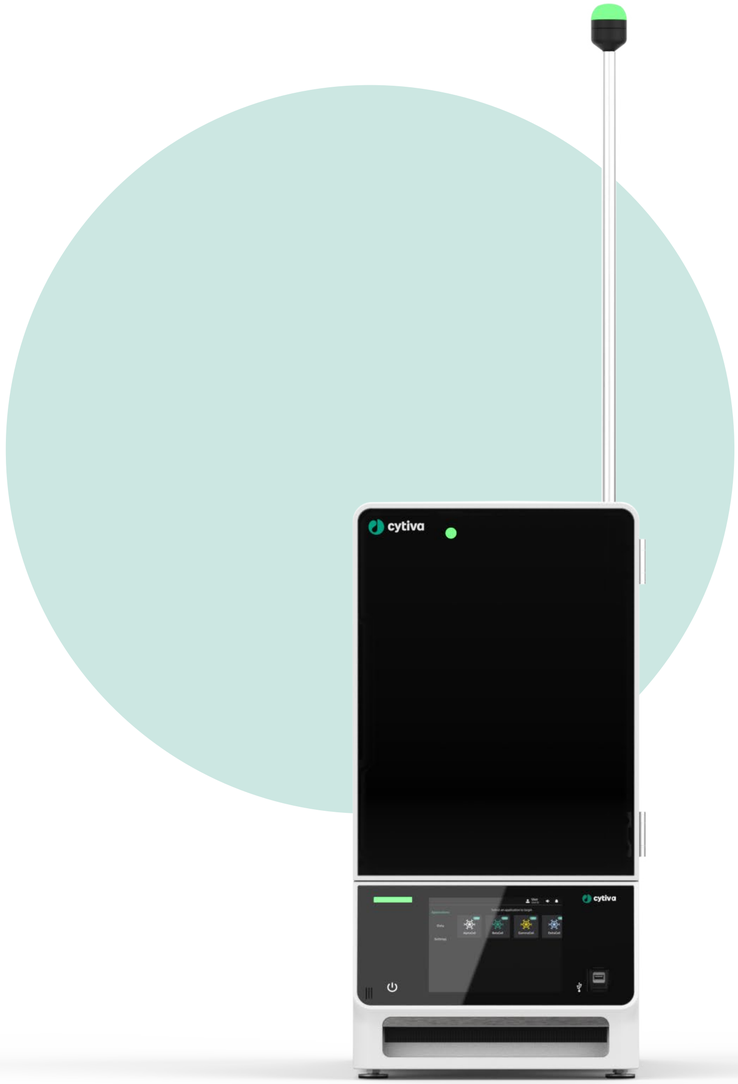








CLICK TO
VIEW ANGLES



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

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.

