CUSTOMIZED BARRIER SYSTEMS FOR CONTAINMENT AND ASEPTIC PROCESSES

PROVIDING HIGH QUALITY SOLUTIONS TO MAXIMIZE OPERATOR AND PRODUCT PROTECTION

TEMA SINERGIE
High tech, high care

www.temasinergie.com

THE CUTTING EDGE TECHNOLOGY THAT MEETS YOUR NEEDS

QUALITY-BY-DESIGN

Tema Sinergie utilizes a remarkably experienced staff composed of technical sales engineers, designers, technicians, fitters for all projects. Client expectations are met or exceeded through the continuous improvement of manufacturing methods and superior design.

ENGINEERING

The Barrier Isolation Technology Technical Team considers all engineering aspects of a project, from concept design (preliminary study) to detailed design, mechanical, hardware, and software, plus Piping & Instrumentation Diagram (P&ID).

TECHNOLOGY

Fully welded AISI 316L stainless steel, certified materials, and welders. Highest quality commercial components.
Fully PLC controlled isolator system, latest Siemens technology. User friendly Human Machine Interface (HMI) available in different languages. Supervisory Control And Data Acquisition (SCADA) upon customer request.

COMPLIANCE

cGMP and FDA compliance, 21 CFR part 11, GAMP5 managing software.

VALIDATION

Tema Sinergie provides with complete validation packages,
Factory Acceptance Test (FAT), and Site Acceptance Test (SAT).

AFTER-SALES

On-line technical support 24/7, and remote service by VPN connection.
Highly qualified Service Team ready to fly all over the world.

BARRIER ISOLATION TECHNOLOGY

A BARRIER ISOLATOR SYSTEM PROVIDES A PHYSICAL BARRIER BETWEEN OPERATORS AND WORK PROCESSES. THIS TYPE OF EQUIPMENT IS COMMONLY USED FOR A WIDE RANGE OF PROCESSES IN VARIOUS INDUSTRIES; FROM FRUIT JUICE FILLING LINES IN THE ALIMENTARY INDUSTRY, TO THE PREPARATION OF CYTOTOXIC COMPOUNDS IN THE PHARMACEUTICAL INDUSTRY, TO CRITICAL MANUFACTURING PROCESSES IN THE ELECTRONICS INDUSTRY.

WITH OUR EQUIPMENT IT IS POSSIBLE TO:

- securely weigh and dispense HPAPIs
- fill vials or syringes under aseptic conditions
- perform reliable sterility testing
- manipulate cell cultures in aseptic environments
- transfer products into classified environments after bio-decontamination
- prepare hospital drugs, ensuring protection to both products and operators
- perform glove integrity testing on isolators and RABSs

CUSTOMIZED ISOLATORS FOR CONTAINMENT AND ASEPTIC PROCESSES

PHARMACEUTICAL PRIMARY PRODUCTION

Tema Sinergie can provide customized equipment to cover a wide range of processes, **from HPAPI synthesis to final formulation for both R&D and production**.

Customized solutions for chemical synthesis and manufacturing processes that comply with user requirements, such as standard and custom-designed Multi-stages Containment Isolator Systems that guarantee the lowest Operator Exposure Levels (OEL).

Class 2 leakage testing according to ISO 10648-2. Explosive proof (ATEX) compliant applications.

Full integration of process equipment, such as Vacuum Dryers, Reactors, Weighing Scales, and High Containment Split Butterfly Valves (HCSBv).

High Containment Isolator Systems

Tema Sinergie Containment Isolators have been designed for handling high potent compounds and offer guaranteed very high levels of operator protection.

