COMECER ISOLATION TECHNOLOGY

TAILOR MADE TO YOUR NEEDS

COMECER

OUR PAST, **YOUR FUTURE**

THE RIGHT SOLUTION FOR YOUR NEEDS

WE ARE EXPERIENCED SOLUTION PROVIDERS

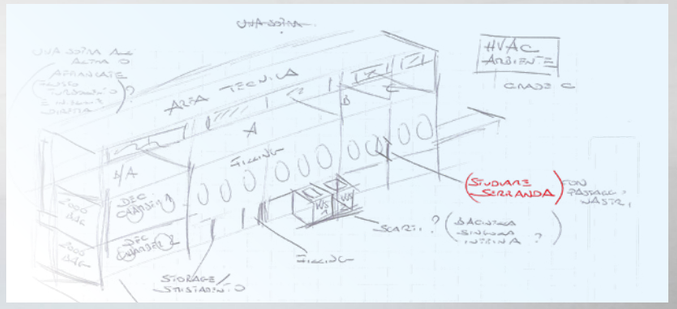
First of all, we are great listeners, because any solution starts with your needs.

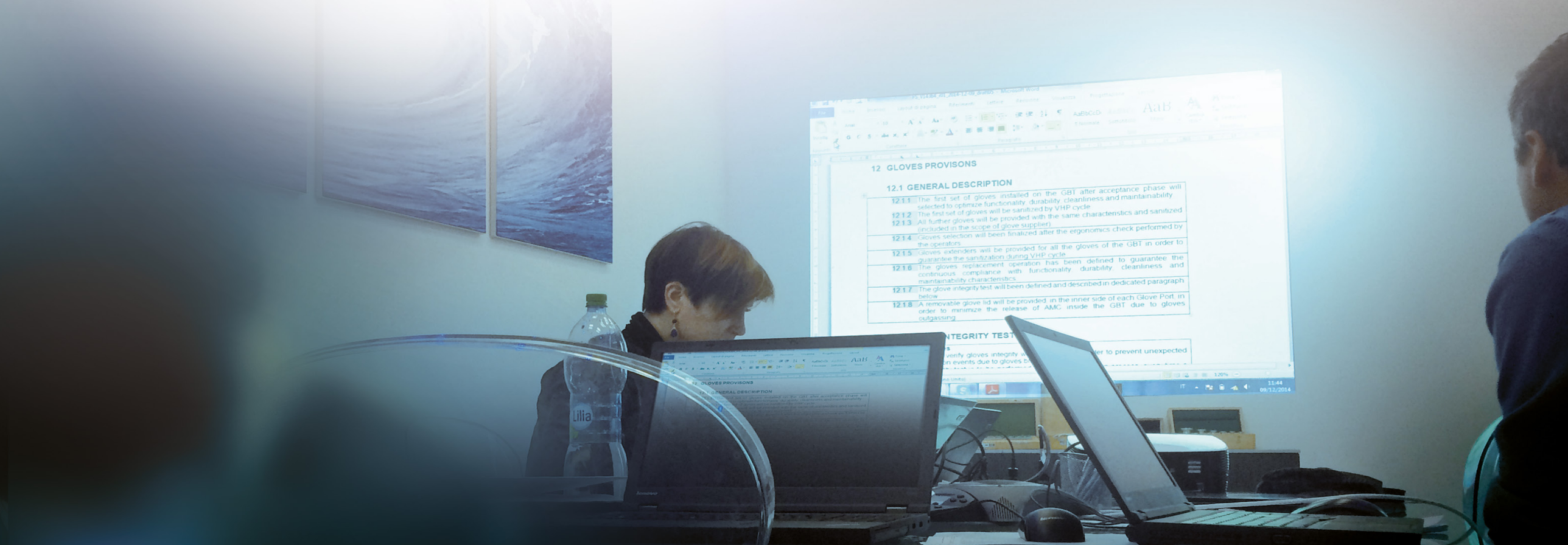
Then we **analyze and understand** your processes and your environment, since no two organizations are the same.

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

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."





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.