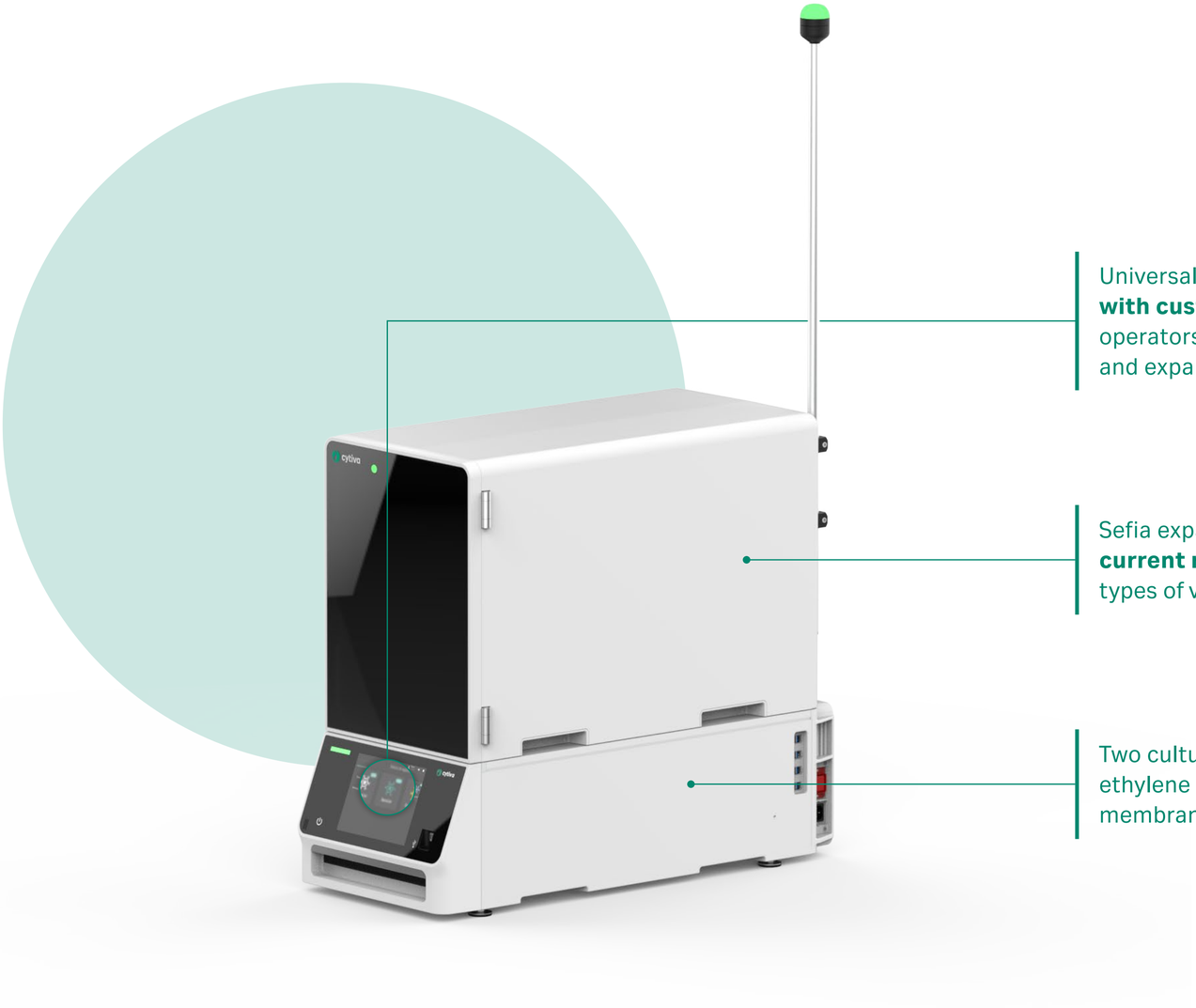








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Universal application offers high flexibility **with customizable parameters** that allow operators to optimize activation, transduction, and expansion steps