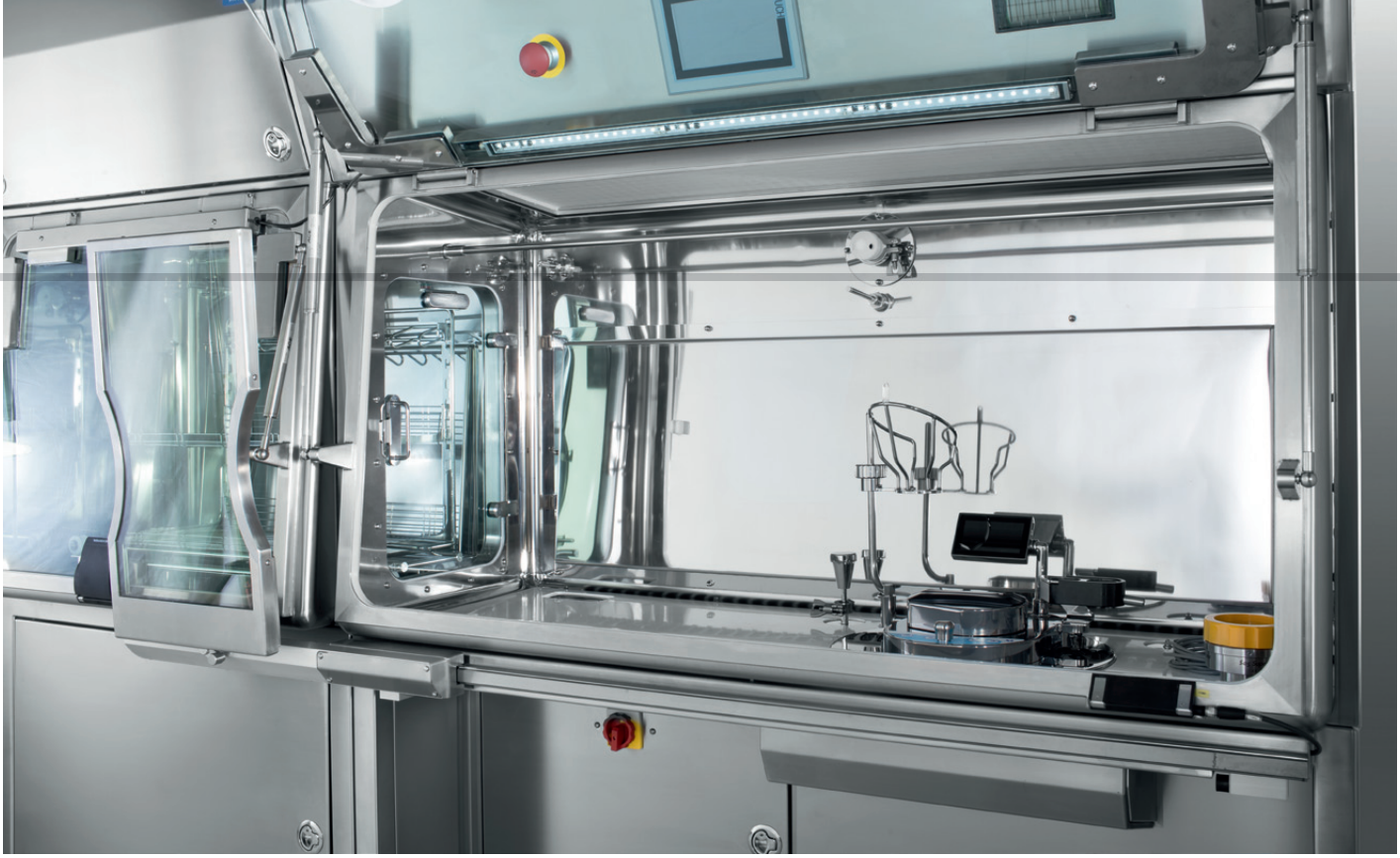
Operator safety is crucial because of the potential dangerous nature of the materials. Maximizing operator protection is the primary characteristic of a containment isolator, a perfect combination of design and manufacturing strategies assure a 100% OEL5 (≤50ng /m³).

Product Transfer, Manual Sampling, Weighing and Dispensing operations of Highly Potent Active Pharmaceutical Ingredients (HPAPI) are some of the default activities our Containment Isolators are designed for.

Downflow Containment Booths

Designed for providing a solution for powder containment during sampling, weighing, and dosing operations.

Reduce the risk of cross-contamination for operators, products and environment, provide protection and guarantee safe conditions during all operational processes. Standard sizes and models available, custom-designed solutions are also possible according to customer requirements.



PHARMACEUTICAL FILLING PROCESSES

As people are the greatest source of contamination during aseptic manufacturing of drugs, reducing personnel interventions into the process zone has significant impact on the quality of the final product.