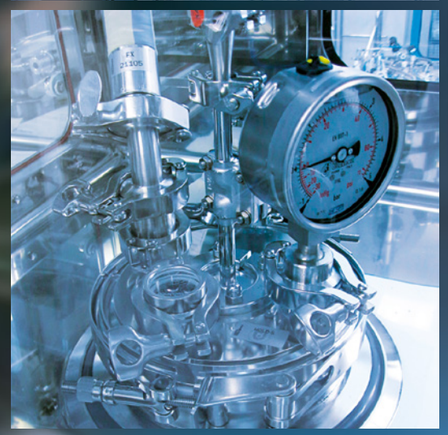
Engineering
We assign a dedicated project team that looks at process engineering, detailed mechanical design and software aspects.
Our R&D department can also take part in specific projects.

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

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.

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

Aftersales
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 **molecular-contamination-free** environments during assembly of aerospace components.

"Solving customer problems requires teamwork."

FIELDS

PRIMARY PHARMACEUTICAL PRODUCTION

Primary chemical industry manufacturing and R&D, high-potent API dispensing and charging in reactor from the chemical synthesis, through the process phases to the final primary packaging.
Scale up R&D pilot batches.

FILL FINISH MANUFACTURING

Aseptic processing during final formulation, storage and filling processes for powder and liquid forms. High-speed turnkey solutions for vials, syringes, bags and bottles, for small or large batches. Customized process automation integrated in isolation technology.

REGENERATIVE MEDICINE

Operations on living cell preparations under aseptic and GMP compliant environment: separation, cultivation/ expansion, thawing, sampling, observing, scaffold perfusing, filling and delivering, including gene therapy preparations.

R&D, LABORATORY AND HOSPITAL PHARMACY

Adaptable and configurable systems for a variety of containment applications, asepsis and “dual-usage”: from pilot scale, oncology and high toxicity to cellular labelling, chemotherapy, sterility testing and other aseptic manipulations.

ASEPTIC FOOD PROCESSING

Integration of automatic machines as well as specific processes requiring the highest standard of effective and reliable asepsis within the food industry.

AEROSPACE & SEMICONDUCTOR MANUFACTURING

Isolation technology is suitable for challenging processes needing very low AMC molecular contamination and ultra-clean systems integration, such as aerospace device assembly or semiconductor manufacturing.

ACCESSORIES

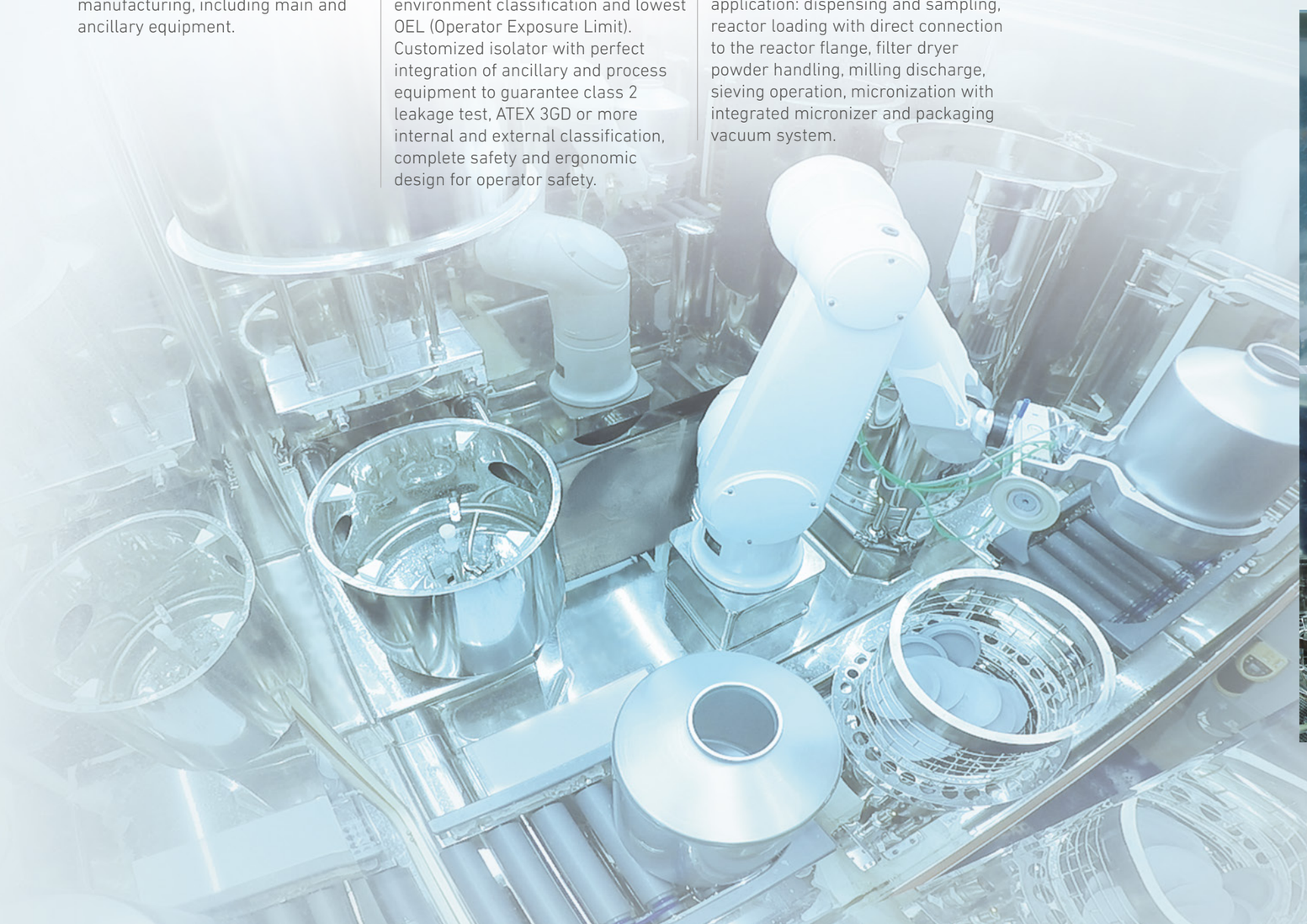
A variety of accessories to integrate and complete our equipment: automatic glove testers, VPHP generators, transfer hatches, downflow booths, weighing benches, LAF carts and more.