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

Deep dive

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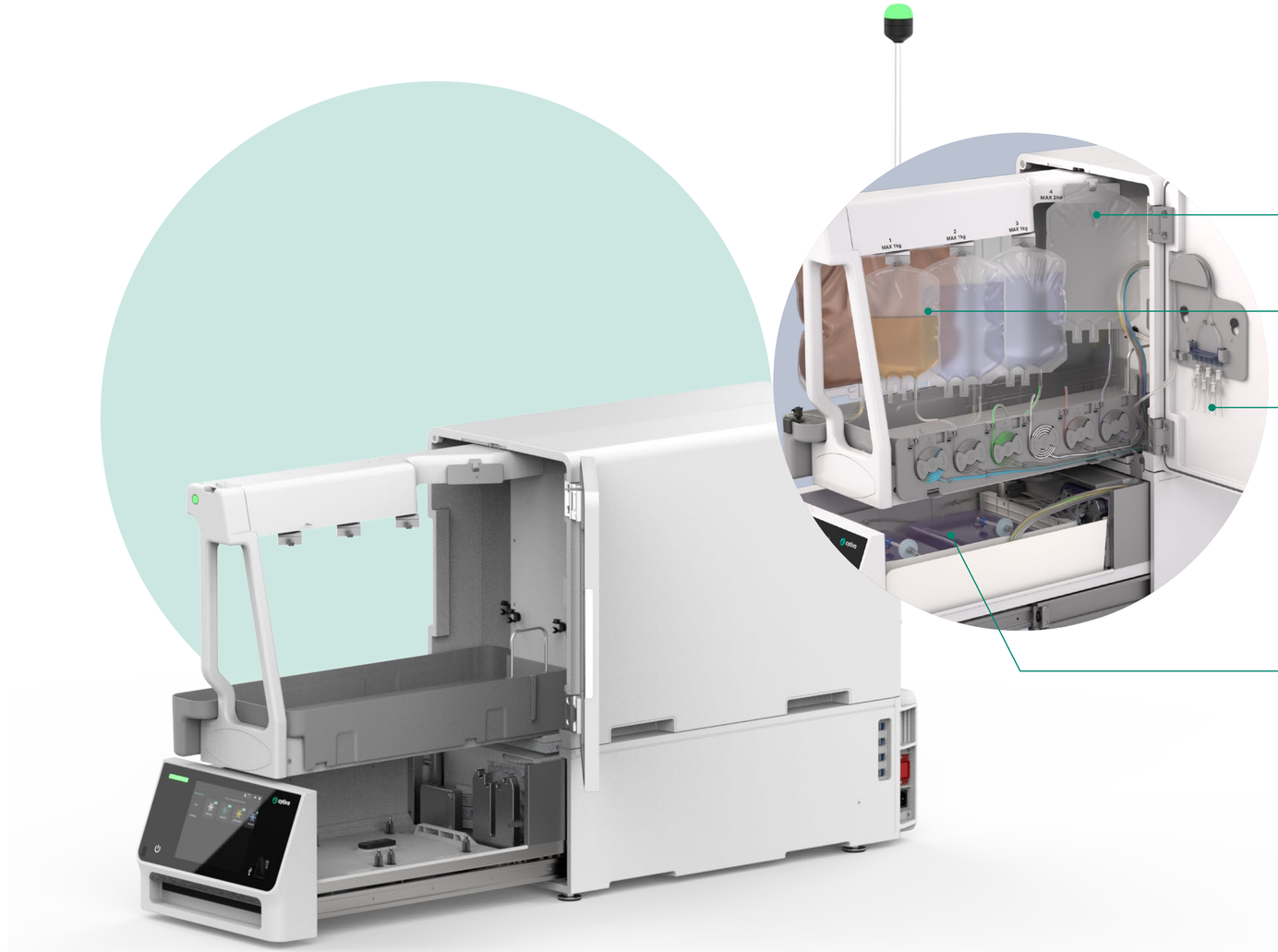








