At Extract Technology, we have designed a comprehensive range of Aseptic Isolators that provide physical barrier solutions for the testing of pharmaceutical products in a reliable, safe and sterile environment.

Designs include Cell Therapy and Sterility testing, compounding, filling line Isolators and Restricted Access Barrier Systems, offering increased sterility assurance and protection levels for both the product and the operator.

The range of Aseptic solutions are designed and manufactured with a varied range of advantages compared to traditional cleanroom operation and suit each client’s individual requirements. Our sales and engineering staff will work closely with you to design the optimum system to meet your needs. Extract offers complete in-house design, engineering, fabrication and installation.

**Design Advantages**

- Creating a high quality product with total efficiency
- Increased safety by reducing contamination risks (increased patient safety)
- Cost efficient compared to a traditional clean room environment
- Ergonomic design generated by the use of sloping operator interface panels, large oval PharmaPort gloveports (safe change)
- EU GMP compliant design
- Full process equipment integration within grade ISO 5 environment
- Easier process separation
- Different pressure regimes available within each chamber

FOR MORE INFORMATION ON ASEPTIC ISOLATORS CALL +44 (0) 1484 432 727 OR VISIT www.extract-technology.com
Extract Technology's Cell Therapy isolators are designed to provide an ergonomic and practical alternative to traditional cleanrooms for stringent cGMP and International regulations for the production of cells for clinical use.

Extract Technology design and manufacture a varied range of Cell Therapy Isolators to suit each clients individual requirements.

→ Ergonomic design generated with the aid of full scale mock-ups.
→ Multiple chamber arrangements providing defined barriers between process steps, enhancing aseptic performance
→ Fully welded fabrications of 316L stainless steel, providing crevice free construction with internally radiused corners.
→ On-board recirculation laminar flow air flow system guaranteeing ISO 5 classification.
→ Integration of proprietary devices e.g. RTP's incubators, centrifuge and decontamination system etc.

The client is regarded as a regional leader in the area of cell industrialisation and tissue processing and commissioned Extract Technology for the turn key supply of a bespoke cell therapy isolator.

With advancements in using human cells to treat patients' illnesses the traditional approach of current medicine may become a thing of the past, with these changes isolator technology faces new challenges including time to market, high level of innovation, flexibility and cost effective solutions. The seven chamber isolator incorporated full process integration of incubators and microscopes within a grade A laminar flow environment, dedicated chambers for process separation, different pressure regime control within each chamber and integrated hydrogen peroxide system for decontamination. Moreover the EU GMP compliant design resulted in increased sterility by reducing potential contamination and cross contamination risks.

The new facility for regenerative medicine and tissue engineering now hosts one of the most advanced cell therapy isolators on the market the utilisation of this isolator technology will minimise human interventions in processing areas which will result in a significant decrease in the risk of microbiological contamination of aseptically manufactured products from the environment.
Extract Technology Filling Line Isolators are designed and manufactured to provide a controlled, aseptic environment in which the manufacture of compounded products would be performed, or alternatively an environment in which any form of filling, stoppering and capping machines together with their ancillary devices would be installed.

The operators control the loading/unloading of product and/or equipment, thus providing a defined barrier between the product, the operator and the surrounding environment.

Case Study

Vial Filling Isolators for a national Bio – Therapeutics products manufacturer

A project to provide two identical Vial Filling Isolators was recently completed by Extract Technology, each Isolator being designed around a Flexicon FP50 Filling Machine with associated ancillary devices.

The internal layout of the Isolators was designed not only to suit the machine but also to ensure that suitable storage for vial trays, both before and after filling was provided with maximum operator interface. To prove this and all other interfaces a full scale mock-up of the isolator, filling machine, product transfer devices, and other equipment features was built and operational reviews were also undertaken at Extract Technology by the Client’s Technicians at regular intervals throughout the design phase of the project.

Each Isolator incorporates full recirculatory vertical laminar flow, a fully integrated particle monitoring system, Rapid transfer port and a Clarus PORT entry/exit points and a full Hydrogen Peroxide Vapour Interface.

→ Creating a high quality product with total efficiency
→ Increased safety by reducing contamination risks (increased patient safety)
→ Cost efficient compare to a traditional clean room environment
→ Easier process separation
Compounding Isolators

Extract Technology

Compounding aseptic isolators are specifically designed for compounding pharmaceutical ingredients or preparations.

They are manufactured to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

- Total enclosure of the drug compounding process.
- Full process equipment integration within grade ISO 5 environment.
- Different pressure regimes available within each chamber.
- Material transfer processes that allow material transfer without contamination to product or environment.
- Recirculation laminar flow airflow system available providing ISO 5 classification.
- Easier process separation.
- Energy efficiency.

Pharmacy Compounding Isolators for European Site

A global medical products healthcare company recently awarded Extract Technology a contract to design and manufacture two Compounding Isolators.

Identical Isolators were provided for the compounding of parenterals and/or cytotoxic products incorporating double sided access with individual workstations for up to four operators.

A uniquely designed supply/exhaust air system not only prevented cross contamination through each of the work stations but also created and maintained an EU Grade A (ISO5) environment without the need for external ducts or increasing the operating footprint.

The integration of a gassing-in-place system the “Aseptic Hold” is based upon two weekly gassing cycles of the entire Isolator, securing material transfer with 6 log sporicidal decontamination steps at each load transfer via Clarus PORTS.

Specific to the design of the units was the integration of a product transfer system matching that of the ports, refrigeration storage units mounted into the base of the Isolators and individual computer work terminals.

www.extract-technology.com
Extract Technology’s Sterility Test Isolators are designed to allow operators to perform sterility testing in an aseptic environment providing assurance of process integrity. They also provide a controlled means of loading and removing the processed product and waste materials from the Isolator enclosure.

