LFU, RABS, AND ISOLATORS
[OPEN AND CLOSED SYSTEMS]

STERILINE BARRIER SYSTEMS (ISOLATORS, RABS, LFU): Are typically designed for the production of toxic or potent compounds. These systems provide protection for the operator from the product and/or the product from the operator and the surrounding space, preventing contamination by keeping the production process enclosed in a confined area. The enclosed space provides HEPA filtered, unidirectional air flows vertically over the interior area.

LAMINAR FLOW UNITS AND OPEN RABS ***Steriline containment products begin with standard laminar flow units that provide an ISO 5 environment to the critical area.*** These systems are frequently upgraded to an open RABS by addition of one or more sets of gloves that allow the operator or technician access to the interior area and equipment while limiting the direct access through an open access door. When upgrading to a oRABS. safety devices are included to stop the interior equipment to prevent potentially danger to the operator when accessing the interior through the gloves.

AWS BIO-PHARMA TECHNOLOGIES

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LFU, RABS, AND ISOLATORS
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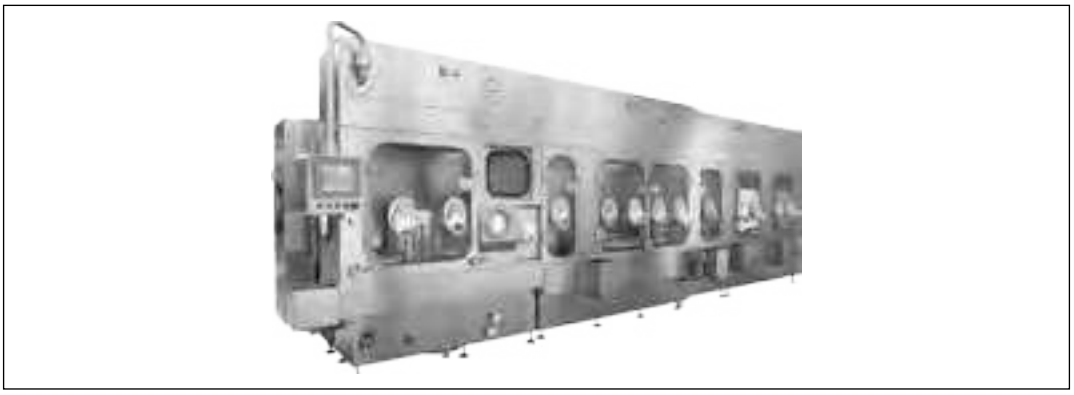
Steriline offers state-of-the-art closed RABS and Isolators for more demanding separation of the interior space from the surrounding area. Typically these Steriline systems are designed for production of sterile products, whether toxic, potent, or non-toxic. Both our cRABS and isolators maintain uncompromising, continuous isolation of the interior from the external environment. An ISO 5 environment is achieved by HEPA filtered, unidirectional air that vertically flows over the process area. An exhaust fan maintains the pressure difference between the interior and the exterior environments. The exhaust air is HEPA filtered by "Bag-in/ Bag-out" (BIBO) filters. Generally cRABS are installed in Grade B (ISO 6) rooms; while Steriline isolators can be installed in Grade C (ISO 7) or Grade D (ISO 8) rooms. These high level containment systems can be either stand-alone equipment (used for weighing operations, dispensing, sterility testing, quality control, research and development, sampling, or compounding.) or fully integrated into an aseptic production line, in compliance with cGMP regulations. The primary difference between these methods of containment is that the Isolator also includes the capability for sterilization through the use of vapor phase hydrogen peroxide (VHP) or a similar gas.

VHP SANITIZATION IS BASED ON THE FOLLOWING APPROACH Steriline provides a fully integrated isolator package with VHP (Vaporized Hydrogen Peroxide) generator for the sanitization cycle with a choice of several systems. ***The sanitization cycle includes the following steps:***

1. ***Preparation, including tightness test***
2. ***Conditioning by increasing the VHP concentration to the set point***
3. ***Sanitization at constant VHP concentration***
4. ***Aeration to lower the VHP concentration less than 1 ppm***

THE PLC CONTROLS AND THE ONBOARD HMI HIGHLIGHTS ALL MAIN FUNCTIONAL PROCESS PARAMETERS

1. ***The speed of the vertical air flow***
2. ***The differential pressure between the confined area and the surrounding room***
3. ***The temperature and relative humidity***



All Steriline processing systems are in compliance with cGMP, GAMP and 21CFR Part11 requirements.
Visit our web site at www.sterilineusa.net for more information