

Invetech

Manufacturing Solutions for Your Cell and Gene Therapy Journey

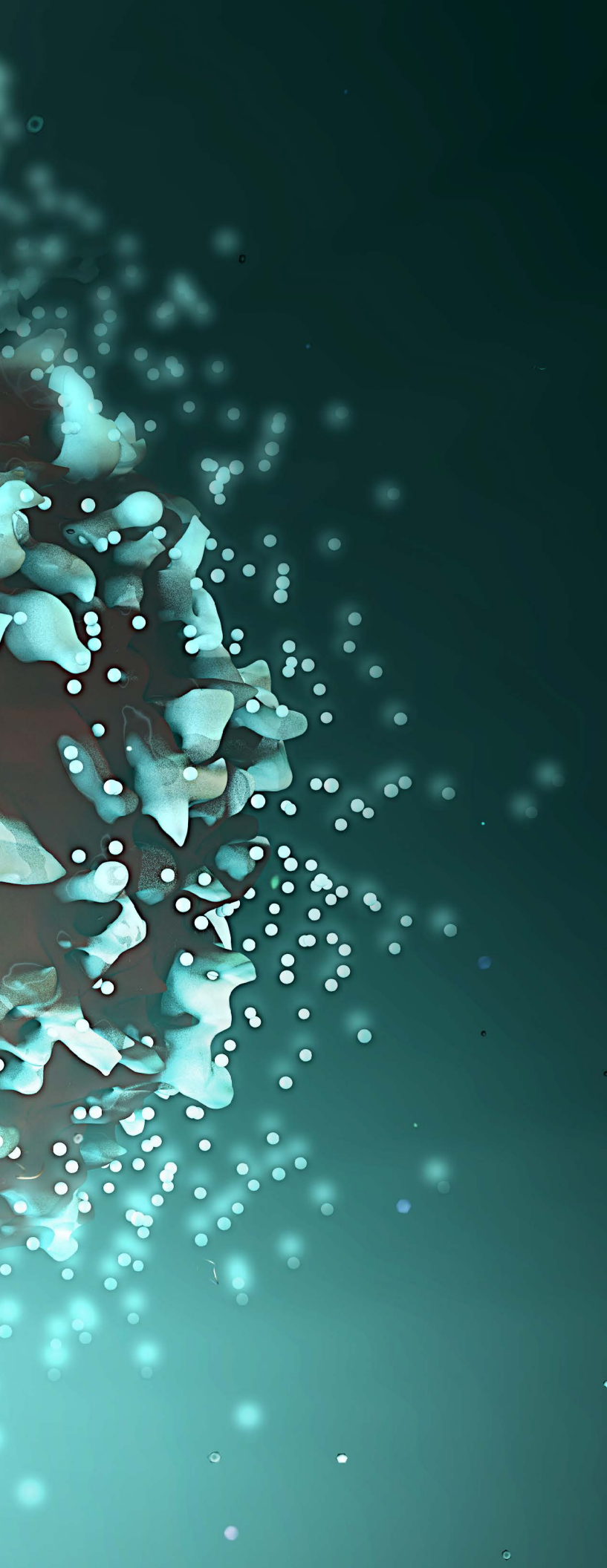
Scale Your Processes to Deliver Therapies
to Patients Faster





In an industry where the product is a living cell, it's important that therapy developers have access to closed, automated platforms that can be configured to fit their own unique unit processes and reduce manufacturing variability.

We find that having biologists and engineers collaborating with cell and gene therapy manufacturers is the key to developing high quality manufacturing systems. This ensures that the biology of the therapeutic product is not inadvertently changed during the migration to these automated processes."



Manufacturing solutions built for cell and gene therapies at scale

Invetech's robust, scalable and production-ready solutions can operate with higher reliability, greater efficiency and lower cost than clinical systems and technologies adapted from other industries.

