## **COMECER ISOLATION TECHNOLOGY** TAILOR MADE TO YOUR NEEDS





## OUR PAST, YOUR FUTURE



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### THE RIGHT SOLUTION FOR YOUR NEEDS WE ARE EXPERIENCED SOLUTION PROVIDERS

First of all, we are great listeners, because any solution starts with your needs.

Then we analyze and understand your processes and your environment, since no two organizations are the alternatives. same.

We collect all your unique requirements, and discuss with you all possible

We take pride in designing the **optimal** solution for you.

"We grow together with our customers, as our customers are our present and our future."



### 12 GLOVES PROVISONS

### 12.1 GENERAL DESCRIPTION

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- 121.1 The first set of gives replaced its the GBI after acceptance phase will selected to optimize functionality durability citantiness and maintamability
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- 1214 Cloves
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### REDEFINING THE STATE OF THE ART

### **Quality by Design**

We follow industry guidelines; we perform risk assessment and obsess over every detail, because we want our solutions to be robust yet flexible, reliable yet forward-looking. Well begun is half done – from the first moment we take on a new project, what guides us is QUALITY BY DESIGN. This is the most important phase in a project and we believe quality aspects are of the utmost importance.

#### Engineering

We assign a dedicated project team that looks at process engineering, detailed mechanical design and software aspects. Our R&D department can also take part in specific projects.

### 316L stainless steel. Certified welding. Skilled personnel. Completely in-house manufacturing. Top-level components. A user-friendly approach to software and controls.

Technology

### **Compliance/Certification**

Full cGMP and FDA compliance. GAMP5 software to manage the entire plant. SCADA system for FDA 21 CFR Part 11, where requested. Quality Management System certified according to ISO 9001 and ISO 13485 standards.

Our team of experts performs standard and R&D testing: FAT, SAT IQ, OQ, PQ, cycle development and SMEPAC.





Benefit from our service personnel. Their comprehensive knowledge and long experience will assist you with answers to your questions and quick solutions for your support needs.

## MORE THAN GLOVE BOXES

AD HOC SOLUTIONS (TAILORED)SKILLED TEAM

Weigh and dispense highly potent active powders, securely and ergonomically, with attention to operator safety.

Fill drums or vials with sterile powder or liquid in a completely automated manner while maintaining product sterility.

Manipulate cell cultures under **aseptic** conditions.

Perform sterility testing on products for a safe

release to the market.

Prepare hospital oncology drugs ensuring both operator and product safety.

Achieve molecularcontamination-free environments during assembly of aerospace components.

"Solving customer problems requires teamwork."



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| PRIMARY<br>PHARMACEUTICAL<br>PRODUCTION   | FILL FINISH<br>MANUFACTURING  | REGENERATIVE<br>MEDICINE  | R&D, LABORATORY<br>AND HOSPITAL<br>PHARMACY   | ASEPTIC FOOD<br>PROCESSING  | AEROSPACE &<br>SEMICONDUCTOR<br>MANUFACTURING   |
|---|---|---|---|---|---|
| Primary chemical<br>industry<br>manufacturing and<br>R&D, high-potent<br>API dispensing and<br>charging in reactor<br>from the chemical<br>synthesis, through<br>the process phases<br>to the final primary<br>packaging.<br>Scale up R&D pilot<br>batches. | Aseptic processing<br>during final<br>formulation, storage<br>and filling processes<br>for powder and liquid<br>forms. High-speed<br>turnkey solutions for<br>vials, syringes, bags<br>and bottles, for small<br>or large batches.<br>Customized process<br>automation integrated<br>in isolation technology. | Operations on living<br>cell preparations<br>under aseptic and<br>GMP compliant<br>environment:<br>separation, cultivation/<br>expansion, thawing,<br>sampling, observing,<br>scaffold perfusing,<br>filling and delivering,<br>including gene therapy<br>preparations. | Adaptable and<br>configurable<br>systems for a variety<br>of containment<br>applications, asepsis<br>and "dual-usage": from<br>pilot scale, oncology<br>and high toxicity to<br>cellular labelling,<br>chemotherapy, sterility<br>testing and other<br>aseptic manipulations. | Integration of<br>automatic machines<br>as well as specific<br>processes requiring<br>the highest standard<br>of effective and<br>reliable asepsis within<br>the food industry. | Isolation technology<br>is suitable for<br>challenging processes<br>needing very low<br>AMC molecular<br>contamination<br>and ultra-clean<br>systems integration,<br>such as aerospace<br>device assembly<br>or semiconductor<br>manufacturing. |

