

Mill Containment System - *Bohle Mill Enclosure*

OVERVIEW

Particle size reduction is commonly required in pharmaceutical manufacturing. Taking into account today's need to mill highly hazardous compounds in conjunction with the need to minimize capital cost spending, the application of flexible containment to an existing Bohle mill design demonstrates the use of this containment strategy under a successful project with a multinational pharmaceutical manufacturer.

The mill in this application is a small volume, size reduction piece of equipment that is used in the drug product development stages. Typically provided without containment, options for the end user in the past were limited to installing a rigid isolator or using personal protective equipment (PPE).

Today, outfitting the system with flexible containment has proven to be successful from operational and business perspectives. Best of all, this has been accomplished on an existing, non contained design without the need for expensive retrofits past the addition of attachment flanges.

This example of how ILC Dover is applying the use of highly engineered materials and state of the art design techniques is described in detail below.

HOW DOES THE SYSTEM WORK?

Containment of this style of mill is provided by a rectangular flexible enclosure with an angled front surrounding the entire mill head including the inlet hopper, outlet nozzle and interlock switch. Integral glove sleeves are positioned to provide a means of charging and collection of product, as well as servicing and cleaning the machine.

A single entry/removal point provides a means for moving product and supplies in and out of the enclosure. This entry/removal point will support use of a bag-in/bag-out (BIBO) sleeve or interface with ancillary containment devices such as an in-process flexible isolator. (Figures 1 and 2)

The enclosure also incorporates HEPA filters into the design to balance the pressure in the enclosure and allow it to move freely as the operators perform various operations.

The system is movable via the incorporation of conductive, locking castors. This allows safe movement between the processing suites and storage areas. The system is lightweight and can easily be moved by personnel from the 5th percentile female to the 95th percentile male without the need for material handling equipment.

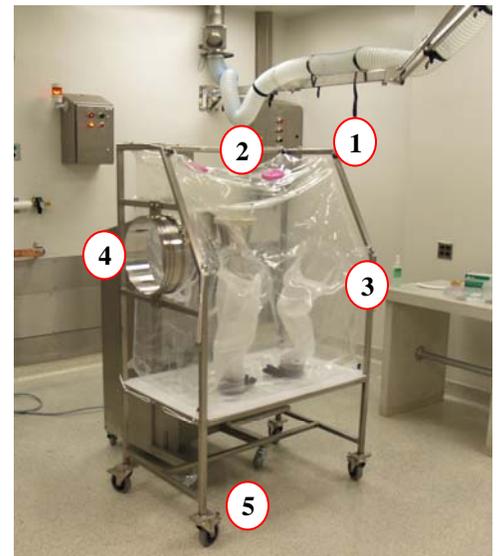


Figure 1

- 1 - Enclosure
- 2 - HEPA Filters
- 3 - Integral Glove Sleeves
- 4 - BIBO Canister
- 5 - Conductive, locking castors

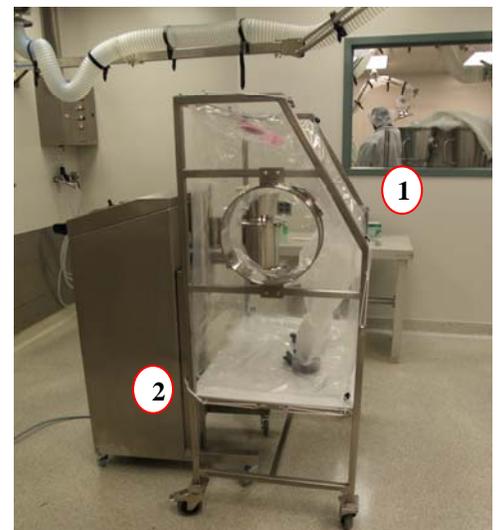


Figure 2

- 1 - Angled front of enclosure
- 2 - Bungee Cords

Installation of the enclosure is accomplished by means of an attachment plate and flange that are secured to the mill drive tube behind the interlock switch. This assembly is attached to the perimeter of the drive shaft tube without modification of the sieve. An external enclosure support frame is constructed to support the enclosure as well as the bag-in canister and product staging table. (Figure 3)

The enclosure is manufactured from clear ArmorFlex® 113 film that allows room light to illuminate inside the enclosure for easy viewing. This rugged film provides a safe working environment while enabling the enhancements developed through numerous installations using this flexible containment technology.

FEATURES

- Process and Technical areas separated
- Clear film
- Flexible materials
- Retrofit to existing mills
- Adaptable to other particle size reduction equipment
- Validated containment technology
- Passive system
- Disposable components

BENEFITS

- Process is contained without contamination of motor, drive shaft, and controls
- Nanogram containment levels achieved
- Supports visibility for maintenance
- Does not affect ATEX and Ex ratings
- Ergonomics maximized
- Reduced cleaning and cleaning validation
- Low capital and operating cost
- Speed of implementation

WHAT CONTAINMENT LEVEL PROVIDED?

OEB 5 with results in the nanogram range. This is based on customer test data, other proven applications, third party testing to the “SMEPAC” protocols on similar designs, and the 100% inflation tests performed on the deliverable systems.

WHY USE THIS OVER OTHER TECHNOLOGIES?

The cost of ownership, ergonomic advantages, and speed of delivery benefits of this flexible solution far outweigh those of rigid isolation systems.

OTHER POTENTIAL APPLICATIONS

Successful installations have been provided for similar size reduction equipment including Quadro and FitzMill® systems as well as micronizers.

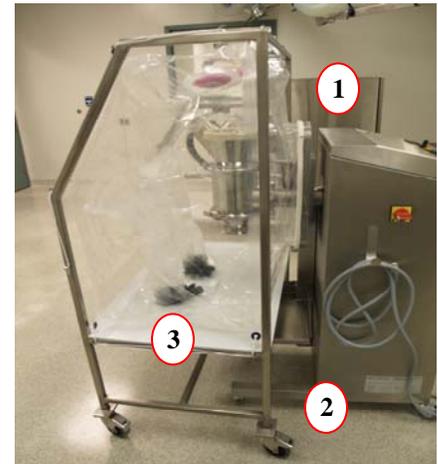


Figure 3

- 1 - Attachment Flange Assembly
- 2 - Enclosure Support Frame
- 3 - Support Table

