Advanced Therapy solutions

TECNIPLAST GROUP

ALL ABOUT
PHARMA

WITH OVER 30 YEARS OF EXPERTISE IN TURN-KEY SOLUTIONS

IWT offers a comprehensive range of cleaning, isolation, and decontamination solutions for the pharmaceutical, cell & gene, nutraceutical, cosmetic markets, and related industries.

IWT specializes in the design, development, manufacture, and installation of outstanding cGMP pharma solutions. Our manufacturing base in Varese, just a few kilometers away from Milan Malpensa International Airport, spans over 20,000 square meters (215,000 square feet) of production areas, R&D, design studios, training, testing, and showroom facilities.

Our production departments are equipped with state-of-the-art laser cutters, orbital welders, and robots for processing stainless steel parts. The warehouse, fully automated in alignment with the most stringent cGMP traceability requirements, features comprehensive oversight and management of products and materials. IWT offers in-house advanced 3D design and simulation technologies, as well as software programming capabilities to ensure complete fulfillment of any user requirements specifications, in terms of quality and flexibility.

Our comprehensive range of cleaning solutions includes full cGMP product contact part washers, as well as high-pressure washing systems for bulk containers in cleaning-in-place applications or cabins for bulk parts and containers cleaning-out-of-place.

Multipurpose modular aseptic isolation technologies are at your disposal, ranging from sterility testing to component preparation, from fill-finishing to Advanced Cell & Gene Therapies.

A decennial expertise in cold decontamination methods, decon chambers and airlock systems, ensures safe and efficient material transfer through physical barriers and differently classified areas.

Both our Isolation and Decontamination product ranges ensure complete compliance with cleanroom standards according to the new EU Annex 1 requirements.

You are always welcome to visit our facilities, to experience IWT Pharma's passion and commitment firsthand, and to witness the quality and efficiency in our daily operations.

IWT Headquarters in Casale Litta (Varese, Italy). We strive to protect our surroundings and keep our ecological footprint as small as possible.

ADVANCED THERAPY
SOLUTIONS

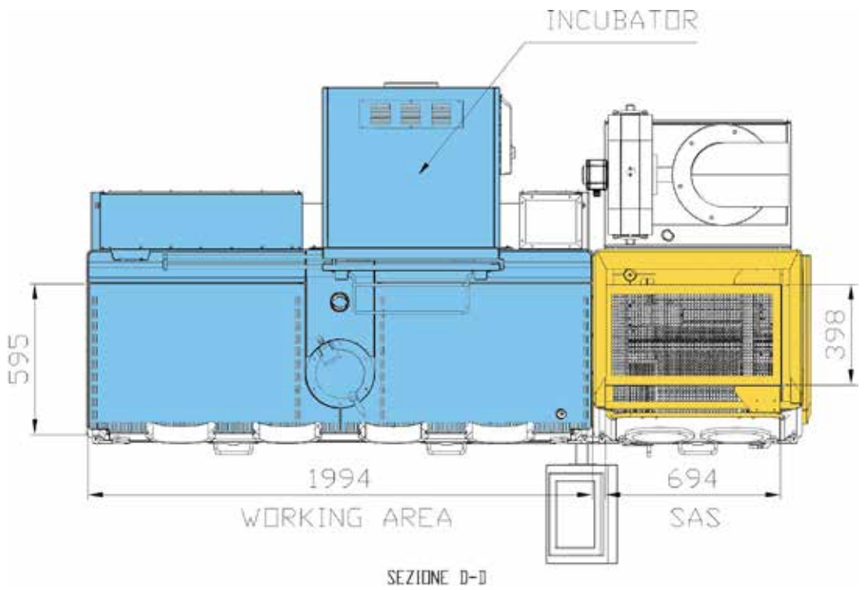
Producing **Advanced Therapy Medicinal Products (ATMPs)** for therapeutic purposes is a complex task that extends beyond the crucial aspect of maintaining aseptic conditions. Alongside ensuring a sterile environment, it involves addressing various other critical aspects. It requires rigorous procedures and highly-trained personnel to properly set up and maintain both the environment and the staff involved in the procedure. This necessitates significant efforts in terms of infrastructure, personnel training, and compliance.
This approach is essential for a wide range of advanced therapeutic methods, including:

- Cell Therapy
- Gene Therapy
- Tissue engineering Therapy
- Regenerative Medicine

IsoCell - Core Configuration

IWT, with its **ISOCell Advanced Therapy Isolator**, provides a streamlined workflow environment that reduces the setup and running costs of cell therapy product preparation while ensuring compliance with stringent regulatory requirements from bodies such as the FDA, EUP, and USP, and adhering to industry guidelines like GMP and PIC/S.

- **Sustainability and Reduced Carbon Footprint:** By locating isolator systems dedicated to ATMP production in a Grade D room, compliant with Eudralex Volume 4 and Annex 1 EU GMP standards, operational costs are dramatically reduced compared to conventional clean room setups.
- **Safety:** Validated sterility of the Grade A work area ensures cross-protection of the product, operator, and environment.
- **Traceability:** Comprehensive traceability for all steps of the sterile handling process.
- **Sterility Maintenance:** Positive pressure of HEPA-filtered air maintains sterility. The outlet HEPA filter prevents the return of non-sterile air.
- **Comfort for the Operator:** Ergonomic design and user-friendly features prioritize operator comfort during operation.
- **GMP Compliance:** The system is designed to be used in validated GMP processes.



First in GMP accreditation for ATMP production

In 2015 SwissMedic issued the certificate of MP compliance for a process at the Centre de Production Cellulaire (CHUV-Lausanne) where six ISOCell units are installed. By achieving this goal **IWT's ISOCell** has become the first isolator recognized as part of a fully validated process to produce artificial tissues to be used in human therapy.

ISOCell

with multifunctional module

▶ In many ATMP production applications, process equipment is necessary to execute crucial workflow steps in different phases of the manufacturing process. For instance, centrifuges are utilized for biological product preparation and separation, while incubators are often used for growth and expansion. Additionally, microscopes or other instruments are employed for in-process analysis. This configuration of the **ISOCell**, featuring three modules, emerges as the preferred and widely adopted choice across numerous ATMP production applications worldwide. Its exceptional flexibility perfectly accommodates the diverse requirements of ATMP production within GMP environments.

▶ The multifunctional module is able to integrate different types of equipment, like centrifuges, bioreactors, etc. The module is endowed with a lifter to increase flexibility and accessibility for set-up and maintenance.

▶ **Integrated CO_2/O_2 incubator**

The incubator is specifically designed to fit into an isolator environment and is connected to the SCADA system to monitor all controlled parameters. It offers full access from the working area, eliminating the need for transporting samples in and out of the Grade A environment during procedures, it allows for complete and rapid bio-decontamination through hydrogen peroxide vapors.

▶ **Unidirectional airflow**

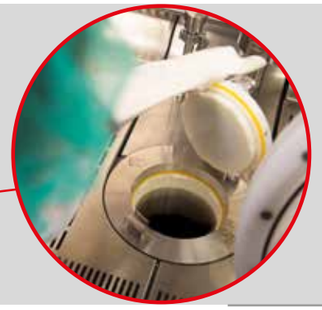
Unidirectional airflow is maintained throughout the three modules, ensuring that the entire internal environment maintains proper classification according to EU-GMP Class A (ISO 5). Integrated instruments provide and record all the necessary information for Environmental Monitoring.

▶ **Traceability**

Important parameters are monitored and may be recorded: the ISOCell has an integrated Supervisory Control And Data Acquisition (SCADA) managing system that complies with the GAMP requirement and 21 CFR part 11 about data registration.

The FMS software Annex-1 is an application designed and built for the management and production of reports concerning the control of particulate contamination present in clean room production in the pharmaceutical industry.

- The process is always controlled by the operator.
- Security for both the operator and the process.



▶ **Integrated Waste Management System**

The waste management system consists of a rapid transfer alpha port and a waste collection system in either rigid form (beta container) or flexible form (beta bag). The beta-container or beta-bag can be connected or disconnected via the RTP port without compromising the sterility of either the isolator or the internal volume of the container.