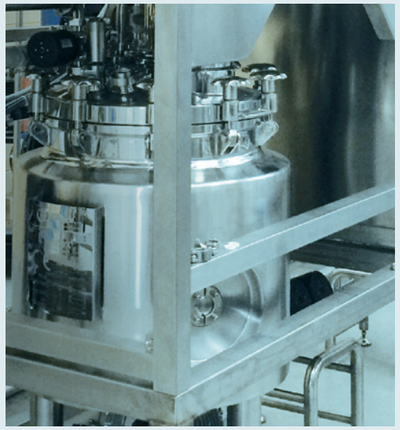
PRIMARY PHARMACEUTICAL PRODUCTION

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 high-speed 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.

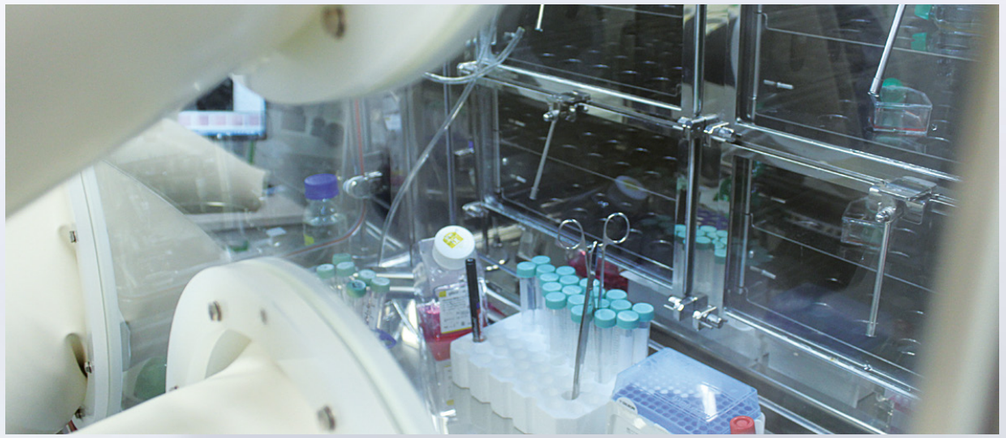
Configurations
From traditional tabletop design to newer balcony design, the whole arrangement of assembly machine plus isolator, with their related accessories, is designed to best suit the existing building or to support a newly designed facility. The entire study is carried out with a particular focus 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.

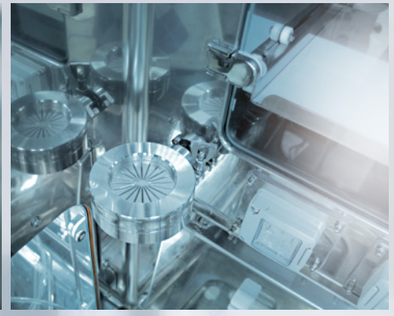
REGENERATIVE MEDICINE

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

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

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.

