



# CUSTOMER CASE STUDY

## STERILITY TESTING IN ISOLATORS

### The Customer

Sigma Scotland is part of the Sigma Aldrich Corporation. Sigma-Aldrich is a leading Life Science and High Technology company with \$1.2 billion in annual sales. Operating in 34 countries and Sigma Aldrich has 6,000 employees providing excellent service worldwide.

### Solution Overview

A uniquely designed sterility test isolator incorporating the Millipore Integral® sterility test unit and linked to the Steris 1000 VHP® vapourised hydrogen peroxide gaseous sterilisation unit, providing a system that is routinely capable of handling up to 100 samples a day.

### Features

Bespoke arrangement of isolator chambers to meet client's processing capacity requirements with maximum flexibility

Interlocked doors between compartments for operational safety.

Based on Envair's well-established Pharm-Assist range of isolators to minimise the utilisation of untested components and technology

D-type transfer chamber to allow product exit whilst maintaining the aseptic integrity of the main chambers.

**Envair are delighted to have supplied an isolator to Sigma Scotland for the sterility testing of cell culture products.**

### Background

Sigma Scotland, part of the Sigma Aldrich Corporation are manufacturers and suppliers of media formulation for the cell culture industries. As a result of their extremely high quality standards, they have developed one of Europe's finest cell culture manufacturing plants for the aseptic production of liquid and powder media, liquid reagents, antibiotic solutions and sera. Sigma Scotland performs a wide range of quality control processes one of these being sterility testing.

### Sterility Testing

The age old question of the accuracy of sterility testing led Sigma Scotland to re-evaluate their existing process which was carried out in a laminar flow cabinet within a Quality Control cleanroom. Approximately 2% of all tests were having to be repeated whereas complete batch incubation of sterility test failures never revealed any contaminated units.

The FDA guidelines only allow repeat testing if there is substantial proof that there is a flaw in the test equipment or method. Sigma were aware that the sterility testing was being carried out in far less stringent conditions than the batch filling operation. They therefore took the decision to carry out sterility testing in an isolator which would be gaseously sterilised by means of a vapourised hydrogen peroxide (VHP) sterilising unit. The outcome is complete confidence in the results of the sterility tests, this eliminating retests and potentially needless batch discards.



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### Pharm Assist Isolators

Positive pressure isolators with an EC GMP Grade A (laminar flow) critical zone for aseptic preparation of IV additives and TPNs. Available in 2-glove or 4-glove versions, in flexible film (PVC) or rigid (coated stainless steel), complete with high air change rate D Type transfer chambers with electromagnetic timed interlocks and PLC controls for easy set up, operation, monitoring and maintenance.

### Sterility Test Isolators

Single or multi-chamber 'Pharm-Assist' based isolators for sterility testing according to GMP, complete with client-specific ergonomic material storage and handling facilities, in-built sterility testing equipment and an integrated system for sporicidal gassing with hydrogen peroxide vapour.

### Envair's Contribution

Together with Sigma Scotland Envair designed an isolator system that would be routinely capable of handling up to 100 samples per day, representing a full days production, with the flexibility of increasing capacity or processing additional samples. The isolator is based on two Envair standard rigid 'Pharm-Assist' units, a two glove and a four glove, together with a D-type transfer chamber, which acts as the exit hatch.

All these compartments are linked with suitably interlocked doors and are piped to the VHP unit so that they can be sterilised separately or together. Upon completion of the sterilisation cycle the trolley is moved through into the already sterile sterility test compartment.

Larger batches can be processed by loading both compartments and keeping the interconnecting door open during the sterilisation cycle. If necessary additional samples can be added later via the sterilising compartment or the transfer chamber using a second sterilisation cycle. Sigma Scotland consider that the equipment supplied by Envair was competitively priced and, an even more important factor, that the Envair team were willing to work with them to progress the concept from design to reality.



Isolator System at Sigma Scotland

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