

Catalent®

UpTempoSM CAR-T Cell Platform



DEVELOPMENT



DELIVERY



SUPPLY

more products. better treatments. reliably supplied.™

OUR MISSION IS TO DEVELOP & SUPPLY PRODUCTS
THAT HELP PEOPLE LIVE BETTER, HEALTHIER LIVES

90 years of drug development and consumer
product and manufacturing

80 billion doses delivered

50 sites on four continents



Proteins
Antibodies



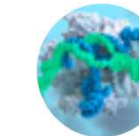
Gene
Therapies



Cell
Therapies



Plasmid
DNA



mRNA
Therapies



iPSCs

Our Experience

Delivering Cell Therapy CDMO services



TECH TRANSFERS & SCALE-UP

20+ tech transfers into GMP

500+ batches manufactured for 20+ customers



PEOPLE

10+ years experience in Cell Therapy

Global organization experienced in clinical & commercial manufacturing



PRODUCTS

Equally experienced in Autologous & Allogeneic

Cell types including:
CAR-T, NK, iPSC, MSC, HSC, TCR-T, TILs



QUALITY

Strong GMP track record

Global team experienced in IND & BLA support to customers

DELIVERING CELL THERAPY CDMO SERVICES FOR 10+ YEARS

Our Cell Therapy Network

Global Campuses, Early Stage Through to Clinical and Commercial-scale

R&D & EARLY-STAGE DEV



Dusseldorf, DE

- Our iPSC Centre of Excellence
- Dedicated teams & facilities for iPSC innovation, development services and characterization
- CGMP suites and storage for producing and storing your iPSC cell banks
- Off the shelf iPSC cell banks

PD/CLINICAL/COMMERCIAL



Gosselies, BE

- Our European Cell Therapy Centre of Excellence
- 86k ft² / 7.9k m² serving your cell therapy process and analytical needs
- 22 Grade B/C CGMP clean rooms
- Full process, analytical, formulation development capabilities
- Dedicated QC facilities & QP services



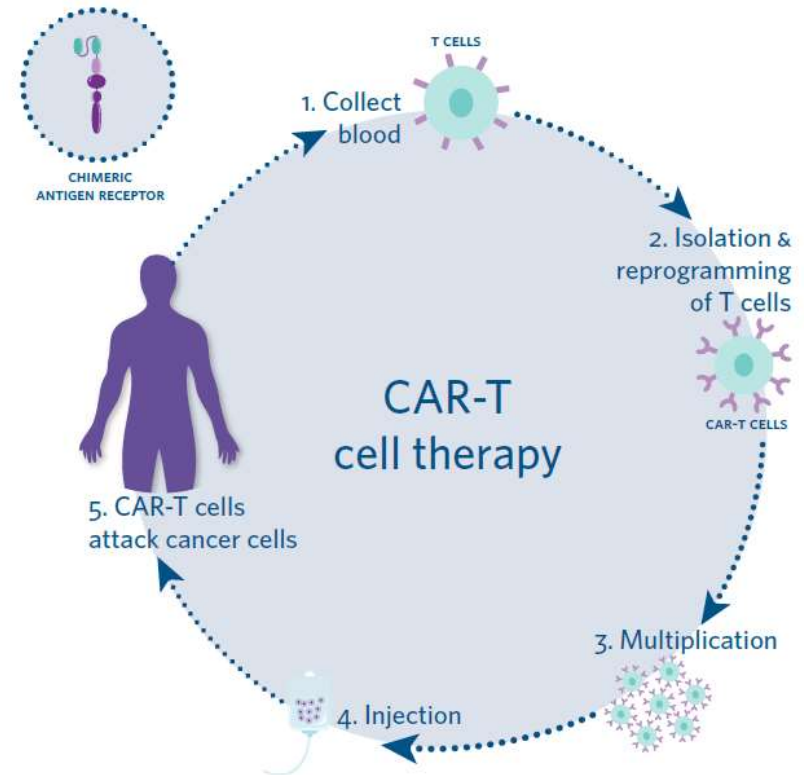
Princeton, NJ

- Our US Cell Therapy Centre of Excellence
- 30k ft² / 2.8k m² serving your cell therapy process and analytical needs
- 16 Grade B CGMP clean rooms
- Dedicated QC facilities
- Significant capacity for future expansion