▶ **Sterilization**

To ensure an aseptic environment, the ISOCell is equipped with a proprietary in-built bio-decontamination system. This system is designed, developed, and tested to perform rapid and automatic decontamination cycles of the entire isolator using dry vapor of H_2O_2. The isolator control system continuously controls and monitors all critical parameters of the decontamination process by governing all parts of the decontamination system.

▶ **Integrated microscope**

A microscope is included in the working area to allow fast and easy observation of the cell and tissue sample without the need to leave the clean area.

- **15” LCD monitor** for real-time observation of samples
- **Ethernet connection**: all images are saved in a network location for later access
- **SCADA interoperability**: all images are viewable via the integrated PC panel

ISOCell

Core Configuration

▶ ISOCell Core Configuration is designed to operate within the typical restrictive confines of various regulatory (FDA, EUP, USP) and related industry guidelines (GMP, PDA, Eudralex vol 4 Part IV, Annex 1, etc.) as a “Closed System” (AinD), providing a series of advantages compared to the production performed in Open Systems: lower total investment cost, lower operating costs, user-friendly working environment, higher sustainability and lower environmental impact.

▶ This two modules configuration, includes, as standard equipment, an integrated Multigas CO_2 Incubator equipped with inflatable gaskets, an inverted Microscope and an RTP port for waste management system.

▶ Based on these simple features, the ISOCell Core configuration provides highly efficient functional support for many sequences of ATMP processes and offers significant flexibility to perform proper aseptic processing in a Grade A classified environment.

ISOCell

The NEW flexible modularity

▶ The ISOCell isolator technology can also be delivered as an “empty” platform, offering a modular aseptic environment ready to be tailored to your individual process requirements. Each module can be customized with different sizes and made available to integrate different equipment necessary for ATMP manufacturing processes. Additionally, various solutions are available to perform automatic or semi-automatic fill and finish operations, compatible with different formats of vials, pre-filled syringes (PFS), and IV bags.

▶ Our engineer department and our scientific team are at your disposal to discuss your specific needs and design with us the ideal configuration for your ATMP production protocols in regulated environment.

ISOCell

Special options

The new ISOCell combines modular design and patented technologies, such as SmartCare and LightCare, to perfectly adapt to process requirements. Efficiency, safety, and quality make this system truly one of a kind.

SMARTCARE:
Process Augmented Reality

▶ Unlock the full potential of your work with Augmented Reality applied to your process. Improve quality and productivity, feeding your operators with projected in-line process information and step by step recipes. Track & Trace every step you want, minimizing risk as required by 21 CFR part 11. Use the power of the SMARTCARE platform to supervise, support and accelerate your process in GMP environments.

LIGHTCARE:
Dynamic Lighting System

▶ The intelligent lighting system is designed to influence operators' well-being and performance.
Light can be adjusted to individual circadian rhythm, reducing fatigue and optimizing operational efficiency.
Personalize light adapted on processes and operators' specific needs.

IWT - TECNIPLAST GROUP

50 year of experience in Contamination Controlled Equipment and Environments

IWT, as part of Tecniplast group, has expanded into the field of Cell and Gene Advanced Therapy, developing customized solutions and manufacturing isolators dedicated to the production of ATMPs in regulated environments. Many ISOCell units have been installed globally in hospitals, academic institutions, and biotech companies, fostering the quality and safety of therapies delivered to patients.
Tecniplast group, together with IWT brings together decades of experience in Cell and Gene Advanced Therapy and expertise in isolation technology and automation applied to aseptic processing in the pharmaceutical industry.
The large and renovated production site of IWT enhances quality excellence throughout project development and manufacturing processes.

