ILC DOVER

Granulator Containment Technology

OVERVIEW

In the pharmaceutical industry, granulation is used to create bonds between multiple particles as part of the oral solid dosage manufacturing process. Two types of granulation technologies are employed, Wet Granulation and Dry Granulation.

The containment systems described in this guide center around wet granulation which involves the massing of a mix of dry primary powder particles using a granulating fluid. The powders can range in properties and potency and are subjected to a variety of additional steps including sieving, drying and milling.

Used for lab scale and production operations at multiple International Pharma manufacturers, our contained Granulator applications take the idea of retrofits to another level. Here, a broad range of existing and new equipment are supported as a tool to eliminate the risk of contained powder processing.

Flange Mount Style

HOW DOES IT WORK?

Two methods of containment have been applied. One uses flanges that are added to the piece of process equipment that then have a flexible enclosure attached to the flange in operation. The second is to totally encapsulate the granulator with a pan mounted flexible enclosure.

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Equipment Mounted Enclosures Separate the Process and Technical Areas

The use of stainless steel flanges added to the granulator enables the containment of the process area. The enclosure is attached to the flange and includes glove sleeves, bungee cords, and HEPA filters. These features support access to the equipment while maximizing ergonomics and support operators from the 5th percentile female to the 95th percentile male.

Pan Mounted Enclosures Encapsulate the Entire Granulator

Pan mounted enclosures allow the entire piece of process equipment to be contained. This is beneficial for equipment that can not be modified to use the flange mounted approach.

Again, the enclosure is supported by bungee cords, attached to the pan, and includes glove sleeves for access to the equipment. The enclosure "moves" with the operator, as is the case with all of our flexible enclosure systems, to maximize ergonomics as noted above.

Pan Mount Style

FEATURES

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

BENEFITS

- Provides the lowest overall cost of process ownership through low capital and operating cost including reduced cleaning and cleaning validation
- Fastest turnaround of a processing suite for subsequent manufacturing campaigns
- Process is contained without contamination of motor, drive shaft, and controls with flange mount design
- Nanogram containment levels achieved
- Supports visibility for maintenance
- Does not affect ATEX and Ex ratings
- Ergonomics maximized
- Speed of implementation

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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.

OEB 1	OEB 2	OEB 3		OEB 4	OEB 5	
10,000 to 1000	1,000 to 100	100 to 50	50 to 10	10 to 1	1 to 0.1	0.1 to 0.01

Occupational Exposure Levels above are in µg/m3.

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.

Tools such as Lean Manufacturing come into play more and more. For example, the time to clean and validate the cleaning are major bottlenecks for processing efficiencies in the plant. Being able to minimize this part of the process results in getting products to market faster and at an overall reduction in operating costs when considering labor, utilities, and waste disposal costs. It also supports getting multiple products to market faster within an existing facility without risking product safety.

Since 1947, ILC Dover has built a global reputation for out-of-the-box thinking that makes the seemingly impossible possible. Our engineered solutions solve our customers' most complex challenges through the creative and efficient application of flexible materials often integrated with advanced equipment and hardware.

We look beyond the boundaries of convention to help customers see what could be. Every day, everything we do brings new solutions to light. Are you ready to take your vision beyond boundaries? *Let's talk.*

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