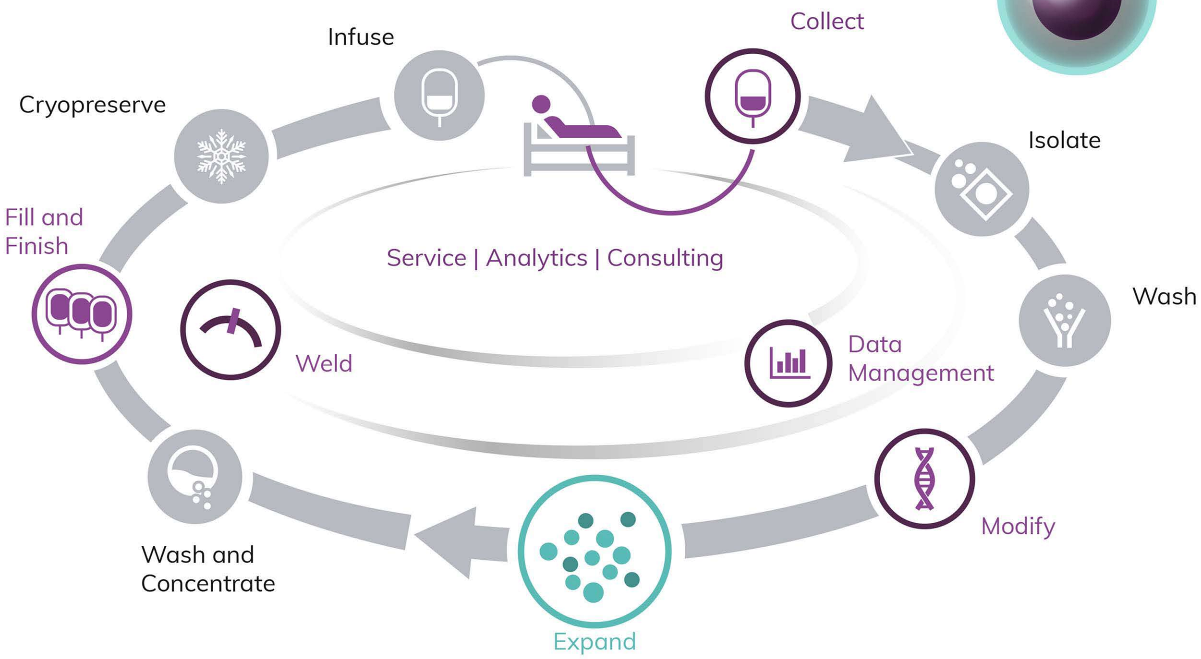
RegMedNet | In focus

Elevate your cell expansion with automated hollow-fiber perfusion technology

Technologies, software and services can be implemented throughout the cell therapy manufacturing process to mitigate risks and overcome challenges