This system provides a cost-effective alternative to the “multi-isolator” approach to sterility testing and is ideal for those customers with limited laboratory space whilst benefiting from the ability to provide rapid decontamination.

- Space saving design
- Integrated Millipore Steritest® Unit or Sartorius Sterisart®NF
- Integrated Hydrogen Peroxide Decontamination
- Bespoke racking and storage to suit the application

**Case Study**

**Sterility test Isolator for Aspen Pharmacare, South Africa**

Aspen Pharmacare, one of Africa’s largest Pharmaceutical companies contracted Extract Technology to engineer, build and validate a Sterility Testing Isolator. Impressed with the quality of the system supplied, Aspen ordered a second Aseptic Isolator for a Hormone processing application.

“Lance Shortt, Technical Specialist on site commented Extract Technology once again proved themselves experts in Aseptic engineering solutions and we have no hesitation in working with them on future applications ensuring the same success.”
Introducing SteriPharm

As part of the standardised product range, SteriPharm is a user and maintenance friendly system providing a cost effective alternative for sterility testing. Available with 4 size standard options, SteriPharm is designed to offer increased protection and quality assurance of process integrity by utilising single pass turbulent airflow achieving a grade A environment.

Configured with 2 or 4 glove product handling chambers and the option of entry / exit airlocks complete with rapid gassing facility to enable operators to handle products in a highly controlled process flow. The SteriPharm Bio-decontamination process ensures a 6 log reduction in bacterial spore population with inclusive safety features to guarantee operator and plant safety. Increased protection from contamination is achieved by reducing human interventions, physical barrier technology, pressure differential and routine Vapour Phase Hydrogen Peroxide decontamination.

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Case Study

SteriPharm Isolator

A South African Biotech manufacturer contacted Extract Technology following the requirement for a cost effective Sterility Testing Isolator for their microbiology laboratory.

The client had stated their need for a modern Sterility Testing process to eliminate the risk of false positives by changing their testing methods from an open LAF to an enclosed testing isolator.

Complete with a fast gassing system, the SteriPharm Isolator met with the clients detailed and concise specifications, resulting with the supply of this ergonomically friendly standard solution.
RABS - Restricted Access Barrier Systems

Extract Technology bespoke Restricted-Access Barrier systems (RABS) provides product protection superior to traditional systems and offers a viable alternative to isolators and cleanrooms. Our bespoke systems are designed to meet all existing requirements for advanced 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 when intervention is required and can be used for many applications in a fill-finish area.

Following years of experience in RAB manufacturing, Extract Technology will advise, design, manufacture and install your desired barrier solution for your new or existing facility.

Extract Technology has developed over many years a diverse engineered RABs portfolio to include:

**Open Passive RABs**
- which utilise existing cleanroom overhead air supply systems to deliver HEPA filtered air over a critical process before returning air back into the clean room without the need for additional fans or filters.

**Open Active RABs**
- which have an on board fan /filtration units to supply HEPA

**Closed RABS**
- is a positive pressure system which has on board fan /filtration units to supply HEPA Filtered air over a critical process which then passes through exhaust filters before being recirculated. Closed RABs can also utilise ETL’s on board VPHP bio decontamination system or alternatively OEM’s stand alone bio decontamination units can be connected directly into the closed RABS.

All systems are designed to create a physical barrier to separate the operator and the product with the primary function to ensure that product quality is not compromised.

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**Case Study**

**Active Restricted Access Barrier System for Autoclave Unloading + Can Filling**

Extract Technology recently supplied a turnkey sterile upgrade solution by offering a value-engineered Active Restricted Access Barrier System following the request for a controlled, aseptic environment for Autoclave unloading & can filling.

Based upon ETL’s experiences with Aseptic and Sterile Isolator projects, the RABS system was designed to provide a controlled aseptic environment, taking into account specific operator ergonomics which was of paramount importance for user friendly access to the client’s aseptic processes. This active RABS system designed and manufactured for this project followed a detailed and concise specification from the client.

In addition to specific operator ergonomics further key functions of the bespoke system also include a ‘Closed loop’ control to maintain operating conditions within the Enclosure at all times. The Enclosures operate with a recirculatory airflow principle (via room return) with a dedicated supply airflow plenum providing Vertical Laminar Flow (0.45m/sec) within the Enclosure achieving ISO 5 – EN ISO 14644-1 (1999) assuring that proposed aseptic level protection and technical specifications are met.
The Control Strategy Pyramid

**EXTRACT’S CONTAINMENT PYRAMID IS SET TO CREATE A STANDARD WITHIN THE INDUSTRY.**

Designed to satisfy both current and projected industry standards it provides pharmaceutical and chemical companies with a clear guide to assessing the level of containment required to safely handle differing hazardous materials.

**Defining the Control Strategy**

The selection grid at the heart of the Control Strategy Pyramid permits the exposure potential rating and operator exposure band to intersect at the recommended Control Strategy selection. This is a simple cross reference to identify the correct equipment to be used to control and handle a specific process.

**Extract Technology Guarantee**

Whatever else you look for in an Aseptic solution, you will want it to be proven, tested and guaranteed. Extract Technology’s Isolators deliver all these things and more.

To maximize both operator and equipment interfaces 3D modeling and full scale mock-ups are used extensively to facilitate the best understanding possible of the pharmaceutical process and the operators involvement whilst ensuring high levels of containment are achieved.

Extract also offers installation, commissioning and IQ/OQ validation and containment testing by our fully trained engineers to ensure the system fully conforms to your requirements. To complete the package, our dedicated Aftersales department will supply total support.