

TIMOTEC



ATMP

**Solutions for
Cell and Gene Therapy**

Together we create tailored solutions

Our core specialization is the manufacturing of custom isolator technology precisely designed to meet the specific requirements of our customers. At the same time, we also offer standardized product lines representing proven solutions for common applications.

STANDARDS AND CERTIFICATIONS

Our manufacturing processes and products comply with international standards including ISO 14937, GMP guidelines (EudraLex Volume 4), ČSN EN ISO 14644-7, and other regulatory requirements, ensuring the highest level of quality and safety.



CELL AND GENE THERAPY

Cell and gene therapy represents advanced therapeutic approaches utilizing living cells or genetic material to specifically target pathological processes.

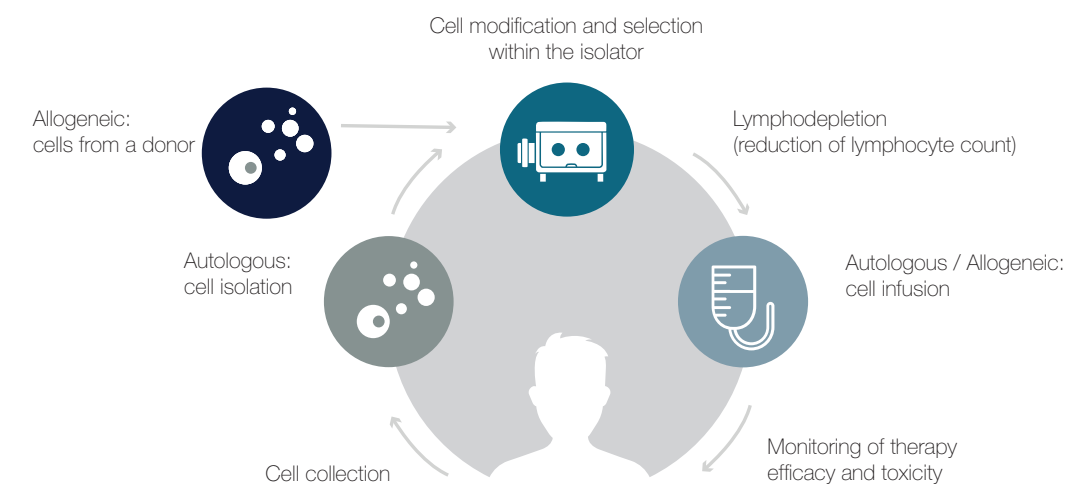
These methods are applied both in research and development phases and in the clinical manufacturing of ATMP products.

A key characteristic of CGT is the handling of highly sensitive biological samples requiring precisely controlled conditions for cultivation, manipulation, and storage throughout the entire processing cycle. From both technological and operational perspectives, cell and gene therapy

places exceptionally high demands on environmental cleanliness, process traceability, and minimization of risks associated with human intervention.

One of the most critical points is the transfer of samples between individual devices, where cultivation conditions may be disrupted and the risk of contamination increased.

For this reason, closed and integrated systems are becoming increasingly important, enabling stable, controlled, and repeatable processing in compliance with GMP requirements and clinical manufacturing standards.



ISOLATOR WITH INTEGRATED INCUBATOR

The aseptic isolator with integrated incubator developed by Timotec represents an advanced solution for cell and gene therapy applications. It provides product protection against environmental contamination, operator exposure, and contamination caused by bacterial growth throughout all stages of the process.

CLEANLINESS CLASS "A" according to EU GMP

TIGHTNESS CLASS 3, according to ISO 10648-2

LAMINAR AIRFLOW, 0,45 m/s $\pm$ 20%
(864-1533 h⁻¹ depending on chamber volume)

CONSTRUCTION MATERIALS

Housing material – stainless steel AISI 304
Chamber – stainless steel AISI 316L and certified
FDA-approved plastics

OPERATING MODE

Positive or negative pressure operation

H₂O₂ DECONTAMINATION

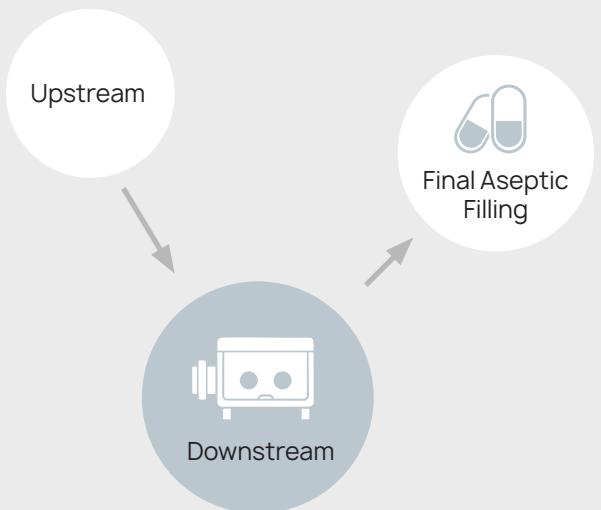
Independent chambers with independent HVAC
systems

