Telstar®
Life Science solutions

Aseptic Barrier Systems

Telstar

Telstar has over 50 years' experience in the development of highly complex projects for pharmaceutical and biotech industries, from integrated process equipment using in-house technologies, to design, engineering and construction of plants, including turnkey project management and support for critical installations.

Telstar is a company with global vision that is acknowledged as a major supplier to the pharmaceutical industry, and has been designing and manufacturing Aseptic and Containment Barrier Isolators for over 25 years.

Installations range from high quality stand alone Isolators to customised solutions; Telstar's solutions are innovative with the capacity to develop and manufacture systems entirely in-house providing a cost effective solution and ensuring high quality control over the whole process.

Telstar has a dynamic team of experienced engineers using state of the art software to produce GMP designs with comprehensive validation packages. As an ISO9001 registered company, Telstar demonstrates a reliable and stringent quality management system including extensive in-house testing and compliance procedures.

Attention to detail makes all the difference when designing the right solution.

Telstar's technical team possess the expertise to understand the client's requirements and processes making Telstar one of the world's leading suppliers of containment and aseptic Isolator systems.

Bottle Filling cRABS

Restricted Access Barrier Systems represent one of the fastest growing technology solutions for products that cannot be terminally sterilized.

Open or closed Restricted Access Barrier Systems (oRABS/cRABS) are an important element in Telstar's product portfolio and provide a viable alternative to Isolation technology where a leak tight option is not necessary but the need for enhanced product protection in a grade B room is still required. These systems can be applied for a variety of aseptic production activities including small to large scale aseptic filling operations where a grade A (ISO 4.8) clean environment is required.

Telstar design and manufacture systems to comply fully with client's requirements for aseptic processing, using a dedicated and experienced design and project engineering team throughout the process.

Typical Features of Telstar's open or closed Restricted Access Barrier Systems:

- Uni-directional laminar flow
- H14 HEPA filtration
- Integral fan units
- PLC control with local HMI
- 21 CFR Part 11 ready
- On board LED lighting
- Inflatable sealed glazed windows
- Large oval gloveports
- Viable / Non-viable monitoring
- Temperature & RH monitoring / control
- PLC based controls with local HMI

Telstar Restricted Access Barrier Systems are commissioned to operate at their optimal level, assuring you of maximum safety and performance. To maintain this exceptional quality we offer valuable inspection, re-testing and service packages that protect your investment and productivity.

Aseptic Isolator Vial Filling and Closing

Double chamber integrated to a Filling/Closing Machi
coupled Vial loading modules at the entry end and the

All chambers which make up the aseptic core of the conta
aseptic process environment with an internal air cleanliness

- Internal partitioning segregating different process areas where necessary.
- Multi fan systems enable controlled pressure cascade between process areas or same pressure regime where appropriate.

- Uni-directional laminar flow of H14 HEPA filtered air.
- Air velocity and chamber pressures controlled via closed loop control system.
- Temperature and RH monitored, controlled throughout (as necessary)

Aseptic Barrier Isolation line

Telstar has designed, manufactured and successfully installed an Aseptic Barrier Isolation line for a vial filling freeze dryer/load/unload and capping process for a leading European Pharmacy manufacturer.

It was essential that the product had to be produced and capped within an aseptically controlled environment before exiting the Barrier Isolator System.

All chambers incorporated integral Bio-decontamination, and the Isolator system was designed to achieve a minimum of ISO 4.8 (Grade A) classification.

In addition the equipment had to be integrated into a clean room complete with a pressure tight barrier.

Implementing complex projects is achieved by close collaboration between Telstar's global centres of excellence in both Spain and the UK.

Our meticulous attention to detail throughout every project carries significant benefits for our clients.

Isolator

ine, Automatic Tunnel Conveyor System and close Vial Washing Machine at the exit end

inment system are designed to offer a positive pressure of ISO Class 4.8

- Multiple operator access points arranged ergonomically for general set up and periodic critical interventions.
- Light safety barriers ensure operators safeguard by halting moving parts during unauthorized operator access.

- Sealed vials exit the Isolator via a fully integrated 3rd party washing machine connected by a tunnel Isolator.
- Wash Isolator operates under negative pressure preventing contamination escape to cleanroom.

Following a competitive tender process which resulted in Telstar being awarded the major contract to design, manufacture and supply the system detailed below we supplied the following:

- Single chamber filling Isolator for vial filling flanged to a filling machine bed plate featuring an automated vial conveyor for the transfer of filled vials through the chamber to the Vial Transfer/Buffer Isolator.
- Single chamber Lyo load/unload Isolator interfacing with the loading door of the Telstar LyoMega freeze dryer with auto loading/unloading of the filled vials to and from the Lyo before and after lyophilisation.
- Single chamber capping Isolator flanged to the capping machine bed plate for the capping of lyophilised vials before exit from the Isolator system.

