

Flexible Containment Solutions Guide



Drum Sampling Enclosure System

OVERVIEW

Sampling of active pharmaceutical ingredients, sensitizers, and other highly hazardous compounds for quality assurance purposes is a process that is performed on a routine basis. The ability to perform this work in a warehouse or other parts of the facility, on a task operation basis, and without having to make significant capital expenditures are key in meeting this operational need.

The Drum Sampling Enclosure (DSE) system, a proven containment solution, supports accessing drummed materials - with the drum fully contained. Some processes advocate the safety of removing the drum lid before placing the drum inside the containment device. Experience proves the risk exists, even with a dual inner liner, that cross contamination and operator exposure can occur when the lid can not be removed within a robust flexible enclosure.

HOW DOES IT WORK?

The DSE System consists of a Flexible Enclosure and Support Stand. Sampling to an integral flexible sleeve, bottles or a thief are all proven capabilities.

The enclosure includes one pair of integral glove sleeves, a storage sleeve and sampling sleeve. Loops for supporting the enclosure by the stand are added to provide the attachment mechanism for the bungee cords. The combination of HEPA filters and bungee cords support the flexibility of the ergonomic design.

Operationally, the following basic steps are employed:

1. Sampling tools are preloaded into the 14"/350mm diameter sleeve and the open bottom of the enclosure is stretched over the drum and then taped to the drum wall.
2. The integral grommets on the top of the enclosure are connected to the support frame to provide the operator with space to work using the supplied bungee cords.
3. The drum lid is removed and placed along side of the drum but remains inside the containment area. The inner drum liners are then opened.
4. The sample is taken via the 4"/100mm sleeve using the process desired scooping directly into the sleeve or a sample bottle that is placed in the sleeve or using a standard sample thief and depositing that sample in the sleeve or a sample bottle. The samples can then be removed from the enclosure through the 4"/100 mm diameter sleeve by using the ILC Dover developed Crimping process.
5. The inner drum liner is resealed and the drum lid is put back into place without breaking containment.



FEATURES

- Clear film allows use of existing light from the process area
- Static dissipative film
- Re-usable for repeated sampling
- Tamper Proof sampling
- Portable
- Small footprint does not take up a lot of floor space
- Enclosure is attached to drum wall allowing lid to be contained
- Stretch on enclosure interfaces with common size drums but can also be customized
- One person operation

BENEFITS

- Can be used in any part of the facility
- No cross contamination transfer to other parts of the plant
- Ergonomics and secure operations are maximized with the integrity of ArmorFlex® materials
- Low capital, depreciation and operating costs maximizes true cost of ownership
- Immediate implementation supports Production and Lab processes in any part of the plant
- Reduced cleaning and cleaning validation
- Drums can be moved freely without breaking containment

WHAT CONTAINMENT LEVEL PROVIDED?

OEB 5 with results in the nanogram range. Even lower to non-detectable levels would be expected if the system were to be used in conjunction with an existing down flow booth. This is anticipated given actual customer feedback and third party IH test results from similar designs as well as the 100% inflation tests performed on the deliverable enclosures.

WHY USE THIS OVER OTHER TECHNOLOGIES?

The cost of ownership, ergonomic advantages, ease of use, integrity of the ArmorFlex material and speed of delivery benefits of this proven flexible solution far outweigh those of rigid isolation systems.

OTHER POTENTIAL APPLICATIONS

This technology is applicable for multiple process steps and includes, but is not limited to:

- cGMP access to buffer prep powders
- Liquid sampling
- Dispensing



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