Reduce your process variability

Since 2003, cell and gene therapy (CGT) developers have partnered with Invetech to design manufacturing solutions that prioritize repeatable cell quality and batch-to-batch consistency in a GMP environment. Our closed and automated CGT manufacturing solutions reduce manufacturing inefficiencies and variability for early-stage and mature life science companies.

Characterize and control your CGT process

CGT manufacturing requires increasingly adaptive process strategies to account for the inherent variability of the starting material. Invetech's platforms are configurable, robust and flexible.

Through process characterization and maintaining high control over process parameters, we can help to adapt the process to account for a wide range of starting material and cells.

Our extensible technology platforms offer performance with flexibility.



Invetech is a pioneer in closing, integrating and automating end-to-end manufacturing processes for cell and gene therapies.

Technology and solutions that adapt to your process

Our technologies and solutions grow with you from process development to commercial scale. They help transition manufacturing from pre-clinical to large-scale GMP manufacturing.

→ **Manufacturing consulting and roadmapping**

Our team partners with you to craft manufacturing strategies that grow with your process by considering: available commercial-scale processing technologies, short and long-term tech transfer requirements as well as GMP manufacturing planning and total cost of ownership.

→ **Configured platforms**

Our platforms are designed for maximum flexibility to accommodate your specific requirements for integrated, semi-automated or fully automated production. All elements are robust, GMP compliant, closed, cleanable and designed to speed process validation.

All our platforms are supported through extended warranty and service programs.

→ **Custom manufacturing solutions**

The range of manufacturing needs in CGT is wide, and sometimes a custom manufacturing solution is needed. Our custom engineering and design services deliver high quality manufacturing solutions that fit your business case and process requirements.

→ **Fit for purpose single-use sets**

Our closed and sterile single-use sets are designed to fit with Invetech's equipment solutions to streamline manufacturing operations and ensure consistent performance. All sets are manufactured to meet GMP requirements.

The Invetech supply chain team collaborates with our customers to routinely review forecasts and supply chain demand to ensure business continuity.

→ **Applications laboratory services**

Our applications laboratory services support your process. See next page for more.



Control your process with our applications laboratory services

Our cell biologists work with you to understand your manufacturing requirements so you can optimize and retain control of your process during and after migration from open to closed manufacturing solutions.

This includes:

➔ **Process characterization**

Including immunophenotyping, cell expansion kinetics and residual testing to develop a well-defined, controlled, GMP-compliant manufacturing process.

➔ **Process optimization**

Migrates open processes to closed systems, which increases reproducibility, minimizes yield loss, reduces the number of operators and supports meeting applicable regulatory requirements.

➔ **Integration of unit operations**

Streamline your manufacturing process.

➔ **Industrialization**

Create scalable, repeatable processes to assure Confidence

Confidence in quality and reproducibility

Our cell biologists and engineers work together to help assure your therapy remains unchanged by the clinical and commercial manufacturing processes.

We integrate unit operations to fully automate production systems that reduce costs, variability and errors associated with manual processes.

Set your cells up for downstream success with Korus™

The cell and gene therapy manufacturing process is tough on cells. The Korus™ system's elutriation application gently prepares your starting material to optimize downstream performance: higher cell selection recovery and growth. It also selects the cells you need while depleting the cells and contaminants you don't need. The result is a stronger intermediary product for downstream processing.

The Invetech Korus™ Counterflow Centrifugation System

The Korus™ system supports wash and cell isolation using gentle counterflow centrifugation. It offers better overall process performance through higher recovery and purity of your target cells:

- 85.2% lymphocyte recovery and 90.3% purity¹
- 88.6% monocyte recovery and 75.0% purity¹
- Over 90% platelet depletion¹

¹ Averages from Invetech protocol development study



Optimize your elutriation and wash protocols on the Korus™ system

Flexibility to configure and optimize your own protocol

With the Korus™, you are empowered to finetune your protocol to your unique starting materials and process conditions. At the transition to GMP manufacturing, you can lock down your protocol to reduce errors and ensure better batch to batch consistency.



