Achieving Contained (Dust-Free) Milling

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Abstract

Implementing a closed system for handling material with strict OEL/OEB requirements is becoming a growing challenge for pharmaceutical manufacturers. This article outlines the challenges and offers real-world solutions for achieving genuine contained milling.

While there are numerous methods to achieve containment, this article will primarily focus on:

> container-to-container milling,
> in-line vacuum transfer,
> milling inside an isolator.

Introduction

The increasing use of high-potency APIs has led to a need for total process containment (including dust-free milling). Ingredients are often hazardous and can be dangerous to both the environment and personnel if mishandled – this is a particular concern during milling, a process often associated with dust generation.

To protect both the operator and the process environment, it is important to consider how to overcome this problem, preferably without restricting throughput.

Container-to-Container Milling

This solution uses the principle of gravity to feed product through the mill. By positioning a container or IBC above the mill, and another container below the mill, product is released from the top container through a split butterfly valve, milled, and then passes directly through a split butterfly valve into the bottom container, as shown in Figure 1. This process configuration is best achieved by utilising a hoist to position the top IBC and allows for easy and repeatable handling. This keeps the product contained without affecting throughput.

Figure 1: Conical mill with high containment split valves installed on inlet / outlet

Containment: with dust-tight transfer between the bins, the powder flows down using gravity. This keeps the process in-line and protects the operator from exposure to the product. To allow for the displacement of air during the transfer process the lower container must be fitted with a vent-filter.

Throughput: the in-line nature of the process is optimal and compact, and while this system will not compete with the speed of transfer achieved using vacuum, the ease of bin changeover (either feeding drum or receiving drum) can offer capacity advantages over existing process methods.

This creates a totally contained, in-line solution for dust-free milling. Not only does this contain the product during the milling phase, but this is also a simple and effective method for transferring product from bin-to-bin and cone milling the product during transfer, thus avoiding double-handling.

In-Line Vacuum Transfer

Integrating vacuum transfer with milling offers a variety of benefits. Not only does this method keep the powder fully contained, it also increases throughput, keeps the product cool and enables faster transfer to the downstream process.

Containment: the dust-tight transfer method ensures the powder is contained within the system. This protects the operator from exposure to the product, while minimising waste by preventing spillage.

Increased throughput: rather than relying on gravity, in-line vacuum transfer actually pulls the product through the mill. This can dramatically increase the feed rate of the mill and help to boost throughput.

Keeps the product cool: as the air used to transfer the product passes through the machine housing, this will help to keep the internal components of the mill and product itself cool. Reduced processing temperature helps to prevent caking and unwanted changes to the material characteristics.

Faster transfer to downstream process: by using the system to manipulate the transfer process, the product can be easily transferred to a downstream process. This helps to transform dual-stage processes into a single process, by eliminating unnecessary storage and transportation. For example, the product can be transferred from the drum through the mill and directly into the receiving IBC.

Feeding and discharging from a cone mill using vacuum is a particularly effective method for achieving dust-free milling. Using an in-line vacuum transfer system (such as the Hanningfield Uni-Vac) offers a variety of benefits, enabling the material to be automatically fed into the inlet chute and automatically drawn from the outlet of the mill (to a downstream process). This ensures that from pick-up to discharge, the system is fast and fully contained.

Alternatively, instead of vacuum transfer through the mill, the vacuum hopper can be situated on top of the mill to discharge directly into the inlet.

Isolator Milling

Another method for containing powder during milling is the use of an isolator or ‘glove-box’ to ensure all excess material remains contained. This ensures the fine dust particles are not exposed to either the atmosphere or operator during processing.

Cone mill integration within the isolator is performed by means of a through-the-wall fixing flange. This fixing flange and particular configuration of the cone mill allow for a physical division of the cone mill head from the technical area that is left outside the isolator. Thanks to this special configuration, all cone mill cleaning operations are performed within the isolator by means of gloves or half-suit, reducing any risk of exposure for the operator and avoiding any transport to the cleaning room.

Figure 2: Isolator milling - the milling head is contained within the isolator, with the motor and controls mounted externally

Containment: an isolator is one of the most widely recognised and widely adopted means of containment. Indeed, the raison purpose of the isolator is to prevent exposure, with typical operator exposure levels of < 0.1 µg/m3.

Throughput: at first thought, the isolator may represent an obstacle to increased throughput. However, by minimising the need for operator suiting or cumbersome containment, the purpose-built nature of the isolator provides a safe and ergonomic method for milling.

Another benefit of isolator milling is for achieving a zoned area such as ATEX. The isolator itself can be designed to create an ATEX environment for milling, ensuring the entire process environment (including motors and controls) do not need to be changed to comply with the necessary requirements.

Conclusion

In a modern process, containing dust is extremely important. This can be easily achieved during the cone milling stage, simply by employing one of the methods listed above. Each solution will be more or less suited to any particular application.