INTERNATIONAL COVERAGE FOR YOUR CLINICAL & COMMERCIAL NEEDS

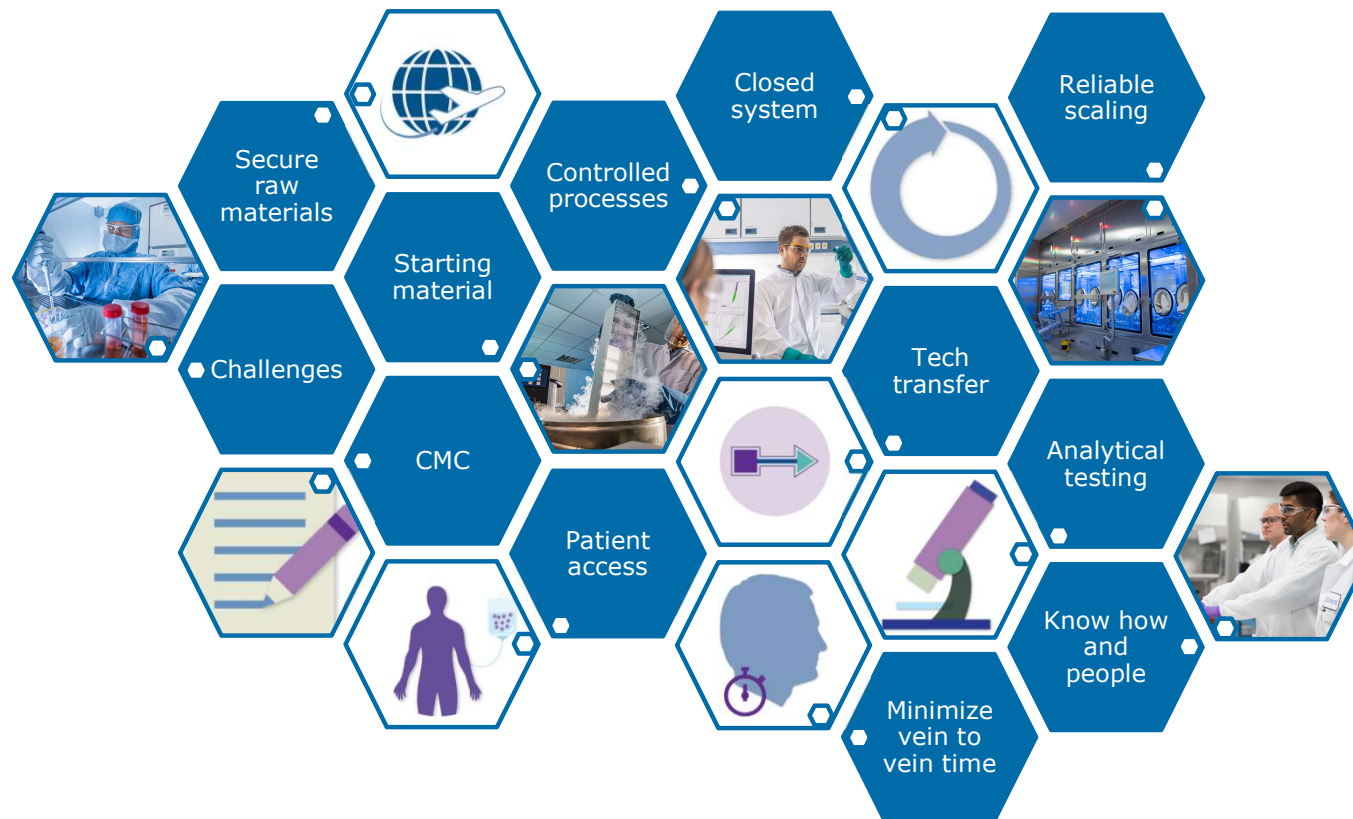
Cell Therapy Market Drivers

- **Growing number of cell therapies in the late clinical phases**
- **Therapeutic reach of cell therapies is expanding**
 - Earlier line treatments
 - New indications + patient populations
- **Autologous front runner**
- **CAR-T most prominent approach**