### ACCESSORIES

A variety of accessories to integrate and complete our equipment: automatic glove testers, VPHP generators, transfer hatches, downflow booths, weighing benches, LAF carts and more.

### PRIMARY PHARMACEUTICAL PRODUCTION

### Applications

We cover the widest range of processes, from early API or excipient synthesis to final formulations. In this field, we handle all the various processes, from R&D to manufacturing, including main and ancillary equipment.

#### Features

Specific solutions for all R&D chemical synthesis and manufacturing processes that match customer requirements, such as equipment integration, ATEX environment classification and lowest OEL (Operator Exposure Limit). Customized isolator with perfect integration of ancillary and process equipment to guarantee class 2 leakage test, ATEX 3GD or more internal and external classification, complete safety and ergonomic design for operator safety.

### Configurations

R&D or pilot scale application: multistage chambers isolator with kilo-labo reactor, vacuum tray dryer and laboratory scale integration. Manufacturing process isolator application: dispensing and sampling, reactor loading with direct connection to the reactor flange, filter dryer powder handling, milling discharge, sieving operation, micronization with integrated micronizer and packaging vacuum system.







### FILL FINISH MANUFACTURING

#### **Applications**

From small batch, lab scale production to large batch and highspeed filling lines. Different container types (vials, syringes, bags, etc.), speeds, and product forms (liquid, powder or gel).

Our expertise extends to all fields that require special attention to the asepsis of the filling operations and, if requested, to the filling automation itself with dedicated technical solutions.

Especially in case of cytotoxic products, demanding customers give high value to a package of isolation technology integrating the automatic machine as well as the rest of the formulation process.

### Features

A perfect fit solution, with full integration between the isolator or RABs and the automatic and semiautomatic machine. We can either integrate an off-the-shelf machine, thus providing a single interface to the customer and directly manage the relationship with the automatic machine manufacturer, or design a fully custom solution for the automatic machine together with the barrier system (isolator or RABs). Our solutions can also include the formulation and storage tanks or other compounding plant. In addition, specific accessories can also be part of the supply, so as to cover all the small steps performed through ancillary systems, such as component preparation isolators, laminar airflow carts and other transfer hatches to

fulfill the entire process needs.

### Configurations

From traditional tabletop design to newer balcony design, the whole arrangement of assembly machine plus isolator, with their related accessories, is designed to best suit the existing building or to support a newly designed facility. The entire study is carried out with a particular focus on process efficiency, from a large picture perspective of the entire manufacturing flow to a close look at the specific details for the aseptic processing, where required.





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### **REGENERATIVE MEDICINE**

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### Applications

GMP compliant manipulation of Advanced Cell Therapy medical treatments and research procedures: stem cells, genetic and immunogenic applications, biomaterials engineering and more.

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### Features

Fully welded system with superior level of finishing. A specific ventilation and filtration strategy allows a controlled atmosphere, creating a physical and aerodynamic barrier.  $H_2O_2$  decontamination system, allowing huge flexibility in operation. Full laminar airflow on board with Grade A, ISO 5 classification.

### Configurations

Many arrangements, from standard to fully customized. Possibility of integrating all fundamental laboratory equipment to perform a complete cell processing procedure.



## R&D, LABORATORY AND HOSPITAL PHARMACY

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### Applications

Latest generation professional equipment dedicated to multiple uses:

- Sterility testing
- R&D and small scale production Reconstitution of cytotoxic drugs
- Oncological applications
- Chemotherapy
- Treatment of highly toxic substances (CMR drugs)
- Cellular labelling
- Simple aseptic manipulations.