From small to large batch production systems our proficiency extends to **all fields that require particular attention to asepsis during filling processes for both non-toxic sterile and cytotoxic products which require totally enclosed environments.**

Tema Sinergie develops custom-designed barrier systems by directly managing the integration activities with the third party machine manufacturers.

Specific equipment can be also supplied along with the barrier system, such as Preparation Isolator Systems, Unidirectional Airflow carts, Active Bio-decon Pass Through Chambers, Sterility Testing Isolators to perform all the process steps.

Restricted Access Barrier Systems (RABS)

Our equipment are designed to meet all existing requirements for aseptic processing. RABS provide protection by delivering a physical and aerodynamic barrier over a critical process zone with easier access to the process in the event a human intervention is required.

Tema Sinergie develops different kinds of RABS.

- **Open Passive RABS:** barrier system which utilizes existing cleanroom overhead air supply systems to deliver HEPA filtered air over a critical process before returning air back into the clean room.
- **Open Active RABS:** barrier system which has an integrated ventilation system to supply HEPA filtered air over a critical process before returning air back into the clean room.
- **Closed RABS:** a positive pressure system which has an integrated ventilation system to supply HEPA filtered air over a critical process, which can pass through return filters before being recirculated. Closed RABS can also be integrated with Bio-decontamination system to provide with a CGMP class A/ISO 5 environment.

Aseptic Processing Isolator Systems

Aseptic Processing Isolator Systems designed for QC Labs and pharmaceutical production.

The high level of aseptic conditions achievable makes these isolators the perfect flexible equipment for different applications, such as Sterility Testing, Aseptic Dispensing & Sampling, and Aseptic Product Transfer. Specific applications for Beta emitters available.

Recirculating Unidirectional Air Flow with return filters, and integrated Bio-decontamination system to allow 6-log bacterial reduction. Rapid Gas Chamber (RGC) with integrated VPHP technology for a fastest and safest bio-decontamination transfer process ($T_{max} \leq 25'$ full aeration, VHP concentration ≤ 1ppm).

Modular based configurations or custom design to fit specific user requirements.

Active Bio-decon Pass Through Chambers

Active Bio-decon Pass Through Chambers enable aseptic transfer of material into cleanrooms.

The materials are sterilized in the Pass Through Chamber by means of integrated Bio-decontamination system.

The integrated ventilation system of the chamber guarantees a pressure cascade between the adjoining rooms and the chamber itself.

This cascade preserves the asepsis of the materials after the termination of bio-decontamination process prior to extraction into the cleanroom.

Walk-in models available. Custom design to fit individual applications.

OTHER APPLICATIONS

REGENERATIVE MEDICINE

GMP compliant manipulation of Advanced Cell Therapy for medical treatments or research purposes into CGMP Class A/ISO 5 isolated environments equipped with Unidirectional Air Flow, and Integrated bio-decontamination system to allow 6-log bacterial reduction.
Full integration of specific process equipment, such as incubator, digital microscope, and centrifuge.

LABORATORY & HOSPITAL PHARMACY

Aseptic Containment Isolator Systems suitable for a safe handling of hazardous compounds (Chemotherapy, Oncological Applications).

Increased operator safety with better ergonomics into CGMP Class A/ISO 5 isolated environments.
Fully integrated Bio-decontamination system to allow 6-log bacterial reduction.

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Automatic Glove Leak Testing System

GMP compliant glove integrity testing system for isolators and RABSs developed in compliancy to the international standard ISO 14644-7 Annex E5.

A user-friendly interface allows the operator to control the testing unit through basic and intuitive commands.
No external piping for power and compressed air is required.
Wireless Wi-Fi data transmission to supervisor via TCP/IP-based protocol. Automatic glove identification by means of Radio Frequency Identification (RFID) Technology.

Tema Sinergie, established in 1985, has become a world leader in the design and manufacture of shielded isolators for the nuclear medicine market.
Presently the focus of the company is customized high-quality stainless steel barrier isolator systems for aseptic and containment processes for the pharmaceutical and chemical sectors as an additional business unit.
Tema Sinergie enhances its position in the pharmaceutical equipment market and promotes internal growth by anticipating industry demands with innovative ideas.
The company is certified according to international standards ISO 9001 and ISO 13485.

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