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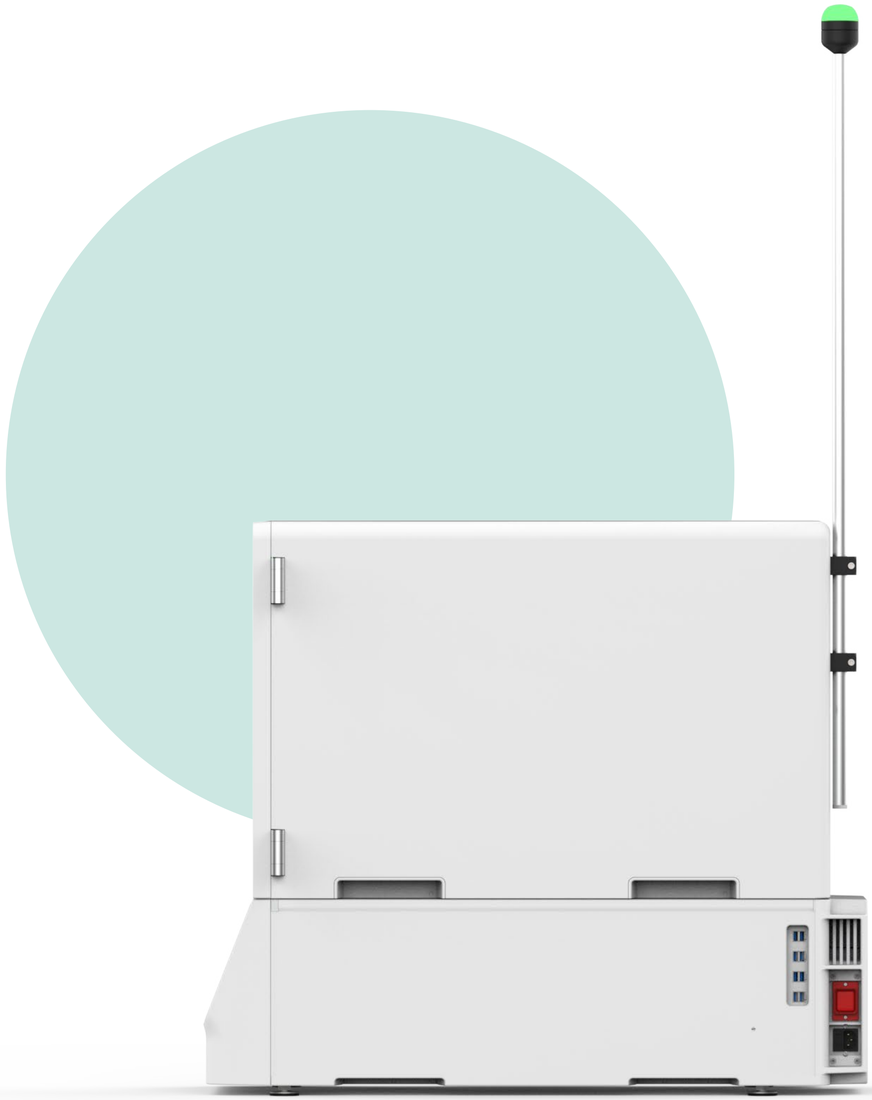








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Performances[5]