### Features

Suitable for the safe handling of a variety of dangerous compounds (pathogenic, CMR and hazardous agents) as well as aseptic products (chemotherapic, microbiological, hematological fields). All operations are performed within safe and sterile conditions. The operator is completely isolated from the manipulated substance, dressed with simple laboratory gowning.

### Configurations

Adaptable & configurable design with integrated devices and components to create unique solutions for specific needs. Increased operator safety and optimal ergonomics within an aseptic environment.

The systems can be arranged to perform the preparation of different substances by using bags, containers, vials or syringes.





### ASEPTIC FOOD PROCESSING

#### **Applications**

Increasingly the food and beverage industry is getting closer to asepsis requirements in the final packaging stage of high-value products. The growing demand in this industry for "organic" products is driving the need for strictly controlled atmospheres in which these products are formulated and filled, to prevent unexpected growth of bacteria that would put at risk the consumer perception of product quality. Isolation technology can also be used during R&D and quality control phases.

#### Features

Applying isolation technology to such different processes requires deep innovation. Our approach, supported by full customization capabilities, can give precise directions on the technological solutions as well as the procedures to be implemented. Configurations

Fermentation, separation, mixing and filling will require integration of the specific equipment or filling machine. Batch size and process flow will define the best configuration in order to assure asepsis throughout the manufacturing, therefore staging of the process in different chambers, in and out material flow, and ergonomics will be defined in close cooperation with the end user.





## AEROSPACE AND SEMICONDUCTOR MANUFACTURING

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### **Applications**

Molecular and microbiological contamination levels in aerospace and semiconductor manufacturing are huge requirements and are all in constant improvement.

Isolation technology is evolving to cover and meet these requirements, so processes can be confined in space with dedicated and filtered airflow, while dedicated monitoring systems for molecular or microbiological control can be integrated for continuous sampling.

#### Features

Isolators are designed following a detailed R&D analysis of all the critical process features, for example: molecular and absolute air filtration systems with special filters, special systems for parts and components cleaning, materials chosen to match low off-gassing release and high performance  $H_2O_2$  decontamination systems.

### Configurations

Multistage chambers isolator with material loading, cleaning, storage and assembly chambers, integrated CO<sub>2</sub> snow cleaning system, H<sub>2</sub>O<sub>2</sub> generator, molecular and microbiological realtime sampling systems.

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## ACCESSORIES

A VARIETY OF ANCILLARY EQUIPMENT TO COMPLETE OUR OFFERING

### Automatic Glove Tester

Speedy Glove, our new automatic glove tester, is a portable, batterypowered device that performs integrity tests on gloves installed in isolator or RABS in environments where the separation between the isolated area and the external environment is critical. The system performs the integrity test using the pressure decay method in conformance with ISO 14644-7 Annex E.5. Its key features include complete touch-screen operation, RFID technology, Wi-Fi ready, VPHP compatibility for Reverse Test and cGMP compliance.

### Transportable LAF carts

(UDAF: unidirectional air flow) Guarantee grade A continuity, in case the operations have to be performed aseptically or when a part of the process or material has to be transferred without breaking sterility. A UPS provides power continuity. H14 LAF filters allow high efficiency. Easy handling with channel rails for material transfer and easy interface to other aseptic equipment (e.g. filling isolator, RABS, VPHP hatches).

### **Transfer hatches**

Decontamination airlocks allow going through walls between different clean room areas with different classification (B to A, C to B, etc.). High operability and simplicity of use (unsterilized version also available). Custom design to fit individual applications.

### **Downflow booths**

Containment booths are engineered to segregate powders and particles developed in the clean room working zone. The result is a first stage protection for the product and the operator, avoiding crosscontamination of the different clean room environments. Personalized assembly and customized execution upon request.

### Weighing benches

Designed for the safe handling of toxic material. The ventilation system is dimensioned to guarantee an inward protective airflow from the lab towards the internal volume of the bench hood to allow the manipulation of OEL 3 powders.