Cell therapies have unique potential to address unmet patient needs, but there is still work to be done to overcome the many challenges associated with developing and commercializing cell therapies

Cell Therapy Innovator Pain Points



Bashor, C.J., Hilton, I.B., Bandukwala, H. et al. Engineering the next generation of cell-based therapeutics. *Nat Rev Drug Discov* 21, 655–675 (2022)
 Pike R., Motlagh D., Hanley P. Autologous versus allogeneic: the future of manufacturing and standardization in cell therapies. *Cell & Gene Therapy Insights* 2022; 8(7), 1083–1095
 Song H., Somerville R., Stroncek D., Highfill S. Scaling up and scaling out: advances and challenges in manufacturing engineered T cell Therapies . *Int Rev Immunol*, 2022

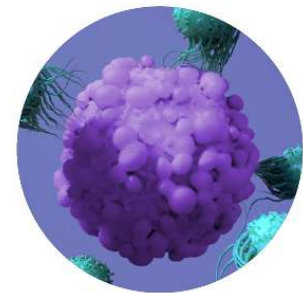
Cell Therapy Process Optimization

- **There is an industry need to:**
 - Standardize and simplify cell therapy manufacturing processes
 - Integrate new technologies and improved manufacturing processes
 - Improve speed to patients

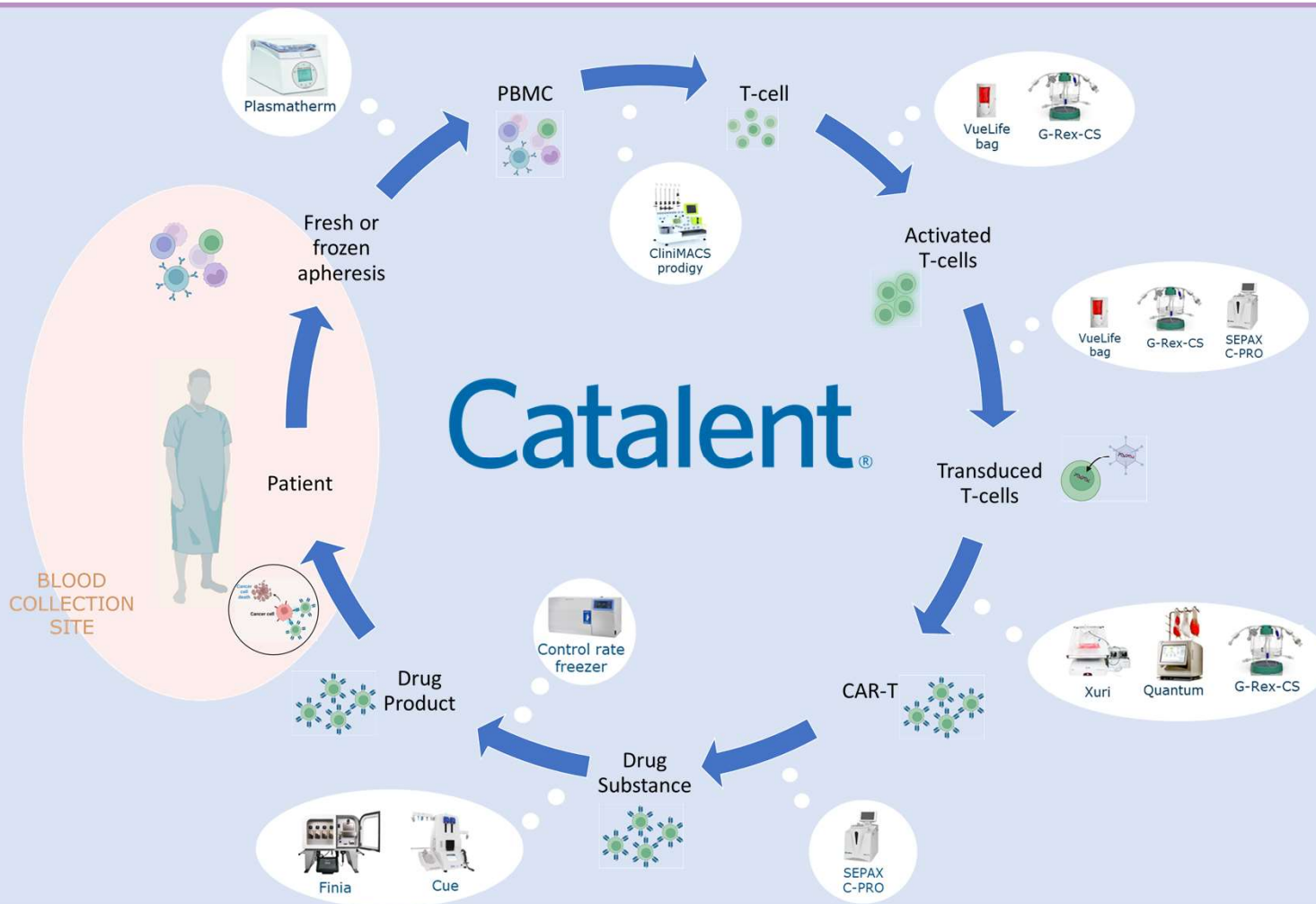


Scalable, customizable, integrated workflows can minimize open processes and reduce manual touchpoints, decrease complexity and ultimately reduce manufacturing failures and increase speed to patients.

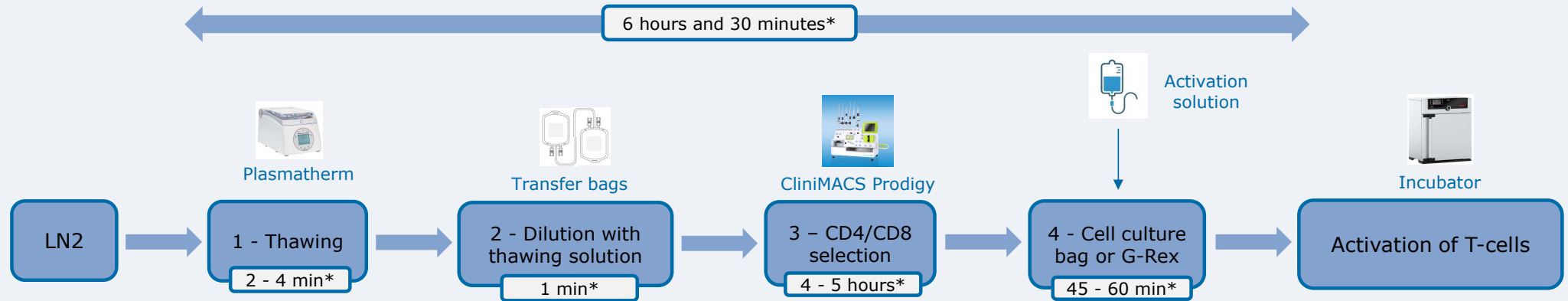
Catalent has launched **UPTEMPOSM CAR-T CELL THERAPY PLATFORM**: A fully closed GMP-compliant CAR-T cell therapy workflow



Fully Closed Platform for Autologous CAR-T Cell Manufacturing



Thawing and Seeding Module



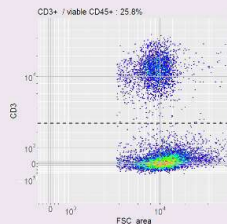
Production

In process control

Pre-selection sampling

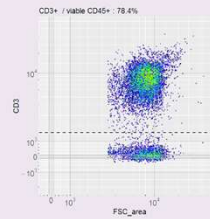
- ✓ Total cell count
- ✓ viability
- ✓ Sterility (BacT or EP2.6.1)**
- ✓ Flow cytometry
- ✓ CoA

Pre-enrichment and post T-cell counts measured by automated flow cytometry (Accellix) CD3+ / viable CD45+



