

# Using vacuum pneumatic conveying to improve pharmaceutical processing

Doan Pendleton    Vac-U-Max

The FDA has eased the way for pharmaceutical manufacturers to automate processing lines with safe, fast, and adaptable vacuum transfer equipment. This article discusses ways that vacuum technology can improve manufacturing processes for pharmaceuticals and other difficult-to-handle materials.

Vacuum pneumatic conveying systems can improve pharmaceutical manufacturing processes in many ways. Vacuum pneumatic conveying provides safe transfer of bulk dry materials and can help maintain tight industry standards for sanitation and environmental safety. Compared to manual transport and loading, a vacuum conveyor can reduce safety hazards, increase the speed at which a processing line operates, and streamline production through automation.

A basic vacuum pneumatic conveying system consists of a powerful vacuum producer, a high-efficiency filter, and a conveying line (or piping). In operation, the vacuum producer generates an airstream inside the piping that carries material from one point in the plant to another. When the material reaches its destination, the high-efficiency filter separates any remaining airborne particles from the airstream, preventing them from reaching the vacuum producer and escaping into the workspace.

Material can be conveyed using either dilute-phase or dense-phase conveying. In dilute-phase conveying, the material is entrained in the airstream and the air-to-material ratio is high. In dense-phase conveying, the material is transferred in slugs within the piping. Since the material moves slower in dense than in dilute phase, dense conveying is an excellent choice for friable materials or a blend of powders.

While each application is unique, vacuum conveying systems are generally built using standard components

and customized according to need by conveyor manufacturers that have fabricating capabilities.

## FDA regulation and guidance

The use of vacuum conveying in pharmaceutical manufacturing has increased in recent years due, in part, to ongoing support, guidance, and clarifications from the FDA. The FDA oversees pharmaceutical manufacturing practices, in part, by requiring that the agency be notified of various levels of equipment, technology, and process changes. FDA regulations and guidances have made it easier for pharmaceutical processors to implement new production technologies by documenting the changes in annual reports rather than in time-consuming supplements.

According to the FDA, implementing material handling equipment technology, such as a pneumatic conveyor, is a level-one change that now requires submitting documentation with annual reports. The language discussing these changes varies from document to document, but all documents indicate that automated material transfer is the preferred method to deliver bulk powders and solids in a pharmaceutical environment. This is because vacuum



**Implementing material handling equipment technology, such as a pneumatic conveying system (pictured), is a level-one change that simply requires submitting documentation with annual reports according to FDA regulations and guidances.**

conveying equipment is unlikely to have an adverse effect on product quality.

For example, Appendix A in the FDA's "CMC Post-Approval Manufacturing Changes to be Documented in Annual Reports"<sup>1</sup> states that a "decrease in the number of open handling steps or manual operation procedures" has "minimal potential to have an adverse effect on product quality." This correlates with the assertion in "Immediate Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, *In Vitro* Dissolution Testing, and *In Vitro* Bioequivalence Documentation" that "change from non-automated or non-mechanical equipment to automated or mechanical equipment to move ingredients" is "unlikely to have any detectable impact on formulation quality and performance."

This FDA guidance opened the door for pharmaceutical companies to make changes that increased production and protected products and workers. However, because vacuum conveyors operate in semi-continuous and continuous cycles, there was still confusion about how vacuum systems operating in these modes coincided with batch processing and how this apparent conflict between continuous and batch processing fit into the reporting changes.

In some industries, the term "continuous" means operating 24 hours per day, seven days per week and shutting down only once or twice per year. In other industries, it can mean something different, since the idea of continuous processing is associated with a specific mode of manufacturing. To get away from the definition of a batch being tied to the manufacturing mode, the FDA changed the definition of batch in CFR Title 21 210.3(b)(2) to read:

*"Batch means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture."*

This single-cycle batch process can be continuous or semi-continuous depending on the level of automation employed. Vacuum conveying is at the center of many continuous processes, moving dry bulk materials from one processing machine to the next, including mixers and reactors, hammermills, tablet presses, and gel cap and packaging machinery.

While it's possible to completely automate drug manufacturing with sophisticated equipment that requires very little human intervention, fully automated systems require a complete system

overhaul, which can be costly and shut down production for a long period of time. Instead, many drug manufacturers are investing in versatile vacuum pneumatic conveyors that are easy to integrate into existing processes by routing conveying lines between floors, through partitions, and around machinery and can be easily rerouted to accommodate process modifications. These systems are cleaner, safer, more accurate, and more cost effective than manual material handling methods but more practical and affordable than completely automated processes.

The benefits of vacuum equipment include dust containment, ergonomics, segregation prevention, decreased downtime for loading, prevention of material spills and mishandling, and increased throughput.

### Dust containment

Dust containment is one of the principal reasons manufacturers add vacuum pneumatic conveyors to production lines because manually dumping material creates small clouds of fugitive dust with each scoop. Fugitive dust, or particulate matter (PM), is any solid or liquid suspended in the air through wind or human interaction. While half of all fugitive dust particles are greater than 10 microns (a human hair is 70 microns) and settle on surfaces rather quickly, the other half are



**Vacuum transfer systems have virtually no moving parts and can gently transfer pharmaceutical ingredients using mass flow, preventing segregation.**

smaller than 10 microns (not visible to the naked eye) and can remain suspended in the air for days or weeks. Fugitive dust can endanger worker health, settle on equipment and surfaces, and pose cross-contamination risks and explosion hazards. A vacuum pneumatic conveying system prevents these hazards by containing the dust and preventing it from escaping into the workspace.