Additional features supplied by Telstar include:

- Telstar ionHP® Bio- decontamination system
- Telstar automated glove tester

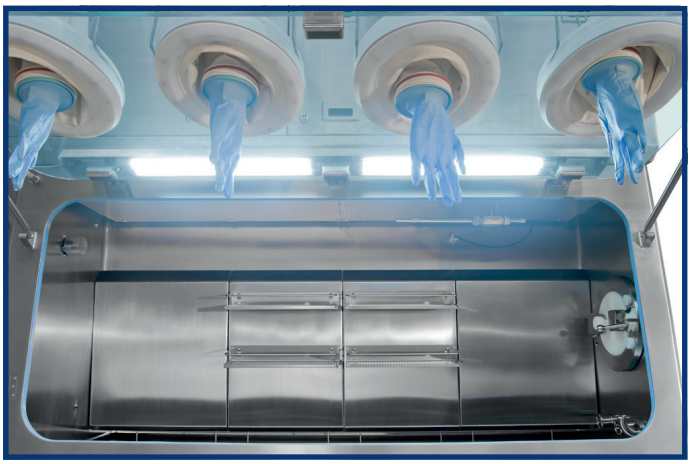
During the initial stages of the project the client requested a full scale wooden mock up of the Isolator system, testing the ergonomics and the access to various parts of the equipment, which were designed by Telstar. The Client visited Telstar UK to participate during the process review.

Aseptic Production Isolator

Telstar manufactures standard Isolators specifically designed for a variety of aseptic production activities such as small scale vial and syringe filling operations. Whether supplied as a single module or as multi-modules with transfer chambers, the Isolators provide a Grade A (ISO 4.8) clean environment throughout to afford maximum product protection for aseptic product handling. The Isolator chambers can be customised to suit the specific process or third party equipment such as filling and capping machines.

Typical features may include:

- Uni-directional laminar flow
- H14 HEPA filtration
- Integral fan units for recirculatory and aeration modes
- PLC control with local HMI
- 21 CFR Part 11 ready
- On board LED lighting
- Inflatable sealed glazed windows
- Large oval gloveports
- Glove hangers
- Viable/Non-viable monitoring
- Integral hydrogen peroxide bio-decontamination system
- Catalytic converter
- Temperature & RH monitoring/control



Options can be included for example:

- Telstar Integrated Glove Tester enabling the in-situ testing of gloves connected to the unit's PLC, to test the glove integrity.
- Room H_2O_2 Monitoring – the sensor shall be interfaced with the Isolators control system and will alarm if a dangerous level of H_2O_2 concentration is detected in the room.
- Powered Raise-Lower Support Frame. This option will allow the operating level to be adjusted so operators can adopt a standing or a seating position.

Telstar's approach is based on providing a tailor-made solution to suit the client's specific application. The equipment we propose will balance optimum operator and product protection with cost-effectiveness and ease of use.

Telstar bring their unique experience and expertise to offer technically advanced aseptic solutions which are designed and manufactured for all aspects of manufacturing processes.

Cell Therapy Isolator

Telstar has always been at the forefront of new aseptic technologies and in recent years this has included requirements for Cell Therapy Isolators. Telstar has designed and developed Cell Therapy Isolators to meet these ever increasing demands.

Our success is founded on our precision engineering skills and our proven ability to design and manufacture custom built solutions that will meet each client's individual needs.

Key features and available options:

- Bespoke designs
- Full process equipment supply and integration including laboratory type centrifuge, CO_2 Incubator, microscopes, weighing systems etc.
- Integral H_2O_2 based bio-decontamination system providing rapid and effective sterilisation.
- Transfer hatches can be bio-decontaminated separately to main chamber.
- Ergonomic trials to ensure the process requirements are met.
- Multiple working chambers defining process barriers.
- Viable and non-viable monitoring points.
- Isolator can run in either +ve or -ve pressure mode as required.
- Uni-directional airflow providing ISO 4.8 conditions.
- On-board variable speed fans to all of the chambers.

Telstar guarantees that each Cell Therapy Isolator will comply with the latest standards such as the Good Manufacturing Practice for Advanced Therapy Medicinal Products for the manufacture of cellular therapies intended for human application.

Sound ergonomic design of the unit is combined with thoughtful design-for-manufacture utilising the latest techniques, assuring ease of assembly and efficient inspection and testing.

Telstar
Life Science solutions

Lyophilisation
Integrated Systems
Freeze Drying Process Development
Clean Room Systems
Sterilization Process Development
Sterilization
EPC Management
Process&Water
Construction
Engineering
Consultancy
Barrier Systems

Pharma Process Solutions

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Construction • Integrated Systems

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Construction
Lyophilisation
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Engineering
Barrier Systems
Sterilization Process Development
EPC Management
Consultancy
Process&Water
Clean Room Systems

The production site where the products are made has been assessed and given ISO 9001:2015 approval.
All equipment is manufactured to allow it to be CE marked in accordance with 2006/42/EC Machinery Directive.

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