OPTIONAL INTEGRATION OF ADDITIONAL DEVICES

Particle counter, microbiological monitoring



THE RIGHT SOLUTIONS for your process



APPLICATIONS

- Filling of sterile injection and infusion solutions
- Aseptic preparation of pharmaceuticals in hospital departments
- Handling of cell cultures and viral vectors
- Preparation of sterile media in biotechnology
- Microbiological testing under aseptic conditions
- Advanced gene therapies
- Sterility testing

**INTEGRATED
INCUBATOR**

STERILE ENVIRONMENT

Provides maximum protection of samples against contamination. Rounded corners and polished internal surfaces allow easy chamber cleaning.

**OPTIMAL CONDITIONS
CO₂ ATMOSPHERE**

Carbon dioxide inside the incubator is essential for cell cultivation, as it helps maintain the correct pH level of the culture environment.

SAFETY

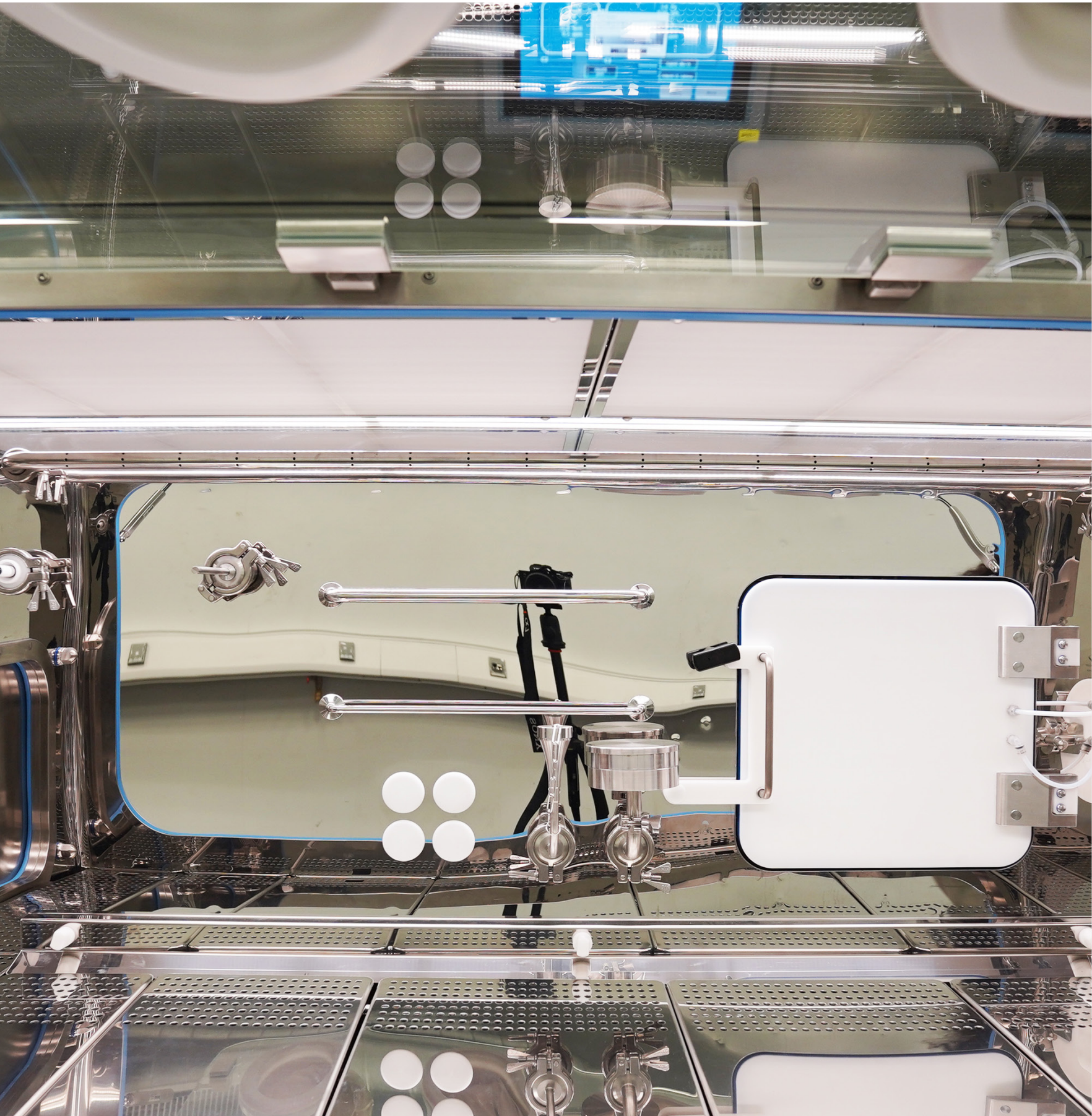
Protects not only the samples but also operators from hazardous substances and microorganisms.