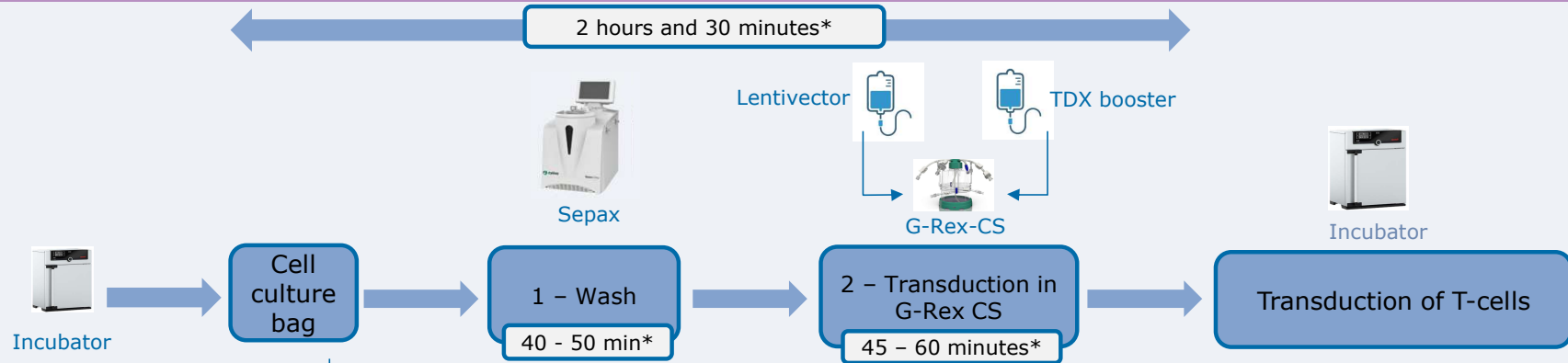
Post-selection sampling

- ✓ Total cell count
- ✓ viability
- ✓ Flow cytometry



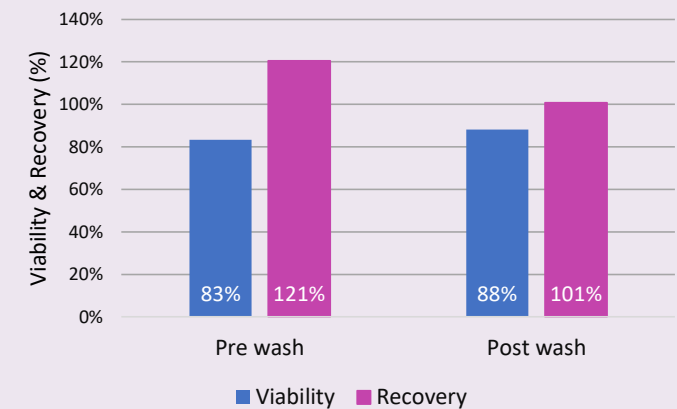
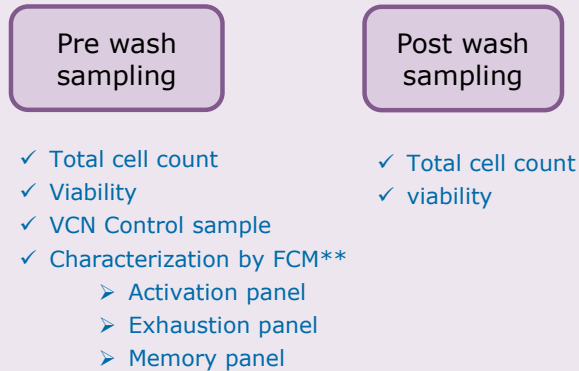
*Timings may vary according to customer project particularities
** optional