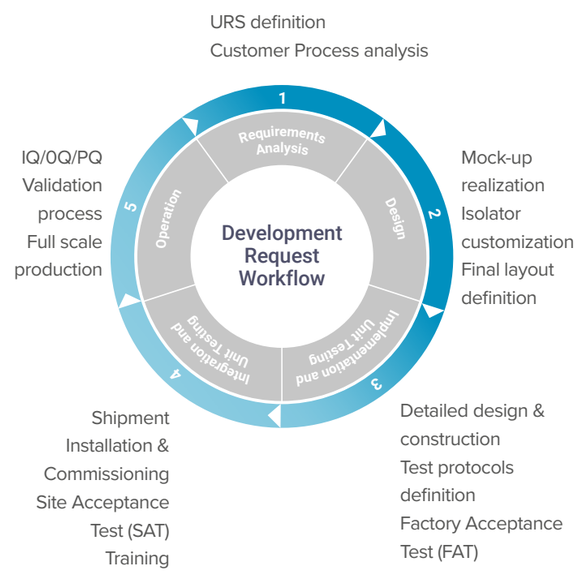
YOUR PROJECT, OUR SOLUTIONS

We can provide a complete support for your project and requirements.

▶ We believe in offering consistent support from the start of your project guiding you through mock-up realization, technical solution identification, installation, training, and final validation. This comprehensive support is crucial for project success.

▶ We've assembled a network of experts dedicated to helping you transfer your processes within ISOCell technology through engineering and scientific support. This ensures the achievement of optimal results in the most reliable and effective manner.

▶ To us, ISOCell is more than just a product; it's a holistic project! So, don't limit yourself to being just a customer; join us to become our partner. We are ready to work alongside you towards a common goal!



The R&D Laboratory for Regenerative Medicine

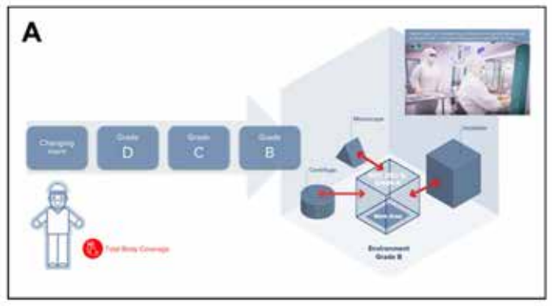
The R&D laboratory for Regenerative Medicine is focused on product development dedicated to regenerative medicine in clinical application. The laboratory for Regenerative Medicine is the core of R&D in IWT group and it is located in the Molecular Biotechnology Centre of Turin University. The cell therapy TEAM laboratory includes scientists skilled in cell biology, stem cells manipulation and protocols development in compliance to GMP regulation. The R&D Lab for the Regenerative Medicine transforms protocols from basic research into clinical application using stem cells manipulated in the isolator thus guaranteeing an Grade A aseptic environment to produce cells and tissues in compliance with the GMP.

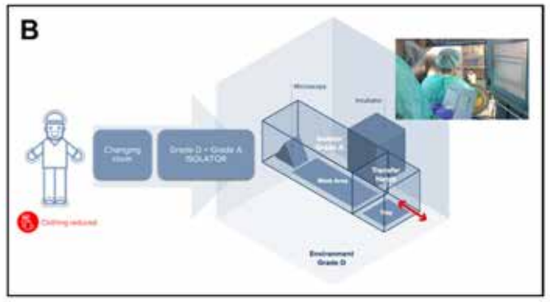
OUR TECH, YOUR GAINS

The pursuit of better quality

When it comes to producing **Advanced Therapy Medicinal Products (ATMPs)**, maintaining a sterile environment is crucial. Traditionally, clean rooms equipped with laminar flow cabinets have been the standard, providing a Grade A environment within a Grade B background. However, aseptic isolators are now emerging as a superior technology, offering the same Grade A environment but within a Grade D background. The benefits of using an isolator are clear when considering enhanced sterility assurance and improved safety, both of which are critical for ATMPs since these products cannot be sterilized after production and must remain sterile throughout the entire manufacturing process. Here's how isolators excel:

- **Lower Contamination Risks**: Isolators provide a completely sealed environment that significantly reduces the risk of contamination from external sources, including operators. Transfers of biological products out of the Grade A environment are less frequent since mostprocess equipment are integrated within the isolator, ensuring Grade A continuity throughout the manufacturing process. Transfers of materials and components are more proceduralized, thanks to validated transfer methods and technologies.
- **Better Containment:** Isolators ensure higher sterility levels with a controlled, smaller volumes compared to larger clean rooms, enabling more efficient air quality control
- **Operator Protection**: Isolators offer better protection, particularly when dealing with hazardous materials like viral vectors used in gene therapies.
- **Product Integrity**: Isolators maintain the quality and integrity of ATMPs by utilizing advanced control systems to continuously monitor and regulate all process steps, ensuring accuracy and consistency.





