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TECHNICAL ARTICLE PHARMACEUTICAL-GRADE FEEDER

Metering dry powders in the pharmaceutical industry is not a new idea. Several common applications have been using gravimetric and volumetric dry material feeders for many years. Until recently, these feeders were customized versions of industrial or food-grade equipment or one-off-type machines engineered for a specific application. Driven by increasing demand, an equipment manufacturer embarked on an effort to create a standard dry material feeder engineered to meet the pharmaceutical industry's needs.

As part of this process, common pharmaceutical applications using feeders were identified: milling/particle size reduction; mix tank and reactor charging; mixing; pharmaceutical-grade plastics extrusion; tablet coating; interprocess packaging; and continuous granulation.

Once the applications were identified, a multifunctional research and design team interviewed technical people from companies that built equipment specifically for the pharmaceutical industry as well as companies that built equipment specifically for the pharmaceutical industry as well as companies that would use the equipment in their own production efforts. This research was conducted in North America and Europe to provide a global picture of the requirements for the product.

Many design hurdles were discovered during the interviews and review of feeding equipment requirements for these applications. The hurdles were made even more complicated by the fact that there were no widely accepted industry standards for the manufacturing of processing equipment. Each manufacturer and end user held different standards important.

The major criteria addressed during design included: equipment capacities and rates; Food and Drug Administration (FDA)- approved materials of construction; surface finishes of welds and metals used in fabrication; cleaning processes used on the equipment during production including frequent assembly and disassembly; validations; and feeding accuracy. The following paragraphs elaborate on the various design criteria for the equipment.

Equipment Capacities and Rates

During interviews, the research and design team studied capacities of typical downstream processing equipment that would be paired with the dry material feeder. Based on the most common sizes of these machines, two distinct application feed rate ranges were determined: 20 g/hr to 2,000 g/hr and 0.5 kg/hr to 150 kg/hr.

These ranges were used to determine the appropriate size and design of equipment. For the purpose of this article, we will review the design process for the machine at the higher range of 0.5 kg/hr to 150 kg/hr.

FDA-Approved Materials of Construction

The interviews determined that #316 stainless steel is a preferred material for equipment in the pharmaceutical industry because of its corrosion, chemical, and thermal resistance. Ethylene-propylene-diene-monomer (EPDM) was found to be a widely accepted polymer used for components that have to be elastic, nonporous, and FDA complaint.

The design team worked with various suppliers and molders of EPDM to adapt the polymer for use in the flexible hopper. Flexibility and temperature resistance made it ideal for this application. Additionally, the cost-effective nature of the flexible hopper allows it to be used as a disposable component compared with the higher cost of a typical cleaning operation.

Other nonmetal materials of construction include polytetrafluoroethylene, polyethylene terephthalate, and nylon. Even though the proper selection of construction materials is essential, geometry and surface finish are no less important when designing a pharmaceutical-grade machine.

A dry bulk solids feeder specifically designed for pharmaceutical manufacturing processes.

Welding, Surface Finishes, and General Design Used in Fabrication

Existing experience from food and dairy feeding applications dictated that all welds must be continuous nonporous, and without cracks or undercuts to ensure the machine can be easily cleaned. Using larger surfaces rather than complex designs with undercuts allows easy access for cleaning and maintenance. Additionally, larger, smooth surfaces help eliminate the potential for water or solvent to remain in crevices.

Studies indicated 32 microinch roughness average (Ra) was a widely accepted surface finish; however, certain applications dictated finishes up to 16 microinch Ra. Consequently, standard configurations for 32 Ra and 16 Ra were developed.

If complex design cannot be avoided, then providing easy disassembly for cleaning purposes must be strongly considered. Examples include the use of stainless steel tri-clover-type clamps to secure the extension hopper and discharge nozzle as well as a continuously welded housing, agitation arm, and other peripheral components.

Cleaning Processes

Because product contamination from foreign particles must be strictly avoided, materials of construction have to withstand aggressive cleaning solutions and high temperatures to handle regular maintenance without deterioration or corrosion while maintaining FDA compliance.

Common sense dictates fewer components in the production contact zone will reduce cleaning efforts. External agitation of the material is a good example of this concept and was selected by the design team instead of internal agitation.

Validation

Because pharmaceutical companies are required to verify the product contact materials, it is essential for the manufacturer to keep accurate records of raw material certifications.

The manufacturer implemented procedures to procure raw materials with certification and track them through their plant and manufacturing process to guarantee proper material composition. A standard process was created to generate installation qualification/operational documentation for each individual feeder manufactured.

Feeding Accuracy

Pharmaceutical-grade feeders are often used to feed active pharmaceutical ingredients into a continuous process, so feeding accuracy is essential. Many of those ingredients have different flow behaviors including cohesive and adhesive properties making variable feeder settings advantageous.

The team created an agitation system enabling variable speed and penetration depth. These features allow the user to find the ideal setup for an optimal product flow into the discharge element.

Consistent helix filing is critical for good discharge behavior, resulting in precise accuracies. The control algorithm in gravimetric feeders allows for continual helix speed adjustments depending on the loss in weight over time, which again increases the feeding accuracy. The manufacturer's proven gravimetric control system was used to facilitate this functionality.

When feeding, cohesive materials like the ones typically found in the pharmaceutical industry, often result in an uneven discharge behavior. The material being fed drops off in lumps instead of creating an even flow. One way to prevent this behavior is a screened discharge nozzle, which breaks up agglomerations of bulk materials and produces a more uniform product flow.

The design team gave special considerations for the design of a screened discharge nozzle used to facilitate disassembly and cleaning.

Conclusion

When designing or specifying a pharmaceutical feeder or feeding system, considering basic principles, materials being fed, cleaning processes used, and FDA requirements are important. Implementing a properly designed feeder into your process can save time and reduce overall manufacturing costs.

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