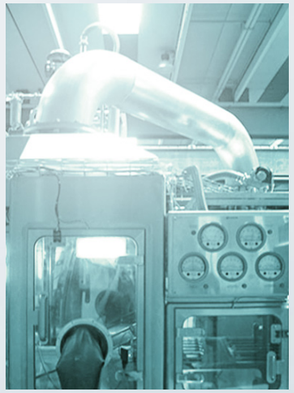
Configurations
Adaptable & configurable design with integrated devices and components to create unique solutions for specific needs. Increased operator safety and optimal ergonomics within an aseptic environment.
The systems can be arranged to perform the preparation of different substances by using 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.

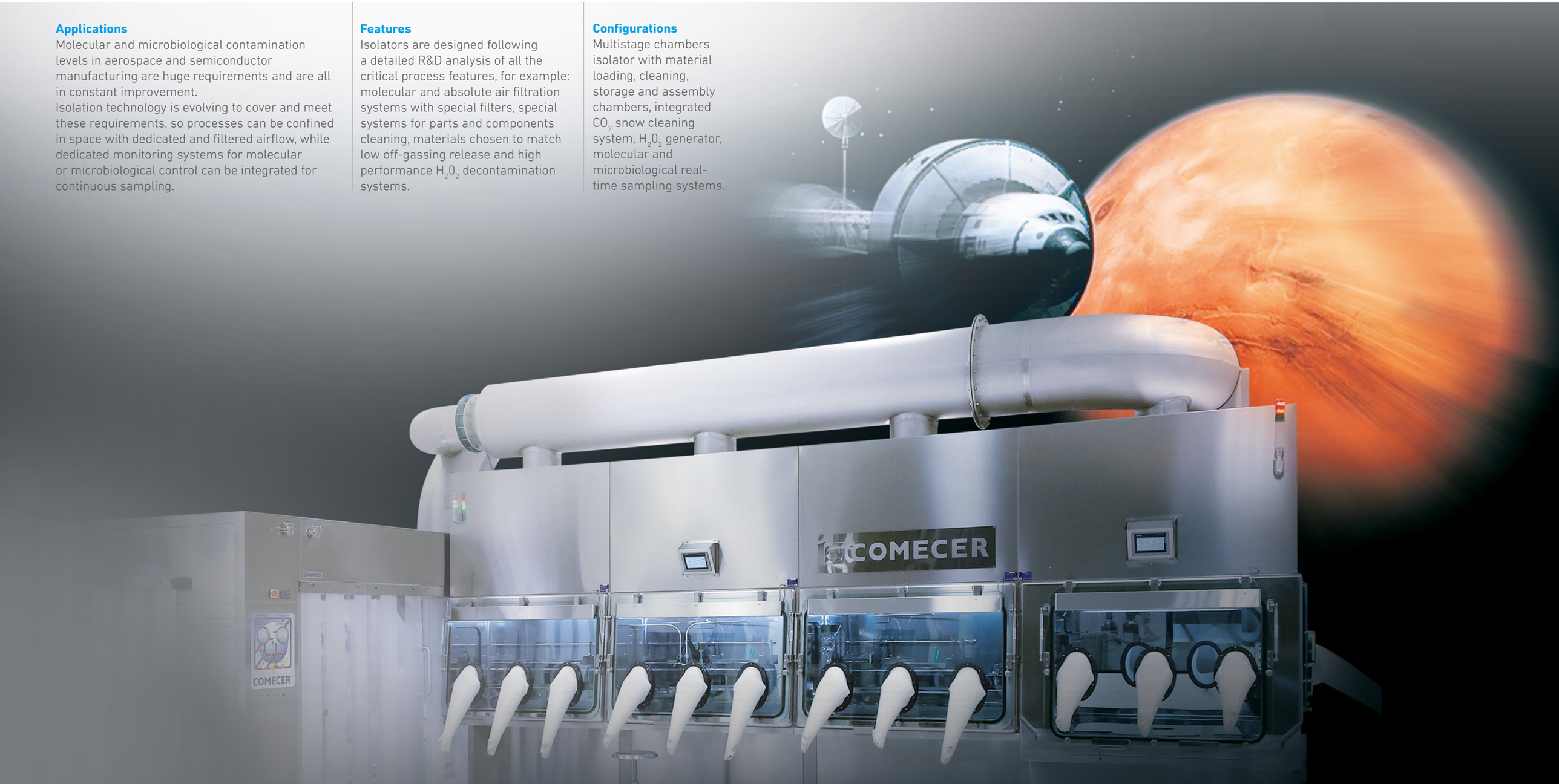


AEROSPACE AND SEMICONDUCTOR MANUFACTURING

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_2 snow cleaning system, H_2O_2 generator, molecular and microbiological real-time sampling systems.