TOWARDS LOWER COSTS & BETTER SUSTAINABILITY

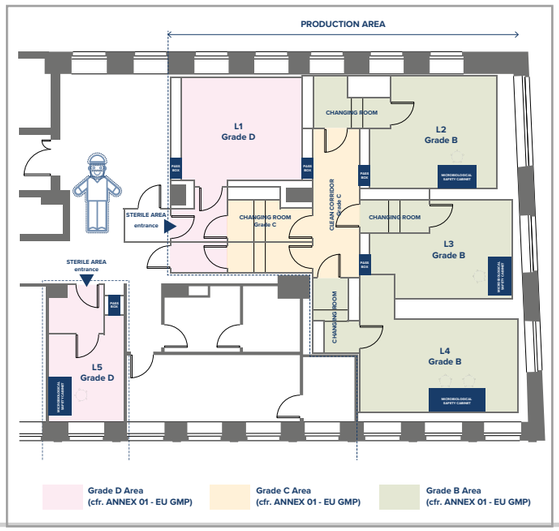
While it may be less obvious, Studies and practical applications have demonstrated that our isolators offer crucial advantages in terms of cost reduction and environmental sustainability. Here's how:

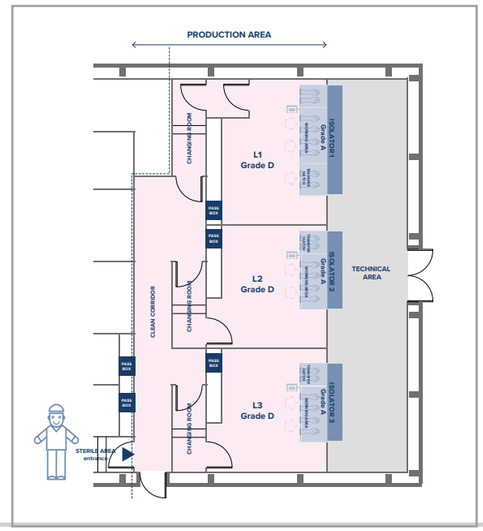
- **Reduced Infrastructure Costs**: Installing isolators in a Grade D background eliminates the need for expensive Grade B clean rooms and their extensive infrastructure. Additionally, Grade D areas are easier to access and require less space for the same working surface, leading to more efficient use of facility space and resources.
- **Lower Operational Costs**: Costs related to energy, heating, HVAC systems, cleaning, environmental controls, personnel, and gowning are significantly lower in an isolator setup, resulting in a lower Total Cost of Ownership (TCO) compared to maintaining clean room environments.

This makes isolators a more cost-effective solution in the long term, reducing the financial burden on manufacturing facilities.In terms of environmental sustainability, isolators also excel:

- **Energy and Resource Efficiency**: Isolators require less energy, fewer materials, and fewer resources to maintain the necessary sterile conditions compared to clean rooms. This leads to lower consumption and a significantly reduced carbon footprint, studies indicate a reduction of about 50% .