REDUCED PROCESS TIME

Thanks to the integration of the incubator directly into the isolator, there is no need to transfer samples between devices, saving time and minimizing handling-related risks.

FLEXIBILITY

The system can be customized to meet specific research requirements.



Pull-out shelves



Incubator door with inflatable sealing.

Door sealing integrity continuously monitored by pressure sensor.

STANDARD
FEATURES



CHAMBER

- FULLY WELDED WORKING CHAMBER
- EASY-TO-CLEAN DESIGN
- SLOPED BOTTOM WITH DRAIN VALVE
- SAFETY GLASS
- HINGED FRONT GLASS
- SAFE GLOVE REPLACEMENT SYSTEM
- CABLE FEEDTHROUGHS

CONTROL SYSTEM

- HMI PANEL
- SENSORS (TEMPERATURE, AIRFLOW)
- VISUAL AND AUDIBLE ALARM
- PRESSURE SAFETY VALVE
- MAIN POWER SWITCH

EQUIPMENT

- INCUBATOR
- INFLATABLE SEALING
- INTEGRATED LED LIGHTING
- SHELF SUSPENSION SYSTEM
- LAMINAR FLOW FRAME
- PERFORATED GRIDS
- H₂O₂ DISTRIBUTION PIPING
- MATERIAL PASS- THROUGH
- TRI-CLAMP VALIDATION PORT
- POWER SOCKETS FOR ADDITIONAL EQUIPMENT
- FOOT SWITCH
- SLIDING DOORS
- SHOWER
- HEPA H14 FILTERS
- ONE-PIECE GLOVES

OPTIONAL
FEATURES

ATEX modification

SOFTWARE 21 CFR Part 11 compliant software (Audit Trail).

SURFACE FINISH - Mirror polish BA (internal/external), sloped bottom, Hastelloy C22 components.

DECONTAMINATION - Catalytic plates, catalyst, UVC light, H₂O₂ distribution (integrated PURITER), preparation for H₂O₂ (external systems).

MONITORING - Microbiological monitoring, particle monitoring.

GLOVES - Two-piece gloves with safe replacement, standard gloves.

CONTROL AND DATA ACQUISITION - SCADA, WinCC, UPS.

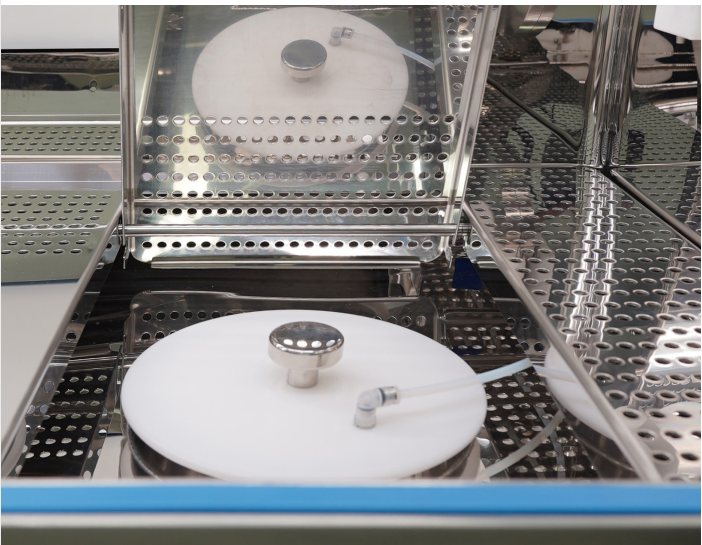
EQUIPMENT - Centrifuge, microscope, camera, magnetic stirrer, sterility test pump, automatic shower (manual cleaning, CIP cleaning of piping and reactors), lyophilizer, paddle dryer, touch screen, display screen, WIP shower system, welder, titrator, scales with terminal, glass reactor, evaporator.