ACCESSORIES

A VARIETY OF ANCILLARY EQUIPMENT TO COMPLETE OUR OFFERING

Automatic Glove Tester
Speedy Glove, our new automatic glove tester, is a portable, battery-powered 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 cross-contamination 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 bio-decontamination system by Comecer. Conceived to decontaminate enclosures up to a volume of about 10 m^3. 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.

MAIN REFERENCES

ABBVIE
Latina, Italy

ACS DOBFAR
Campascio, Switzerland
Meppel, Netherlands
Tribiano, Italy

ACS FACTA
Teramo, ITALY

ACTAVIS
Nerviano, Italy

ADIMMUNE
Taiwan

ALBORZ DAROU
Iran

ANGELINI
Ancona, Italy

BAYER GROUP (IFE/ALGETA)
Norway

BILTHOVEN BIOLOGICAL
Cyrus Poonvalla Group, Netherlands

BIOCEN
Cuba

BRACCO
Germany

BSP
Latina, Italy

CAMBREX PROFARMACO
Milano, Italy

CATALENT
France

CELLTHERA
Volginsky, Russia

CENEXI
Paris, France

CERBIOS PHARMA
Lugano, Switzerland

CHEMI PHARMA
Malta

CHIESI
Parma, Italy

CHUGAI (ROCHE GROUP)
Japan

CIDEM
Cuba

CORDEN PHARMA
Latina Italy

DGMIF
Daegu, South Korea

DKFZ
Germany

ELI LILLY
USA

FARMABIOS
Pavia, Italy

FDC
India

F.I.S.
Montecchio Maggiore, Italy

GOGLIO
Varese, Italy

GSK
Parma, Italy
Bad Oldesloe, Germany (now Aspen Pharma)
Poznan, Poland
Worthing, United Kingdom

GSK BIO
Wavre, Belgium

HOFFMAN-LA ROCHE
Switzerland

HOLOSTEM
Modena, Italy

HYBIO
Shenzen, China

IBSA
Lugano, Switzerland

ITALFARMACO
Madrid, Spain

JANSSEN
Latina, Italy

LISAPHARMA
Como, Italy

MEDLEY (SANOFI GROUP)
Brazil

MERCK-SERONO
Bari, Italy

MERIAL
Lyon, France

NANOLEK
Russia

NESTLE
Switzerland

NOVARTIS
Stein, Switzerland
Siena, Italy
Singapore

NCPC
China

ONCOMED
Brno, Czech Repubblic

PHARMADOX
Malta

PHARMASTANDARD
Kursk, Russia

PIERRE FABRE
France

PFIZER
Ascoli Piceno, Italy
Illertissen, Germany (ISPE "Facility of the year Award 2008" Overall Winner)
Puurs, Belgium

PROCOS
Cameri, Italy

PSICOPHARMA
Mexico

ROMPHARM
Bucarest, Romania
Turkey

SAMSUNG BIOLOGICS
Seoul, South Korea

SANOFI
Bejing, China

SIBP (CNBG)
Shangai

SICOR BIOTECH UAB (TEVA GROUP)
Vilnius, Lithuania

SYNTECO
Pavia, Italy

SOBHAN ONCOLOGY PHARMACEUTICALS
Teheran, Iran

TAKARA BIO
Japan

TEVA
Jerusalem
Opava, Czech Republic
Santhià, Italy

THALES ALENIA SPACE
Torino, Italy

WYETH
Puerto Rico

ZAHRAVI
Iran

ZENTIVA (SANOFI GROUP)
Romania

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

Headquarters: Italy
Via Maestri del Lavoro 90
48014 Castel Bolognese (RA)
t: +39 0546 656375 - f: +39 0546 656353
comecer@comecer.com
www.comecer.com

Subsidiaries:
India
Netherlands
Taiwan
UAE
USA

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