Wash and Transduction Module



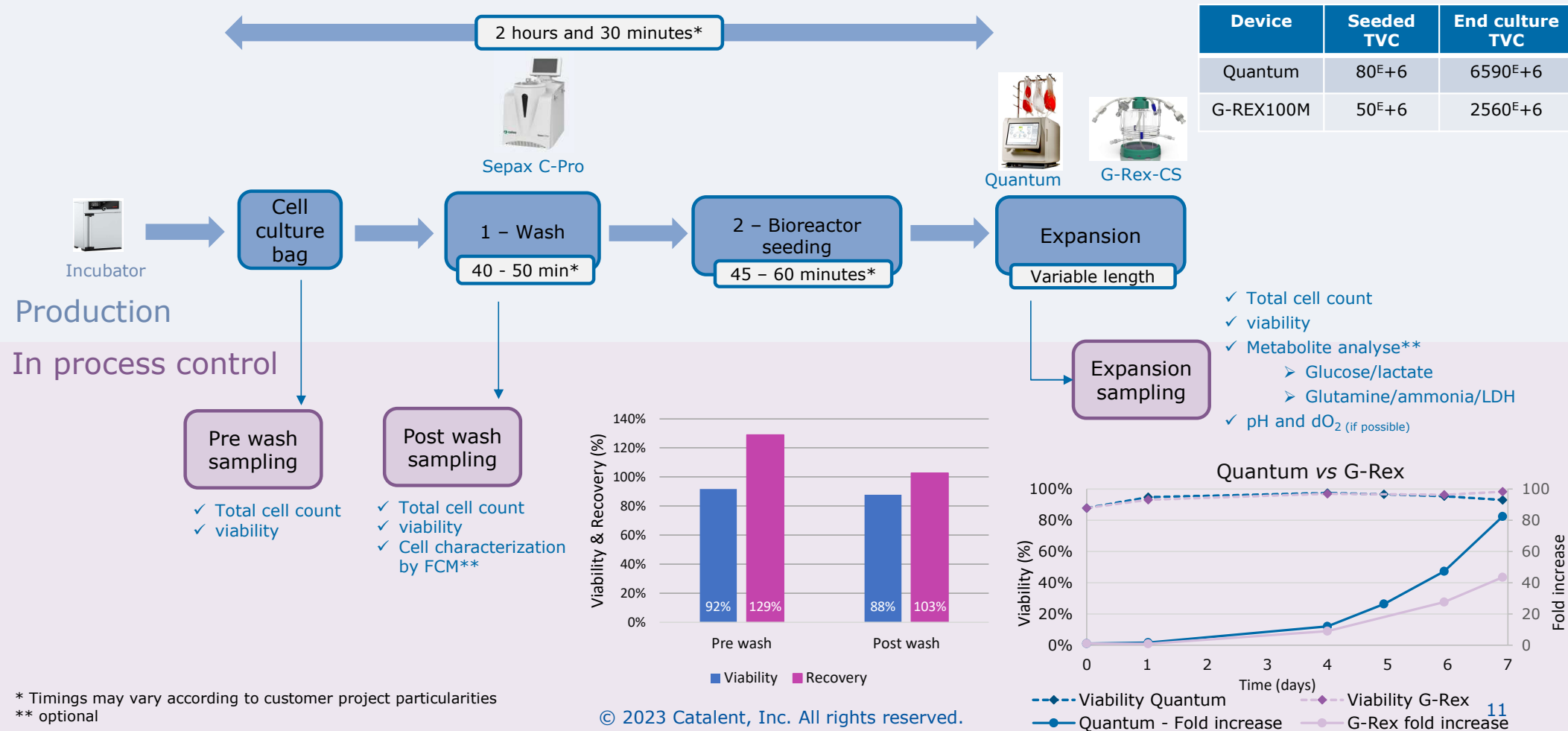
Production

In process control



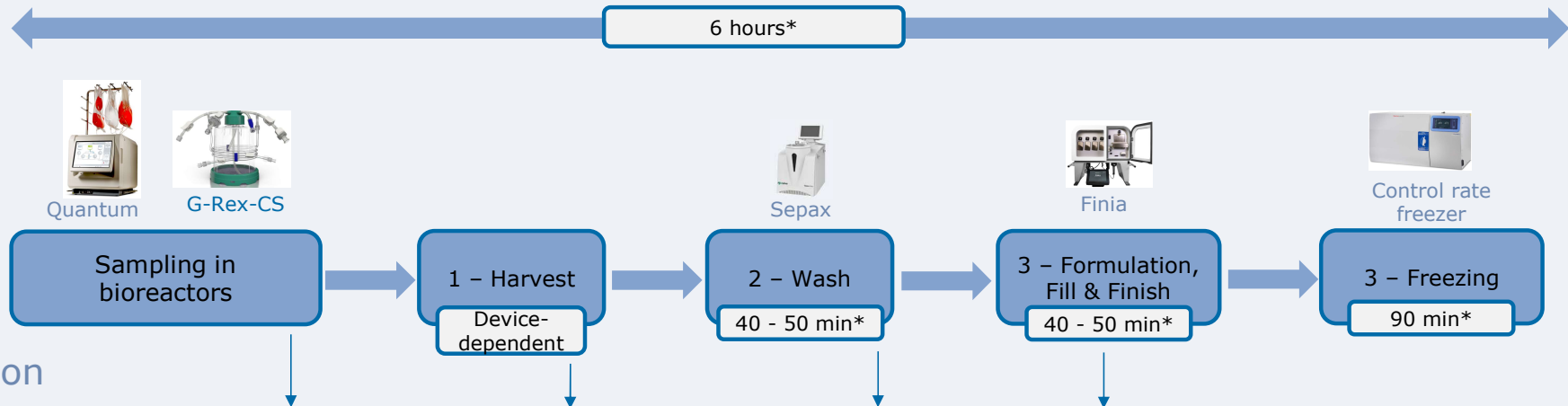
*Timings may vary according to customer project particularities
** optional