Service | Analytics | Consulting

Collect

Isolate

Wash

Modify

Expand

Wash and Concentrate

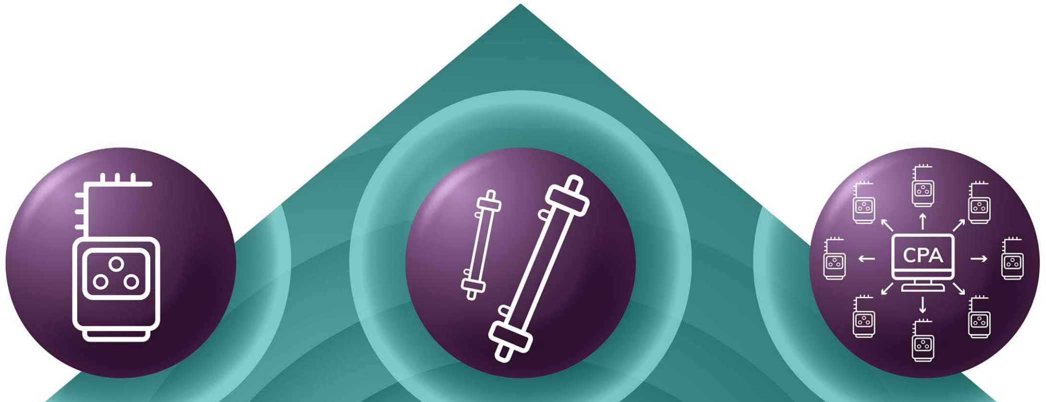
Fill and Finish

Cryopreserve

Infuse

Weld

Data Management

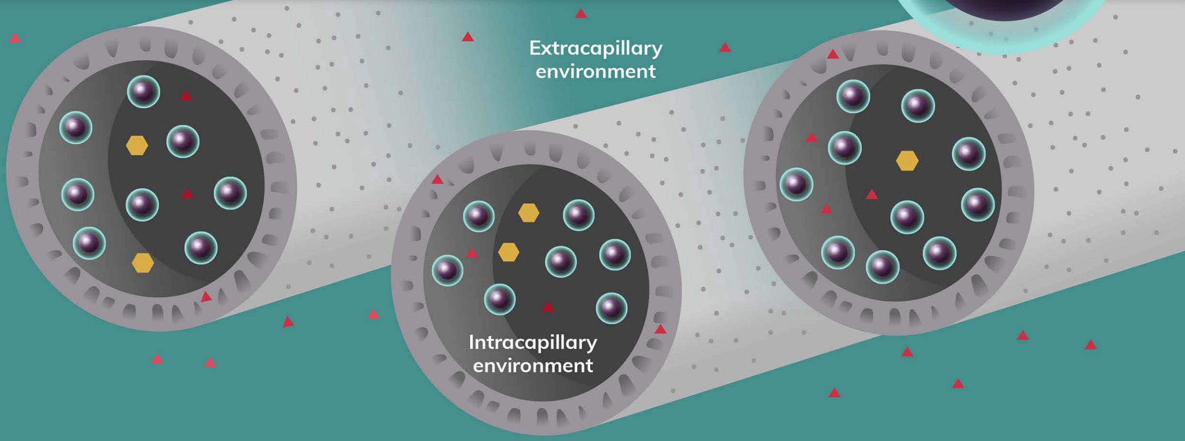


The automated and functionally closed platform allows for the expansion of suspension and adherent cell types

Multiple sizes of hollow-fiber bioreactors facilitate efficient scale-up

The Cell Processing Application (CPA) software enables management of up to 100 devices remotely and facilitates GMP compliance

