

Vacuum Conveying for Continuous Manufacturing

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In its draft Guidance Quality Considerations for Continuous Manufacturing: Guidance for Industry, the FDA stated that “adopting continuous manufacturing for pharmaceutical production will reduce drug product quality issues, lower manufacturing costs, and improve the availability of quality medicines to patients [1].” The widespread use and demonstrated success of vacuum conveying systems in many other industries that employ continuous manufacturing methods may have contributed to these expectations.

The Guidance defines continuous manufacturing (CM), as “an integrated process that consists of a series of two or more unit operations (the system) [2].” In such a process, “the input material(s) are continuously fed into and transformed within the process, and the processed output materials are continuously removed from the system [2].”

The definition of continuous systems in the Guidance also distinguishes between an end-to-end approach, where “the drug substance and the drug product process steps are fully integrated into a single continuous process and there is no isolated drug substance or intermediate,” and a hybrid approach where a “combination of batch and continuous process steps are used for drug substance or drug product manufacture [2].”

Vacuum conveying systems

A standard vacuum conveying system consists of five pieces that work as one: a pickup point, conveying line tubing, a vacuum receiver, a vacuum producer, and a control module.

The most basic vacuum conveying system is a timed system, consisting of two basic cycles: a conveying cycle and a discharge cycle. The control panel, which often works in concert with some type of level control, dictates the amount of time that the system conveys material to the vacuum receiver and then how long the discharge valves are open to drop the material into other equipment or intermediate vessels.



Continuous vacuum conveying of pharmaceutical powders to capsule filling machine.

Vacuum conveying lines can be routed between floors, through partitions, and around machinery and can easily accommodate process modifications through rerouting.

Hybrid approach

Hybrid CM systems are often pre-engineered to be integrated with a specific unit operation, such as blending, mixing, tablet compression, capsule filling, or packaging. This makes the material handling continuous within a specific unit operation, but the unit operations themselves are still separate. Turnkey pre-engineered packages offer an affordable path to eliminate open handling and manual operations that can release fugitive dust into the environment. Fugitive dusts can negatively affect workers' health, contaminate product, and pose combustible dust hazards.

End-to-end approach

In end-to-end CM, vacuum conveying equipment facilitates integration between unit operations, removing materials from one operation and feeding them to the next, using modern computerized technology with pneumatic design.

A fully customized vacuum conveying system completely integrates the system, where the discharge point from one unit becomes the pick-up point for the next. These types of sophisticated systems, which include multi-ingredient handling systems, are custom engineered to suit customers' unique manufacturing processes.

FDA approval

Recognizing that manual material handling can have negative effects on drug product quality, the FDA redefined the types of manufacturing changes that need supplemental FDA approval, making it easier for drug manufacturers to adopt newer, automated technologies by simply requiring changes to be documented in annual reports. Appendix A of CMC Post-Approval Manufacturing Changes to be Documented in Annual Reports asserts that a "decrease in the number of open handling steps or manual operation procedures, when it reduces risk to product and there is no other change to the process [3]..." has "a minimal potential to have an adverse effect on product quality [4]."

The same ideal also appears in Scale Up and Post Approval Changes (SUPAC)-IR, indicating that, "(a) change from non-automated or non-mechanical equipment to automated or mechanical equipment to move ingredients [5]," is a Level 1 change "unlikely to have any detectable impact on formulation quality and performance [6]."

These changes make it easier for drug manufacturers to automate processes with ready-to-operate pre-engineered vacuum conveyors for pharmaceutical applications such as soft-gel and capsule conveyors, tablet press loading conveyors, and direct-charge blender loading.

Whether you require a fully automated, customized system for CM or a general-duty or application-specific pre-engineered system, an experienced and knowledgeable vacuum conveying system supplier can help ensure that your equipment design aligns with FDA guidelines for pharmaceutical manufacture.



Sanitary vacuum receivers for continuous vacuum conveying of pharmaceutical powders to capsule filling machines, packaging machines, and tablet presses.

References

FDA draft Guidance, Quality Considerations for Continuous Manufacturing February 2019: Background, page 2.

FDA draft Guidance, Quality Considerations for Continuous Manufacturing February 2019: Definition of continuous manufacturing, page 22.

FDA Guidance, CMC Post-Approval Manufacturing Changes to be Documented in Annual Reports: Appendix A, section 3.6, page 9.

FDA Guidance, CMC Post-Approval Manufacturing Changes to be Documented in Annual Reports: Discussion, pg 3.

FDA Guidance, Scale Up and Post Approval Changes (SUPAC)-IR: Immediate Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation Manufacturing: Equipment, Level 1 Changes, Definition of Change, pg 18.

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