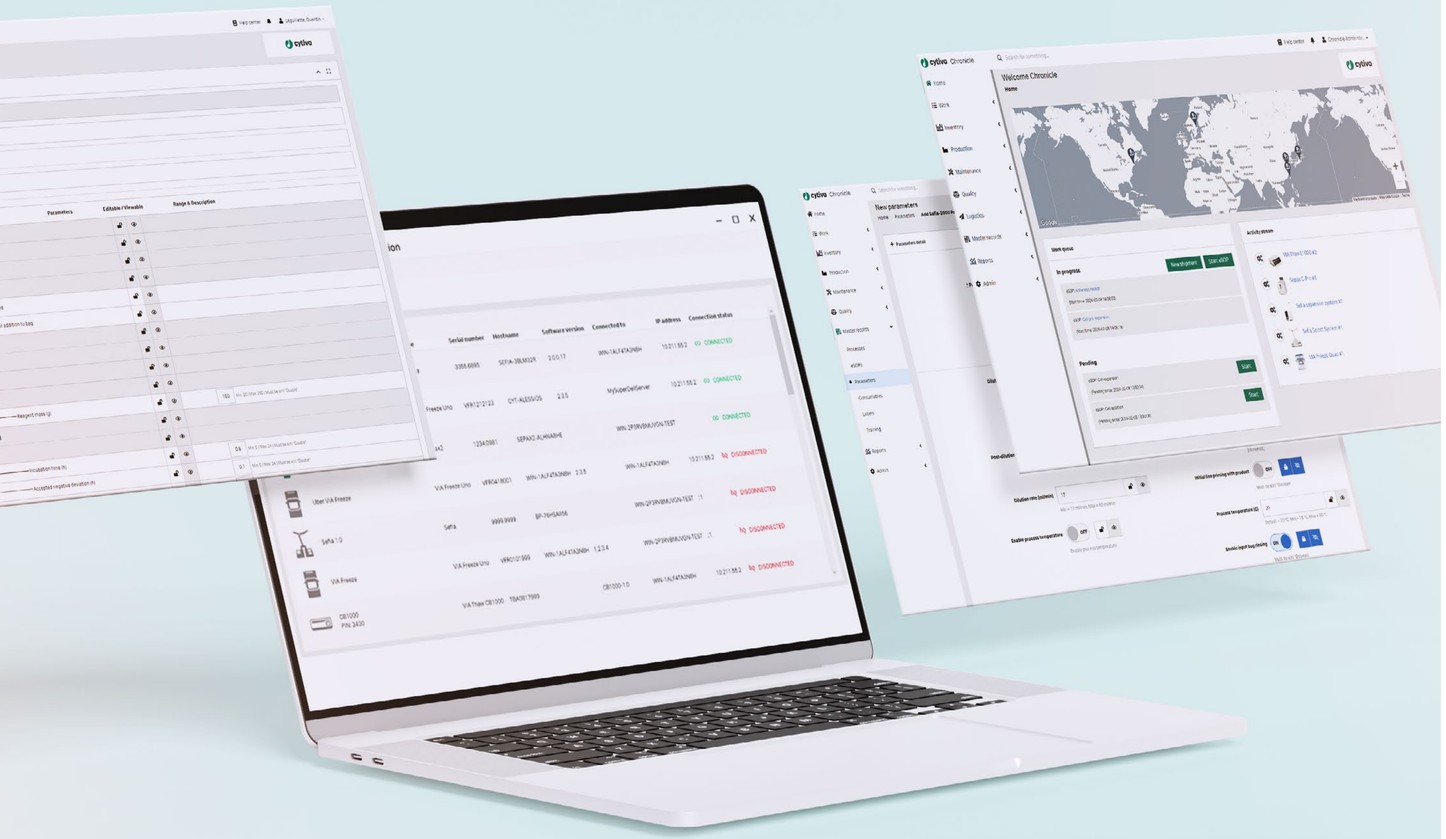
Step	Description	Fresh healthy donor (n = 3)	Frozen healthy donor (n = 3)
Activation	Initial cellular product	Isolated T-cells enriched	Isolated T-cells enriched
	Activator	T Cell TransAct	T Cell TransAct
	Total viable cell seeding number for activation	100×10^6 T cells in 150 mL	100×10^6 T cells in 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	4.9×10^9 T cells (day 8)	2.55×10^9 T cells (day 9)

[5]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.

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.

Chronicle software

A complete, connected solution



Improve your manufacturing experience

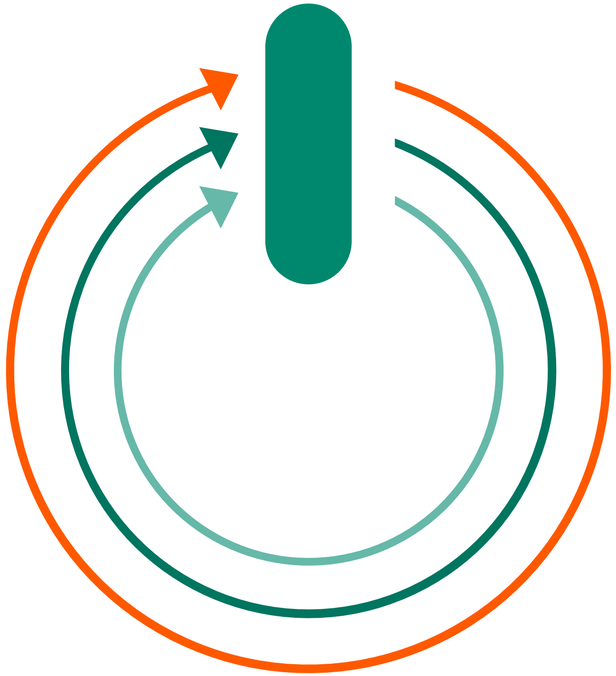
Real-time instrument data monitoring with instant alarm notifications

- 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

From installation to end of life, our equipment services are designed to ensure your equipment delivers maximum performance and value throughout its life cycle, so you can stay on schedule. Whether you have in-house support teams or plan to rely (fully or partially) on Cytiva, we have flexible service offerings to meet your specific needs. Cytiva engineers are certified, recertified, and focused solely on servicing Cytiva equipment, providing hassle-free installation, repair, and maintenance. A comprehensive range of **service plans**, **genuine parts** engineered for reliability, standardized qualification services, and convenient **remote troubleshooting support** are available to protect your investment from day one. **Preventive maintenance**, **tailored training**, and **cost-effective upgrade options** are all designed to help minimize downtime throughout the equipment life cycle.