For transferring ingredients that require higher levels of containment to protect worker health, conveyor equipment design requires additional scrutiny to minimize exposure. A vacuum conveyor's airstream cycles through filters before being exhausted. Using HEPA filtration for exhaust air can offer some additional degree of safety.

### Ergonomics

In addition to providing a safer environment through dust containment, automatic feeding of hammermills, mixers, reactors, and other processing equipment can help eliminate possible ergonomic issues that occur with repetitive motion, lifting, and climbing to manually dump material into feeders.

Employing automated or semi-automated pneumatic conveying systems to deliver material to and from a



**Vacuum transfer can be an efficient, dust-free way to move materials particularly in direct charge blender loading applications where the vacuum-tight process vessel becomes the primary receiver for the material being charged to it.**

hammermill, for example, can eliminate the need for workers to climb stairs or haul heavy containers of material away from the hammermill, alleviating fall hazards and repetitive motion injuries. In addition to reducing costly safety hazards, a pneumatic system may allow you to redeploy workers more economically because only one person needs to monitor the operation.

A manufacturer paying \$250,000 per year in disability suits from manual-transfer-related injuries can produce almost instant ROI, depending upon the level of automation added to the process, by investing in vacuum conveying equipment.

### Segregation prevention

Segregation, the separation of a material's particles by size, shape, density, or other characteristic, is a major concern in pharmaceutical applications, especially during manual transfer of materials in containers and from machine to machine throughout the production process. The vibration caused by moving containers promotes segregation and threatens the quality of the batch.

For this reason, pharmaceutical manufacturers primarily use mass flow methods that move all particles at the same velocity to minimize segregation. Vacuum transfer systems, with virtually no moving parts, can gently transfer pharmaceutical ingredients using mass flow.

### Decreased downtime for loading

Blenders, mixers, reactors, and other types of pharmaceutical equipment require either a mezzanine level for manual loading or specialized equipment such as drum loaders or vacuum conveyors for automatic loading. Although a drum loader is more efficient than manual loading, the ability to load only one drum at a time makes the material delivery to the blender or reactor time-consuming. In some circumstances, it may also be necessary to load multiple ingredients into drums prior to loading the blender or reactor, further slowing the process.

Packaged pneumatic conveying systems designed specifically for direct charge loading of blenders can help speed up the loading process. With a drug processor's blender or mixer as the primary receiver, the conveyor manufacturer provides the rest of the system, including the power source, filters, controls, and adapters.

Systems should be configured specifically for each application and designed to significantly reduce the amount of carryover, eliminating material loss and

ensuring batch integrity. Carryover is the amount of material collected in the filter that separates the conveying air from the material (dust) inside the vessel to prevent material from reaching the vacuum pump during the loading process.

A standing pneumatic conveying unit is readily accessible for cleaning and can be equipped with casters, allowing the unit to service more than one blender. In addition, once the blender is loaded and equalized, carryover releases into an airtight vessel allowing for reuse or safe disposal.

With a suspended pneumatic conveying unit, once the blender is loaded and equalized, material automatically discharges back into the blender, eliminating the need to handle material manually.

Both standing and suspended units are easy to take apart without tools, so clean-up between batches and different materials takes less than an hour. Standard maintenance includes washing down equipment and changing out bags, filters, and hoses (when using different hoses for each material).

### **Prevention of material spills and mishandling**

Manually scooping blended formulations into tablet presses can cause messy spills or mishandling. Fully enclosed tablet press loading systems protect the product from air, dirt, and waste contamination. Vacuum tablet press loading systems are turnkey systems for mounting on customers' presses and are available for single or dual hopper tablet presses — and the construction of the equipment is USDA-approved.

These systems automatically convey tablet granulations from drums or other containers or equipment to surge bins mounted above tablet presses. A tube-hopper material receiver with vertical sides to minimize material hang-up is located above each surge bin, and a control panel and vacuum pump are located in an adjacent room. A single vacuum pump provides the vacuum for all the material receivers above the tablet presses.

### **Increased throughput**

A gel cap conveyor, designed to deliver gel caps, soft gels, or tablets from inspection machines to packaging lines or gel caps to filling machines, is another type of turnkey vacuum conveyor for pharmaceutical processors. These systems can transfer 500 to 1,000 pounds per hour (approximately 2,500 units per minute), increasing product throughput compared to manual transfer.

Pneumatically transferring delicate gel caps requires great care to protect product integrity, especially since gel cap manufacturing can be an expensive process. Also, when pneumatically transferring gel caps, the capsules can sound like little bullets when they hit the side of the hopper, creating additional noise in a facility. To combat this, new tangential inlets can be used to reduce the noise and protect the delicate capsules from damage. **PBE**

### **Reference**

1. Visit [www.fda.gov](http://www.fda.gov) for more information on the regulations and guidances mentioned in this article.

### **For further reading**

Find more information on this topic in articles listed under “Pneumatic conveying” in *Powder and Bulk Engineering*'s comprehensive article index in the December 2017 issue or the Article Archive on *PBE*'s website, [www.powderbulk.com](http://www.powderbulk.com). (All articles listed in the archive are available for free download to registered users.)

---

*Doan Pendleton (doanpendelton@vac-u-max.net, 973-759-4600) is the vice president at Vac-U-Max. He is an expert in vacuum technology with nearly 30 years of experience designing and engineering vacuum conveying systems and industrial vacuum cleaners.*

**Vac-U-Max**

**Belleville, NJ**

**800-822-8629**

**[www.vac-u-max.com](http://www.vac-u-max.com)**