Cell expansion harnessing the power of perfusion by hollow-fiber technology

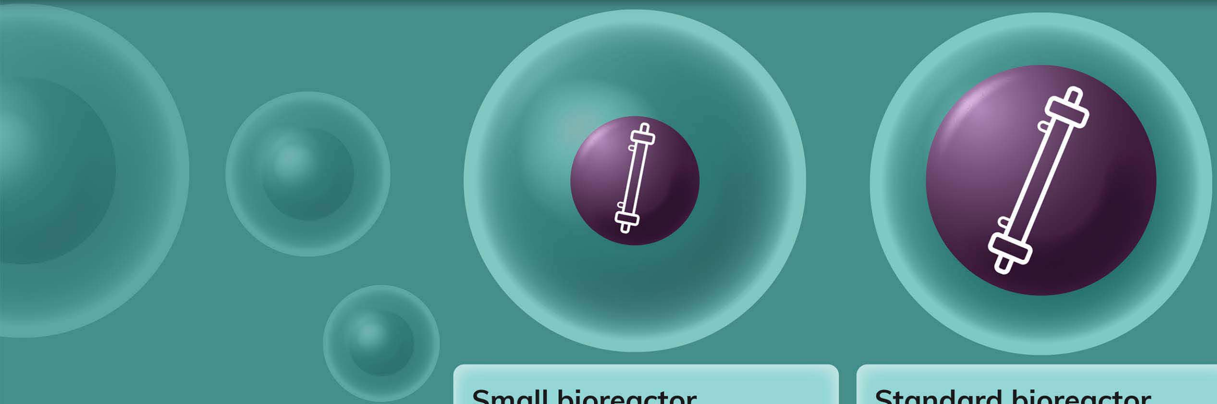


- Hollow fibers are made of a semi-permeable membrane
- Cells are cultured in the intracapillary space
- Cells ● and large molecules ⬢ (serum proteins and cytokines) cannot pass through the pores of the membrane
- Small molecules ▲ (glucose, lactate, salts and gases) can pass freely
- The intracapillary and extracapillary environments have independently controlled circulation loops giving ready access to fresh media, waste removal and gas exchange
- The relatively small culture environment allows for reduced usage of valuable reagents like IL-2 and other cytokines

Use the same hollow-fiber perfusion technology from early phase process development right through to commercial production

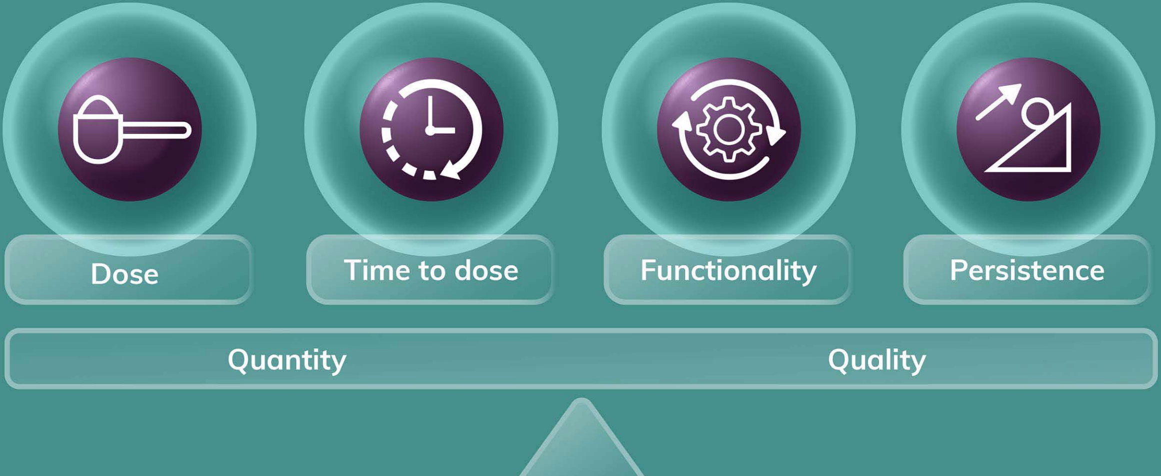
- Eliminate manual preculture steps and open events
- Simplify seed trains
- Expand desirable cell phenotypes
- Scale up smoothly using the same expansion methods

The two bioreactor sizes are effective for expansion of suspension and adherent cells



	Small bioreactor	Standard bioreactor
Membrane area	$0.2m^2$	$2.1m^2$
Effective working volume	14.5mL	138mL
Target yield range	1 billion suspension cells 100 million adherent cells	10 billion suspension cells 1 billion adherent cells

Balancing the quantity and quality of the final cell product



Dose

Time to dose

Functionality

Persistence

Quantity

Quality

Offerings of the Quantum Flex Cell Expansion System

Optimal quality cells

- Functionally closed and automated
- Desirable phenotypes generated during expansion
- Harvest in 0.2 to 0.5L volume

Smooth end-to-end scalability

- Scale-down with small bioreactor
- Scale-up with standard bioreactor
- Scale-out with CPA software

Device versatility and connectivity

- Process development needs
- Compatible with diverse applications to support multiple pipelines
- Central control, remote device monitoring, configuration of multiple devices

Data management and documentation

- Report management and advanced reporting capabilities
- Maintain data integrity and facilitate compliance with FDA 21 CFR Part 11 and EU GMP Annex 11
- Facilitation of cGMP compliance, including with FDA 21 CFR Part 11

This infographic has been created as part of a RegMedNet feature in association with Terumo Blood and Cell Technologies

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