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've 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

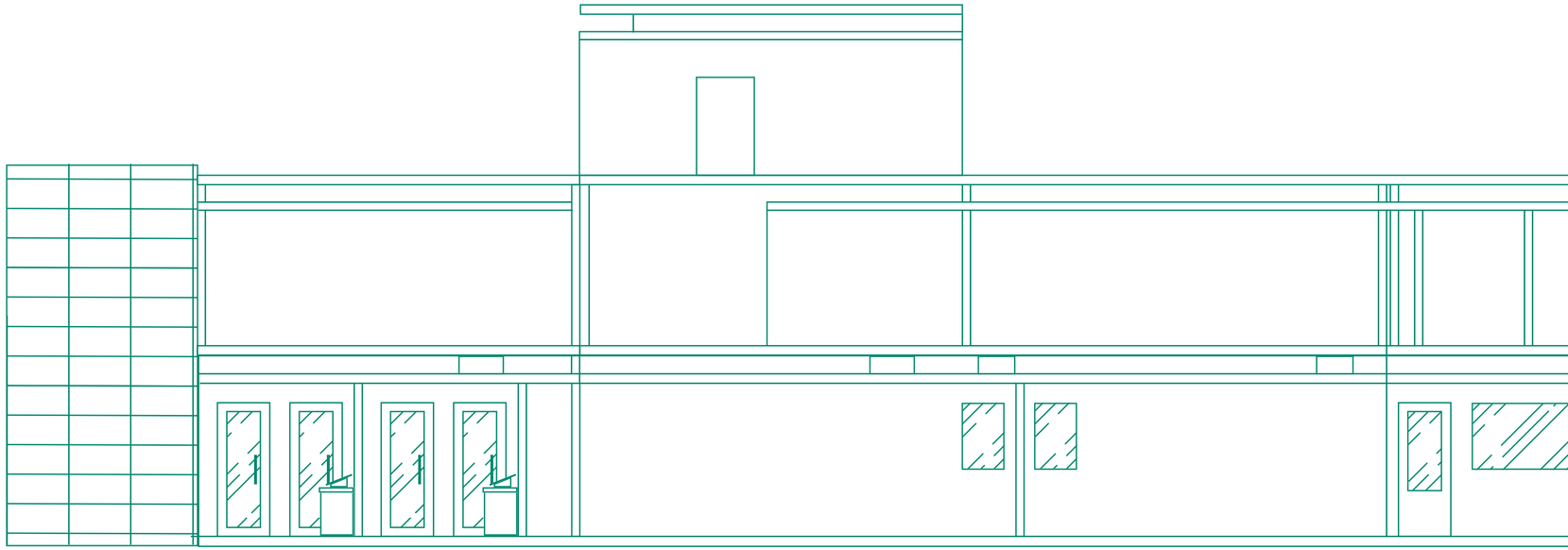
03 harvest and formulation

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.

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.

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.

Instrumentation

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

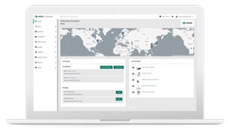
Qualification documentation

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

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
- Harvest
- Formulation



Sefia expansion system

- Activation
- Gene transfer
- Expansion



VIA Thaw™ instrument

- Thawing
- Harvest



Sepax™ C-Pro system

- Isolation
- Gene transfer
- Harvest
- Formulation



Xuri™ W25 system

- Expansion



VIA Freeze™ range

- Cryopreservation



Media and reagents

- Isolation
- Expansion

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

10 out of 15

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

With Cytiva, you're in good hands.



