

EXTRACT TECHNOLOGY

Aseptic Isolators



Cell Therapy Isolator for Therapeutics Unit

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Cell Therapy Isolator

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Vial Filling Isolators

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Cell Therapy Isolator for Therapeutics Unit

Building on their reputation as a respected and innovative manufacturer of Aseptic Isolators, Extract Technology recently installed a three chamber Cell Therapy Isolator at the Cellular Therapeutics Unit of Manchester University.

The Isolator is to be used for Cellular Immunotherapies targeted at Cancer, which has been performed in a clean room environment. Dr Ryan Guest, Leader of this project, stated that there

were several reasons behind the move to using Isolator Technology; higher throughput, less labour intensive and finally lower operational costs as work can be safely carried out in a grade D cleanroom.

The Isolation system includes three identical chambers all complete with uni-directional flow achieving an EU Grade A / ISO5 environment along with a fully integrated continuous particle monitoring system and automated chamber leak test facility. These features all interface with a hydrogen peroxide vapour generator, designed for the gassing-in-place of individual or combinations of chambers.

Following on from the completed installation of the Isolator Dr Ryan Guest commented:

“ We are very impressed with the Isolator supplied by Extract Technology. They fully understood the requirements contained within the specification and fulfilled our expectations throughout the project”.



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.



Hospital Pharmacy Isolators

Extract Technology recently completed a successful installation of four identical processing Isolators for a new pharmacy Aseptic Unit at a local hospital. The new Aseptic Unit required Isolator technology to prepare chemotherapy, antibiotic and parenteral nutrition admixtures to the highest of standards.



Each of the Isolators manufactured for this project followed a detailed and concise specification from the client which included;-

- A centrally positioned work zone and two rigid construction transfer hatches, either side of the working zone, allowing each unit to be capable of being sanitized with Hydrogen Peroxide Vapour.
- Recirculatory vertical laminar airflow system
- Product bag hanging system
- Sterile liquid vehicle system
- PLC controlled
- Hinged viewing panel

Extract Technology designed the Isolators with reliability being given uppermost consideration knowing that the Client had stated their need to operate the Isolators continuously for twenty four hours a day, seven days a week, of paramount importance was the fact that the medicines produced serve a huge populous covering an area of over five hundred square miles.

Sterility test isolator for Africa's largest Pharmaceutical company

Aspen Pharmacare of South Africa contracted Extract Technology to engineer, build and validate a Sterility Testing Isolator. Justifying the need was an easy one as it offset the risk of an operator induced false positive to their process, which would have major repercussions for the business as a whole.

Additionally the Isolator provided other tangible improvements; improved working efficiencies, increased throughput of samples and a reduction in used consumables.

To eliminate the risk of micro organisms being induced during the testing process the Isolator provided a positively pressurised HEPA filtered ISO Class 5 environment with a fully integrated Hydrogen Peroxide Vapour generator. Interlocking doors complete with inflatable seals allowed batches of product to be prepared and transferred into the aseptic core via the pass through hatch without the risk of contamination. The whole process was controlled via a PLC/HMI to provide the best possible user friendly interface.

Four gloveports in the main chamber gave the operator maximum ergonomic comfort and space to carry out the test process providing ample room for product storage and a Millipore Steritest unit.

Impressed with the quality of the system and the professionalism of the Extract team 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".



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.

Neil Cocker, Sales and Technical Manager for Extract Technology stated, "Extract welcomed this opportunity to build on their increasing presence in Europe with their Aseptic Isolator technology solutions, which also called upon their vast experience of bespoke Isolator solutions".

Tablet Filling Application for European Animal Health Care Manufacturer

As part of a consortium of companies Extract were asked to provide an Aseptic Enclosure for a Tablet Filling application designated for a pilot facility being built in The Netherlands producing a new innovative drug for the veterinary industry.

The Tablet Filling machine was based around a rotary indexing ring, with the main processing equipment placed within the ring and facing outwards providing excellent visual and physical access throughout. The Isolator design, based upon a 'donut' type concept provided a central services core and incorporated a Nitrogen atmosphere with three fast purging airlocks for the rapid replenishment of spheres (tablets), cups and lids to the internal stacking and automatic feeding system.

The complete system included a Vapourised Hydrogen Peroxide gassing system, full opening access doors, mouse hole exit for sealed cups and a full array of glove access ports with electrically interlocked access guards.



Recent contracts awarded

- Sterility Test Isolator for a worldwide generic products manufacturer located in Europe.
- Aseptic Process Charge Isolator for an international eye care company in the Far East.
- Aseptic Process Containment Isolator for a major vaccine manufacturer based in Europe.



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