TRANSFER - Continuous liner, hinged doors, passive transfer port, rapid liquid transfer port (Sartorius), RTP rapid transfer port for solids, sliding shelf, product pipelines, roller conveyor, Drumport, high-containment transfer systems (ChargePoint, Ezidock, Andock), filling system.

VALIDATION - DQ, IQ/OQ, Smepak.

SENSORS - CO₂ chamber sensor, H₂O₂ HC sensor (high concentration), H₂O₂ LC sensor (low concentration), O₂ chamber sensor.

ACCESSORIES - Wire program, glove holders, stainless steel glass springs, chamber sockets (230V, USB, Ethernet...), lighting for sensitive materials (red, orange, etc.).



SAVINGS AND BENEFITS



DECONTAMINATION

The system is equipped with an integrated hydrogen peroxide vapor generator.

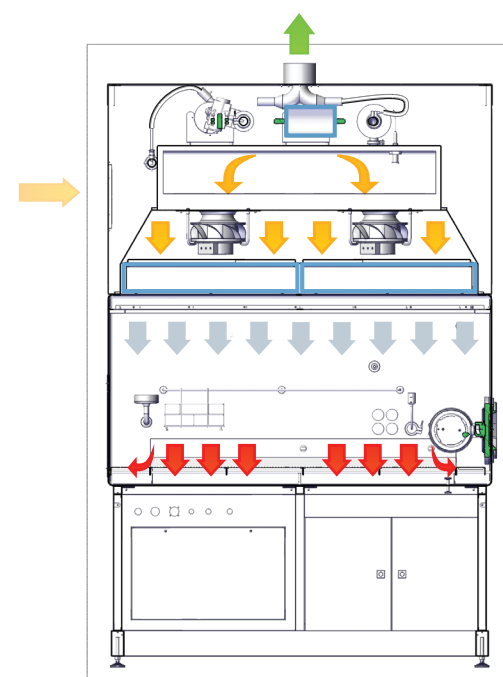
Uniform vapor distribution is achieved through a perforated pipe installed along the entire chamber length.

- **35% hydrogen peroxide**
- **Decontamination process performed at temperatures between 25–35 °C**
- **Surface decontamination of loaded materials with a biological reduction level of 10^{-6}**
- **No toxic residues**
- **Capability for decontamination cycle validation**

LAMINAR AIRFLOW

Laminar airflow is used to achieve cleanliness class "A" where unidirectional vertical airflow is required. The airflow velocity generated by the isolator technology is 0.45 m/s $\pm$ 20%. HEPA H14 filters are used for filtration of both inlet and exhaust air.

- | | |
|--------------------------------|------------------------|
| ● Fresh air | ● Contaminated air |
| ● Fresh air + recirculated air | ● Filtered exhaust air |
| ● Filtered air | ● HEPA H14 filter |



SPACE SAVINGS AND LOWER INFRASTRUCTURE COSTS

Combining two devices into a single system saves valuable laboratory or production space while reducing installation, maintenance, and operating costs associated with separate units.

LOWER CLEANROOM COSTS

Since the isolator with integrated incubator creates its own controlled environment, there is no need for extensive cleanroom facilities. This significantly reduces costs associated with HVAC systems, filtration, and other cleanroom technologies.

MORE EFFICIENT USE OF ENERGY AND RESOURCES

The isolator with integrated incubator optimizes the consumption of energy and decontamination agents, reducing long-term operating costs.

REDUCED PROCESS TIME

Thanks to the direct integration of the incubator into the isolator, there is no need to transfer samples between devices, saving time and minimizing handling-related risks.

LOWER LABOR COSTS

Automated processes within the isolator with integrated incubator reduce the need for manual intervention, lowering both labor requirements and operational costs.

IMPROVED OPERATOR SAFETY

The isolator with integrated incubator protects personnel from exposure to hazardous substances, helping reduce costs associated with personal protective equipment and safety measures.

RETURN ON INVESTMENT

Although the initial investment may be higher, long-term operational savings, increased efficiency, and minimized contamination risks ensure a rapid return on investment.

TIMOTEC



www.timotec.eu

TIMOTEC processes certified by TÜV SÜD:

ISO 9001:2015

ISO 14001:2015

ISO 45001:2018 (OHS)