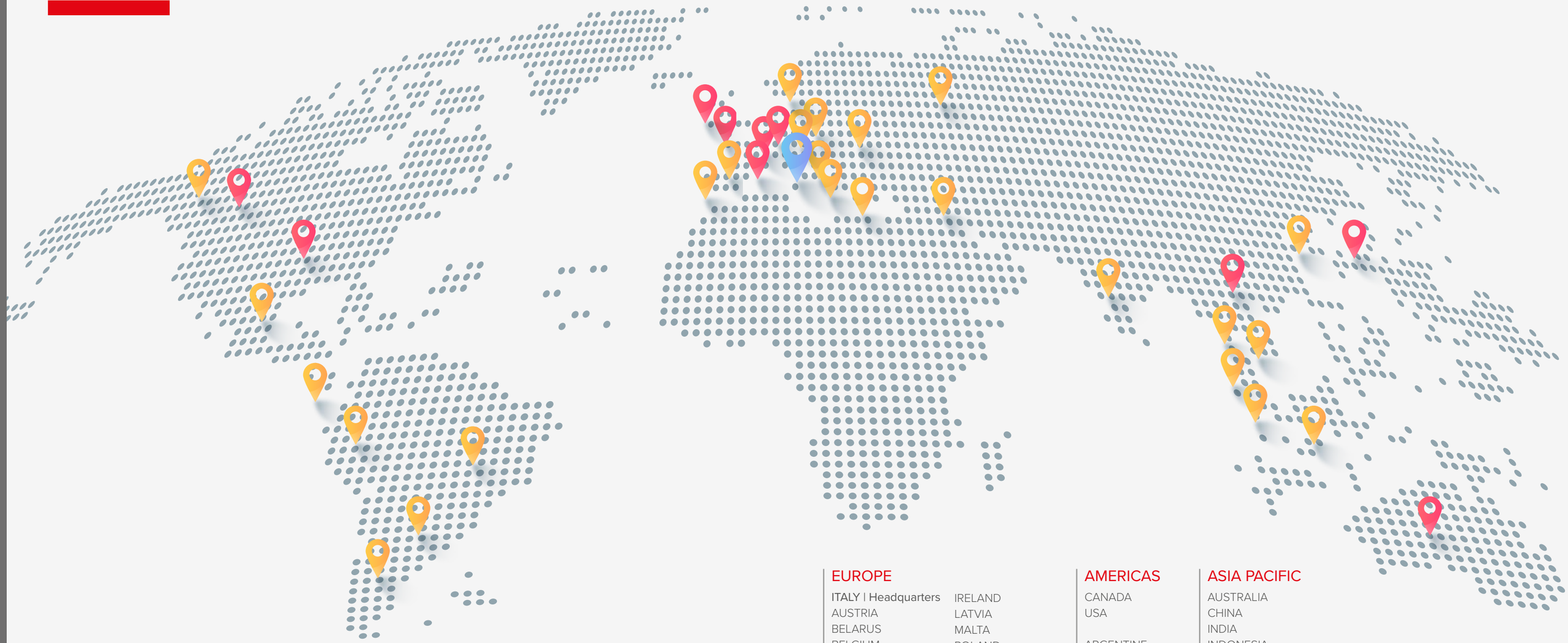
In summary, working in an isolator rather than a clean room for ATMP production offers superior sterility assurance, cost efficiency, improved safety, environmental sustainability, and easier regulatory compliance. These advantages make isolators the optimal choice for modern advanced therapy manufacturing.





WE OPERATE LOCALLY.
WORLDWIDE.

Being a global company, as part of the Tecniplast Group, means we are well aware of the challenges the world is facing.
Our worldwide network of Subsidiaries, Dealers and Agents allows us to understand different cultures, languages and needs, thus perfectly responding to regional expectations.



- IWT Headquarters and production site
- Group Subsidiaries and commercial offices
- Dealers/Agents

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DENMARK
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INDONESIA
JAPAN
MALAYSIA
SINGAPORE
SOUTH KOREA
THAILANDIA
VIETNAM

50+ Countries

325M annual Group turnover

400+ installations

1,500+ employees worldwide

Cleaning | Isolation | Decontamination

TECNIPLAST GROUP

HEADQUARTERS IWT s.r.l.
Tel. +39 0332.96701
www.iwtpharma.com
info@iwtpharma.com

MANAGEMENT SYSTEM CERTIFICATION
DNV
ISO 9001 · ISO 14001

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IWT SRL Società unipersonale | Sede legale e amministrativa: via Galliani 68b
21020 CASALE LITTA (VA) ITALY • C.F. e P.IVA: IT 02002720122