

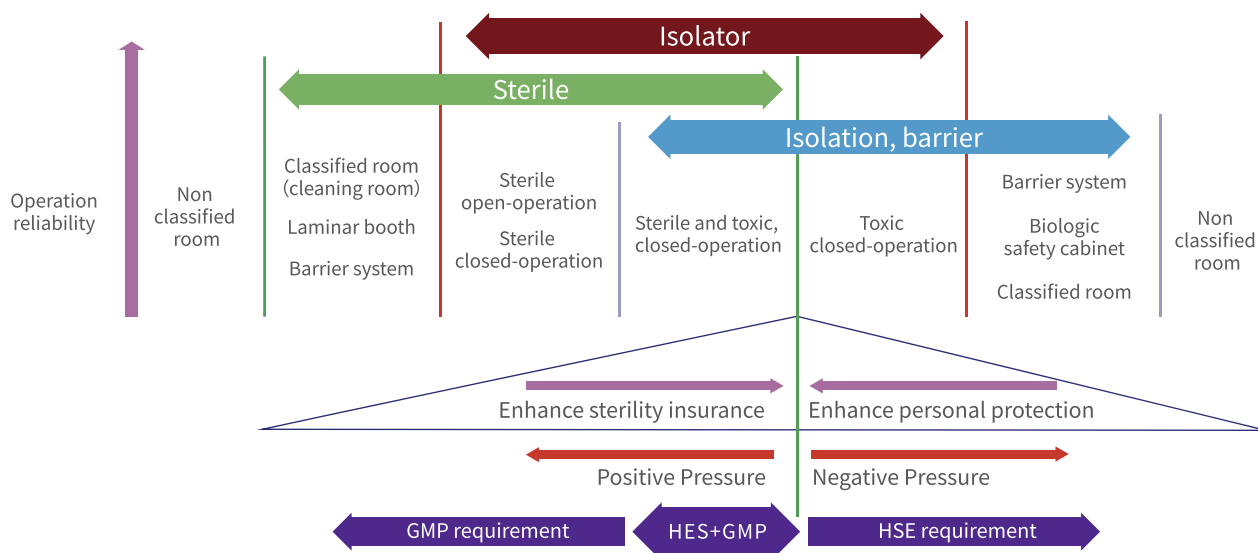
## Containment Barrier System

AU STAR, as an excellent containment technology expert in the pharmaceutical industry, is committed to providing sterility test isolator and containment isolation technology suitable for research and production of highly potent and active substances for global customers for years.

Isolator system is a special environment formed by rigid structures. In the process of production operation of highly potent or active drugs, the isolation system separates the operation space from the operator and surrounding environment, and the operators perform safe operation through gloves, a single or two-piece trousers suit, so as to reduce the risks caused by leakage of highly potent or active substances to the operator and environment during the production operation.



### Isolation Strategies in Different Application Scenarios



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Negative pressure isolators are widely used in highly potent API and OSD processes, and are commonly used to isolate highly potent and active substances in process steps such as feeding, weighing, grinding, and screening.

As recommended by ISPE Vol2-OSD (3rd Edition) guideline, the use of isolators should be considered when weighing highly potent and active hazardous substances. The isolator can be integrated or mobile, but it needs to be equipped with HEPA H13 filter and appropriate glove position for easy operation. The material drum (IBC) may be fed directly from the weighing isolator and the high platform may be used to fit the contained docking of the material container (IBC) at a lower position. The isolator may be located in the upper process area of the feed area of the material transfer drum. Containment operations and isolators are usually supported by additional containment equipment to realize the complete line containment scheme, including closed split butterfly valves, material transfer drums/flexible bags, and AB closed valve docking port.

## PRODUCT FEATURES

- 1 Isolators are applicable to OEB4(OEL=1~10ug/m<sup>3</sup>) and OEB5 (OEL≤1ug/m<sup>3</sup>) toxic materials isolation and protection requirements
- 2 It adopts full supply and exhaust negative pressure design, the negative pressure in the isolator can be automatically adjusted according to the set value, and emergency response function is available at the same time. Once the internal pressure loss of the isolator is detected, it will make automatic response for adjustment to force the air flow to enter the isolator from the external environment of the isolator, and avoid the diffusion of highly potent and active substances.
- 3 Customized isolator internal space design can be integrated with process equipment.
- 4 Turbulent flow is mostly used in the chamber, with no requirement for air speed. The air exchange rate is about 20 times per hour, and the internal dust-producing environment may require more than 100 times per hour.
- 5 The design complies with ergonomics principle, and the wooden model test based on engineering drawing is used for ergonomics and operability test before production. The observation side of the isolator is bevel, with a glass airfoil door.
- 6 PUSH-PUSH filter for easy operation is used.
- 7 ISPE guideline based SMEPAC test service and a third-party test report are provided.
- 8 The design is convenient for cleaning operation, and manual cleaning system is built in the isolator.