### VPHP generator

A robust, fast and reliable  $H_2O_2$  biodecontamination system by Comecer. Conceived to decontaminate enclosures up to a volume of about 10 m<sup>3</sup>. Available in different configurations: column mount, on-wheel and integrated fixed frame (clean room version). The conditioning method used and the

disinfectant introduction, with the help of micro spraying and vaporizing (flash vaporization), are able to efficiently and progressively deliver the hydrogen peroxide to the enclosure. The different cycles are launched from the isolator HMI. All critical parameters and data can be accessed on the display. Closed loop & open loop bio-decontamination versions are available.

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SPEEDY GLOVE

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### MAIN REFERENCES

ABBVIE

ACS DOBFAR Meppel, Netherlands

ACS FACTA

ACTAVIS Nerviano, Italy

ADIMMUNE

ALBORZ DAROU

ANGELINI Ancona, Italy

BAYER GROUP (IFE/ALGETA) Norway

BILTHOVEN BIOLOGICAL

BIOCEN

BRACCO

BSP

CAMBREX PROFARMACO Milano, Italy

CATALENT

CELLTHERA Volginsky, Russia

CENEXI

CERBIOS PHARMA

CHEMI PHARMA Malta

CHIESI

CHUGAI (ROCHE GROUP)

CIDEM

CORDEN PHARMA

DGMIF Daegu, South Korea

DKFZ

ELI LILLY

FARMABIOS

FDC

F.I.S. Montecchio Maggiore, Italy

GOGLIO

GSK Parma, Italy Bad Oldesloe, Germany (now Aspen Worthing, United Kingdom

GSK BIO Wavre, Belgium

HOFFMAN-LA ROCHE

HOLOSTEM Modena, Italy

HYBIO

IBSA

ITALFARMACO Madrid, Spain

JANSSEN

LISAPHARMA

MEDLEY (SANOFI GROUP)

MERCK-SERONO

MERIAL

NANOLEK

NESTLE Switzerland

NOVARTIS Stein, Switzerland Singapore

NCPC

ONCOMED

PHARMADOX Malta

PHARMASTANDARD Kursk. Russia

PIERRE FABRE France

PFIZER Ascoli Piceno, Italy Puurs, Belgium

PROCOS

**PSICOPHARMA** 

ROMPHARM

SAMSUNG BIOLOGICS Seoul, South Korea

SANOFI Bejing, China

SIBP (CNBG)

SICOR BIOTECH UAB (TEVA GROUP)

SYNTECO Pavia, Italy

SOBHAN ONCOLOGY PHARMACEUTICALS

TAKARA BIO

TEVA

THALES ALENIA SPACE

WYETH

ZAHRAVI

ZENTIVA (SANOFI GROUP)



# WHO IS COMECER

The **mission of Comecer**, an Italian company from Castel Bolognese (Province of Ravenna) founded in the mid 1970s, is to design and manufacture high-technology systems in the field of **nuclear medicine**, **isolation technology** and **nuclear power plant equipment**, with the aim to continuously increase the accuracy and the safety of technicians, researchers, and patients. In fact, **"Safety First"** is the philosophy which distinguishes and identifies all Comecer policies and actions. Our **vision** is to contribute to progress and preserve life through the development of highly innovative technologies and sustainable solutions, according to the latest GMP (Good Manufacturing Practice) regulations.

Comecer operates in the **isolation technology** sector, developing tailored projects for the production of isolators for pharmaceutical, biotech, chemical, and food industry applications. We also operate in the field of **nuclear medicine** through the production of shielding systems and equipment for special applications, both for large industrial groups and for research organisations. Finally, we are active in the **nuclear power plant equipment** sector through the production of equipment for the processing, the deactivation and the disposal of radioactive substances deriving from nuclear plants. Comecer products are known and used in hospitals, universities, research centers, pharmaceutical companies and large industrial groups worldwide.

#### **COMECER GROUP**

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