

) ITALIAN OFFICES

MILAN Registered office

and technical office

PARMA GMP services

technical office

FIRENZE GMP services technical office

NAPOLI Technical office

ANAGNI Mechanical Workshop

TORINO Clean rooms, Isolator assembling

INTERNATIONAL OFFICES

CAPETOWN

Branch office

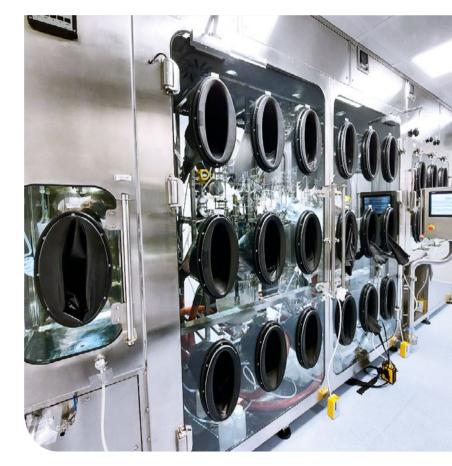
ATHENS Branch office International customer network

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API MANUFACTURING ISOLATION TECHNOLOGY

Twenty-five years of experience in process engineering for HPAPI synthesis has led us to better understand the needs of production operators. Such know-how drives the design of our isolators, enhancing integration with reactors and general production equipment by facilitating related loading and unloading steps.

- Isolators suitable for ATEX processes and environments (up to OEB 5).
- Chambers in AISI 316L and C-22 Hastelloy when aggressive solvents shall be handled.



FINISHED PHARMACEUTICAL FORM ISOLATION TECHNOLOGY

CSV Containment presents its state-of-the-art multiple chambers isolators, to allow the safe management of up to OEB 6 contained processes.

- Full pharma grade custom design to fit client and application requirements/needs, with a special focus where the most demanding requirements shall be satisfied.
- Comfortable docking of both small containers and large BINs through High Containment Transfer Valves.
- Easy integration with production equipment like ovens, micronizers, mills, and reactors.





- Patented DIT (Drum Iris Technology) technology for automatic docking of multiplediameter drums.
- Full CFR 21 Part 11 control system, with premium brand SCADA platform, for isolator control and interfacing with company systems.
- Portable WIP system for inner surfaces decontamination and effluent recovery



- Fully automated system for contained drum and handling.
- Masterclass patented DIT for automatic docking of multiplediameter drums when a high volume of product needs to be quickly handled. The DIT can dock drums with diameters from 50 to 550 mm.
- Customized shapes and sizes are possible to fit existing reactors and their constraints.





BIG BAG IRIS DOCKING

We produce special and innovative big bags, which represent the other possible option to drums for moving materials in the pharmaceutical world. Packages can be equipped to have in-line routes during loading and unloading.

- Available custom shapes and films.
- Hardware to load and unload equipment from both highcontainment big bags and dust-free, GMP applications.



ACRYLIC PLASTIC ISOLATORS

We can produce acrylic plastic isolators, the ideal solution for laboratories. This isolator model offers the following advantages:

- Optimum visibility for operators thanks to complete transparency of all its parts
- Improved ergonomics with the main rounded corners walls
- Fast track delivery
- Easy to clean
- Available in different materials, both antistatic and non-antistatic:
 - Polycarbonate
 - PMMA
 - PEG
 - PVDF





ISO 7 CLEAN ROOM PRODUCTION

Clean production is a must for us. Whether or not your process is developed in a classified environment, we want to keep you safe from any potential risk.

This approach has led to a radical development of our manufacturing facility towards ISO 7 and 8 clean rooms and to qualifying and inspecting suppliers of critical raw materials. The "FlexiLab" is the consequence of our commitments and the place where, from the very beginning, we produce all flexible isolators and disposable parts. All of our environments and processes are qualified. Our clients, pharmaceutical manufacturers, periodically perform audits at our production sites to verify their compliance.







FLEXIBLE ISOLATORS

Elexible isolators are cost-effective and guick to implement solutions for your OEB 4 and OEB 5 containment needs In passive configuration or integrated with a device to maintain internal volumes under negative pressure, they allow existing equipment to be quickly upgraded to meet production requirements of High Potent Products, even when special or inert atmospheres are necessary. The custom design perfectly meets customers' specific needs and allows safe, effective, and operator-friendly use through improved ergonomics. All supplies are codified for easy supply of spare parts and disposable parts over the years. Every dissipative film used has documentation certifying its compliance with EU and US pharmacopoeia.



DISPOSABLES ENCLOSURES

Depending on the application and frequency of use, different configurations of the enclosure can be provided to better meet specific needs.

To reduce installation time and provide an all-in-one system, we can deliver fully welded bags where all gloves, fittings, and components are ready to use. Fast delivery and competitive prices have been key to the international success of this product.



DISPOSABLES

CONTINUOUS LINERS

In our manufacturing facility, we produce compressed and pre-packaged folded or donut wound plastic packs. They can be connected to the isolator and equipment for material transfer and ensure containment during unloading.

- Several solutions with different films, shapes, colours, and dimensions
- Antistatic EU and US compliant LDPE or LLDPE
- Available also with customer films.

TWIN TIE

Twin-tie is a contained separation tool for continuous liners safe closure. It does not require film twisting.

- Fit all continuous liner diameters.
- Containment performance up to OEB 5
 Available in different colours
- Delivered in a case containing a pneumatic/manual gun for tightening the clamps and a cutter for cutting the continuous liner



IRIS MOUSEHOLE

CSV Containment has developed the Iris Mousehole to enable the passage of cables and small items between two isolated environments of different classifications. It offers flexibility, ensures a high level of sealing and represents an ideal solution for interfacing and through-wall systems.

- Standard sizes: 4", 6", 8"
- Tri-clamp connections
- Iris made of EPDM/ FKM/ silicone
- Wall pass-through made of AISI 304 stainless steel or polyoxymethylene (POM)
- FDA compliant



SMEPAC MONITORING

We offer SMEPAC monitoring, to demonstrate that a high-containment isolator reduces the presence of potentially hazardous particles in the air.

It is based on monitoring the background environment to evaluate direct/cross contamination or containment performance.

The SMEPAC monitoring consists of replicating critical operations as they are executed during standard production processes but using a safe product, usually lactose.





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