Bioreactors Cell Expansion Module



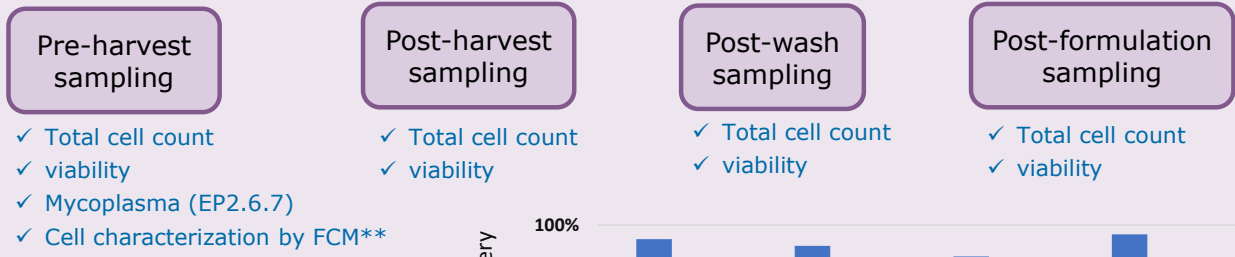
* Timings may vary according to customer project particularities
** optional

Harvest, Fill and Finish Module



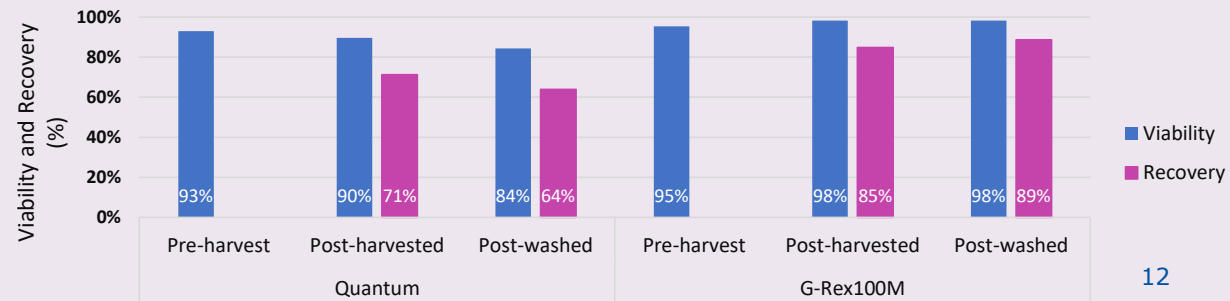
Production

In process control

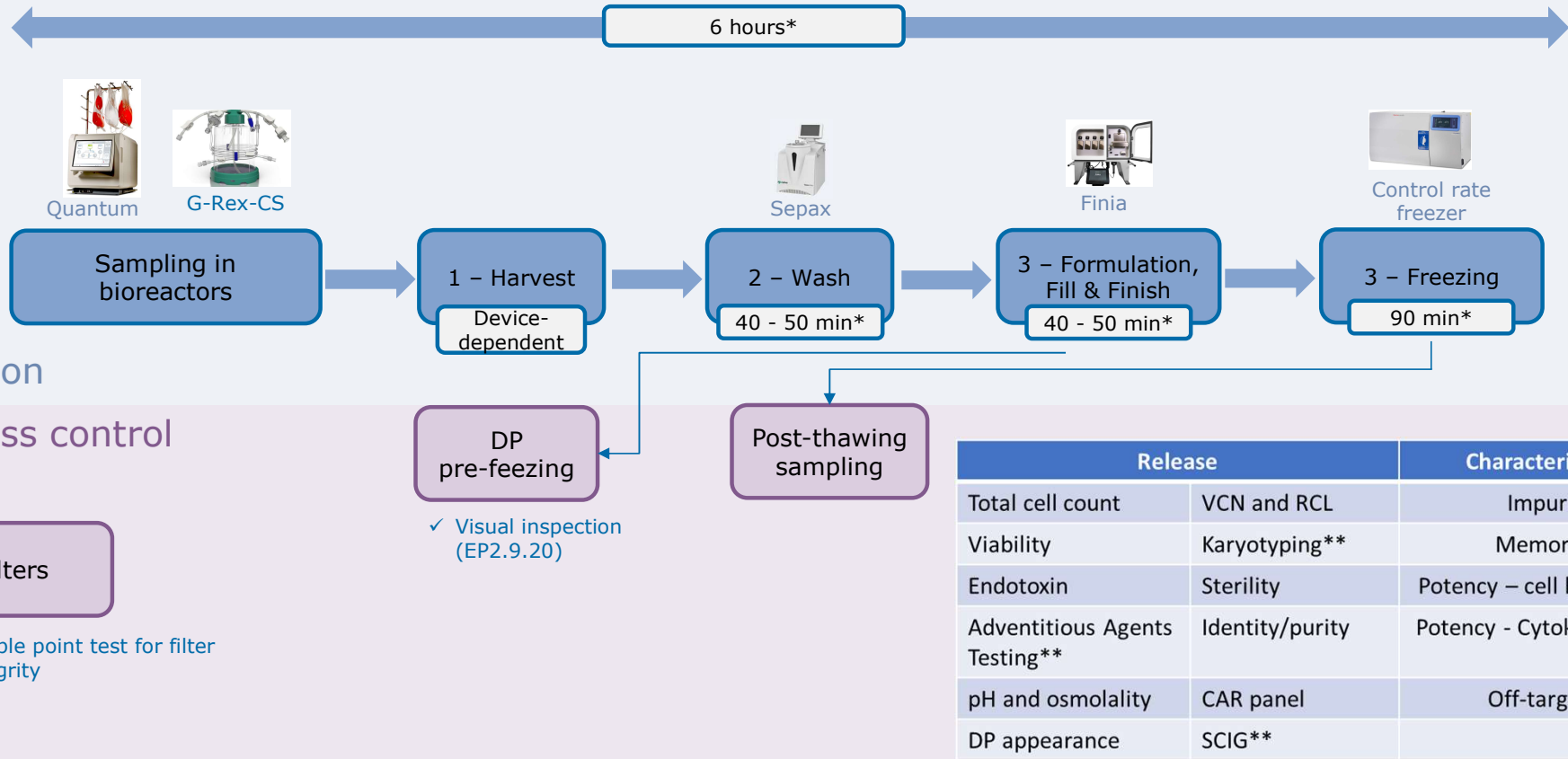


Device	End culture TVC	Harvested TVC
Quantum	6590 ^E +6	4700 ^E +6
G-REX100M	2560 ^E +6	2200 ^E +6

* Timings may vary according to customer project particularities
** optional



Harvest, Fill and Finish Module



* Timings may vary according to customer project particularities
** optional

Conclusion and Next Steps

- **Results generated on primary T-cells and T-cell line, additional testing ongoing**
- **Platform summary:**
 - Accelerate PD to clinic with GMP ready platform ready for clinical manufacturing with minimal optimization
 - Fully closed workflow: designed for grade C background
 - Removes specific APS and reduces environmental monitoring testing
 - COGS and cycle time reduction; secured supply chain
 - Modular platform with flexibility and customizability (plug and play approach)
 - Data-driven guidance to build your workflow, faster
 - Applies Quality by design approach: process optimization leveraging design of experiments
 - Designed for autologous therapies; extendable to allogeneic by allowing scalable processes
 - Supported within Catalent wider, integrated expertise and facilities

Questions?