*current as of September 2026.

cytiva

cytiva.com/CAR-T

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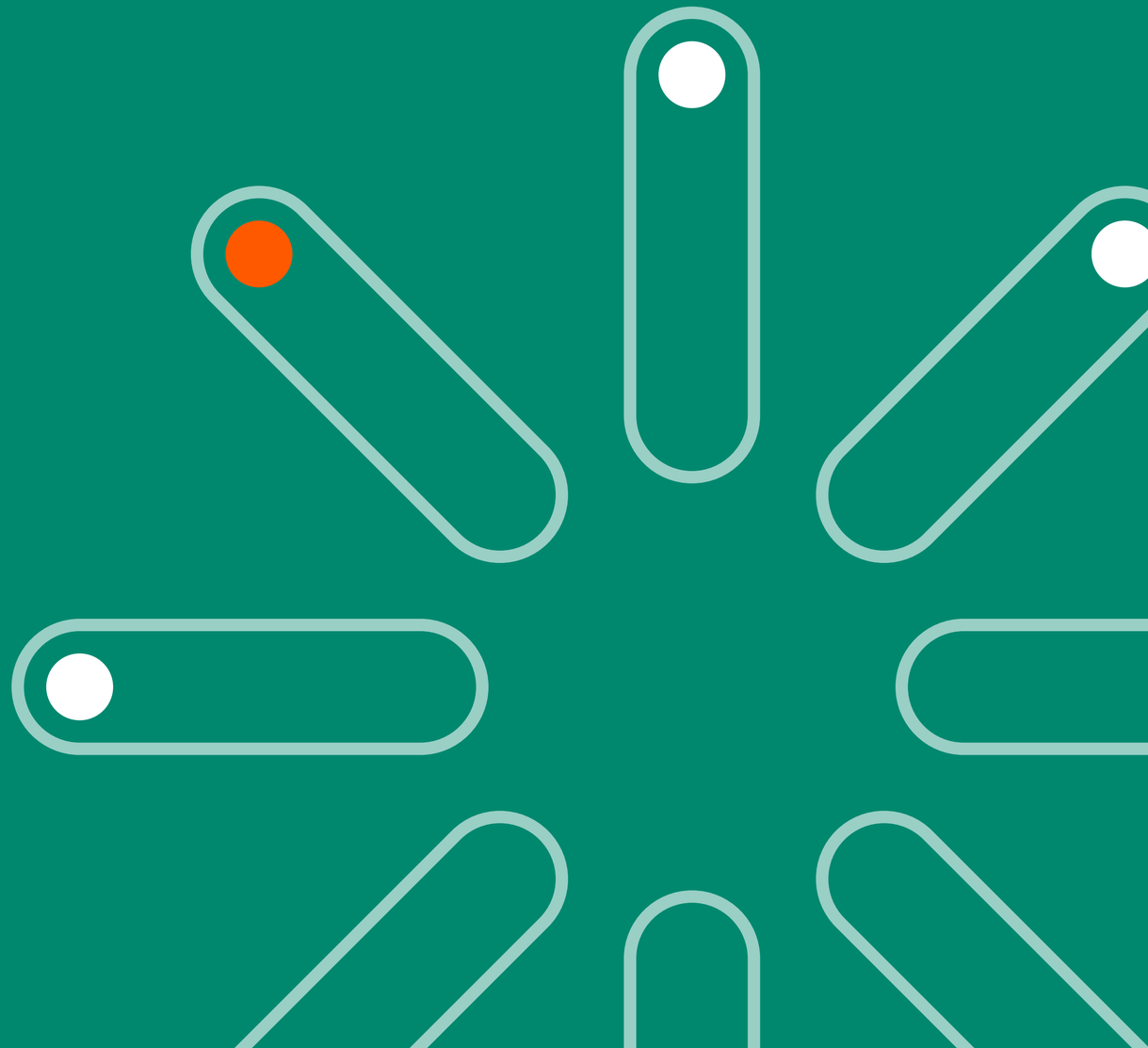
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danaher