Korus™ specifications

Viability loss	<5%
Input volume range	25 mL – 9 L
Output volume range (user defined)	25 mL – 500 mL
Single-use set loading time	<5 minutes
Typical processing time	<1 hour typical
Standard operations	Lymphocyte elutriation Monocyte elutriation with media exchange option Cell wash with media exchange option
Display	Glove compatible color touchscreen
Control system	Enables 21 CFR Part 11 Compliance
Chamber volume	Two 50 mL chambers
Maximum operational RCF	1000 x g
Dimensions	W 1460 mm (57.5 in), H 760 mm (30 in), D 810 mm (32 in)
Weight	195 kg (430 lb)

Processing volume range
25 mL – 9 L

Korus™ single-use set

The Korus™ functionally closed, sterile single-use set has a user-friendly design that can be used in process development or GMP production environments. The set comes ready to use in a sealed tub designed to make loading onto the device easy. The set is designed with weldable tubing, making it possible to attach source material and media in a class C or D (ISO 7 or above) clean space.

Korus™ single-use set components

- Harvest bag
- Fraction bag
- Waste bag
- Rotor with two 50 mL chambers

Korus™ tubing specifications

- 3/32 in ID x 5/32 in OD PVC weldable lines
- Weldable with the Terumo TSCD-II



FURTHER INFORMATION
invetechgroup.com/korus

Raise your manufacturing efficiency with our GMP formulation and fill solutions

Formulate and fill is a critical and sensitive stage in the manufacturing process. It is also typically one of the more open and vulnerable unit processes in CGT manufacturing. Close your manufacturing process with one of Invetech's scalable and automated formulation and fill solutions. These configurable systems are scalable and minimize process variability.

The Invetech Alta™ Automated Bag Filling System

Invetech's award-winning Alta™ automated bag filling system can be configured to accurately dispense therapeutic products or processing material from formulated bulk into individual aliquot bags. Utilizing aseptic single-use sets to provide sterile processing without a barrier isolator, the Alta™ system provides automated, closed, efficient and flexible bag filling in class C or D cleanroom settings.



Specifications	
Output bag size range	50 mL ~ 750 mL
Fill volume (per bag)	10 mL ~ 190 mL
Total dispense volume	Up to 100 L depending on aliquot volume
Fill accuracy	$\leq \pm 5\%$ vol. or ≤ 1 mL
Bags per manifold	Up to 66 aliquot bags per set
Batch capacity	528 bags (via multiple manifolds)
Fill rate	Typically 1 bag per minute

WATCH PRODUCT VIDEO

invetechgroup.com/3rd-generation-filling-system

The Invetech Automated Media Production Platform

The Invetech Automated Media Production Platform is a formulate and fill platform designed to accurately formulate and aliquot media or buffer solutions using flexible pre-defined recipes in a GMP environment. The platform gives confidence to your process utilizing sterile, closed single-use sets which allow for operation in class C or D cleanrooms. It integrates seamlessly with various MES.



Specifications	
Formulate and dispense mixed media input volumes	100 mL – 100 L
Number of starting ingredients	Up to 9
Bag sizes	1 L and 5 L
Fill duration (100 X 1 L bags (incl. setup, tear down))	8 hours with 5% volume accuracy

WATCH PRODUCT VIDEO

invetechgroup.com/formulate-fill

The Automated Media Production Platform is for research, laboratory or further manufacturing use only. It is not intended as a medical device in therapeutic or diagnostic procedures. Customers are responsible for validating the use of the platform within their process or therapy.

Invetech

Invetech helps cell and gene therapy developers to visualize, strategize and manage the future. Through ready-to-run systems and custom solutions, proven processes, expert insights and full-spectrum services, we swiftly accelerate vital, emerging therapies from the clinic to commercial-scale manufacturing. Together with our partners, we expand the reach of next-generation medical advances that are revolutionizing healthcare.

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