Improving Throughput in Packaging of Aseptic Pharmaceutical Syringes

From filling through end-of-line cartoning, the latest improvements in conveyor systems for the packaging of aseptic pharmaceutical syringes integrate automation and devices speed throughput, increase packaging flexibility, and minimize product damage while maintaining industry standards for cleanliness and sterility.

by Robyn Schmitt

The packaging needs for pharmaceutical liquids are quite demanding. For aseptic filling of syringes, the package must be produced, stored, filled, and sealed under conditions that preserve sterility. Glass, although a standard in the aseptic pharmaceutical liquids industry, is not without its limitations. Glass vials are subject to breakage throughout filling and packaging.

Injectables, ophthalmics, biologicals, and vaccines are produced in a number of different types of glass containers including bottles, vials, and ampoules. Protecting the contents of these aseptic liquid drugs through filling and packaging is a critical objective for pharmaceutical producers. Raw materials, in-process fillers and packaging systems, and finished products are continually checked.

Traditional aseptic processing allows a final sterile drug product to be achieved by individually sterilizing the containers, material, and in some cases the equipment in-process, resulting in a unified sterilized product. The processing handles components, materials, and equipment in such a manner that foreign microbial and endotoxin contaminents that exceed predetermined acceptable levels are not introduced to the product stream. To this end, it is critical that all storage, conveying, filling, and container sealing stages be carefully controlled at each step of the process to maintain product sterility.

FDA's 2004 Guidance for Industry Sterile Drug Products Produced by Aseptic Processing states that the design of equipment used in aseptic processing product flow should be optimized to reduce the potential for introducing contaminants to exposed products, container-closures, and the surrounding environment. Achieving this sterility, however, without throughput slow-downs can be a challenge. Inadequate material handling systems that are not specifically designed for the movement of single-dose, glass syringes can cause product damage that can slow or stop a line.

To minimize the potential of system downtime, manufacturers are now relying on more specialized automated material-handling conveying systems to stabilize production throughput while maintaining product integrity and sterility.

CONVEYING SYRINGES

Moving single-dose syringes throughout a pharmaceutical filling and packaging line involves multiple sequential operations requiring precision and careful handling. Tubs and nests populated with between 100 and 160 hanging unit parenterals are typically utilized on open-center conveyor systems. These unfilled syringes are brought by conveyors into sterilizers and filler machines, then when filled and stoppered, the parenterals are conveyed for quality checking and onto end-of-line individual labeling, packaging, and cartoning where they are put into cardboard boxes or bagged as kits.

Pharmaceutical syringes must be conveyed to minimize product damage while maintaining industry standards for cleanliness and sterility.

For conveying systems handling these pharmaceutical syringes, significant challenges must be overcome to maintain product integrity and sterility without impeding throughput. Unfortunately, many manufacturers are plagued with material handling systems that are simply not adequately specialized for their needs. Some of the key material handling problems can have significant impact on their product quality and profitability, such as the following:

- **Inadequate product control on conveyors causing defects.** Material handling systems not designed specifically for handling syringes can cause product marring, defects, and breakage by not providing adequate product control while on the conveyor system. Conveyor designs that allow the product to come into contact with side rails, or fail to adjust adequately to velocity changes around curves, will inevitably introduce unnecessary random product movement on the conveyor, increasing the possibility of damage.
- **Reduced cleanliness from accumulation conveying.** When syringe tubs are in an accumulation mode on a belt or chain conveying system, the product may be stopped awaiting infeed for sterilization or filling, but the belts or chain are continuing to run underneath the tubs. These continually transfer potential contamination particles such as dirt, dust, and lubricants used on these systems.
- **Top- and side-mounted conveyor devices can impact product contamination.** Many conveyors enable the adaption of product control devices such as product stops, pushers, and clamps that can be used to modify the flow of product. Most conveyors bring these devices in from the side or even over the top, such as would be found on belt conveyors, plastic link conveyors, or table-top chain conveyors. Side-mounted devices are limited in their flexibility to control product flow because of their side-only mounting locations, and top-mounted devices are considered even less desirable because of safety and contamination concerns.
- **Rough product handling prompting rejects.** One critical aspect in this conveying process is gentle syringe handling. Aside from the obvious glass breakage potential, filled parenterals can generate microbubbles after filling if moved too roughly through the line. Microbubbles will scatter light similar to particulate in suspension when checked with a laser inspection system and will trigger a product rejection even though there is no particulate in the syringe's liquid. Consequently, potentially good product is being disqualified as contaminated, which directly impacts profitability.

SPECIALIZED CONVEYORS FOR SYRINGES

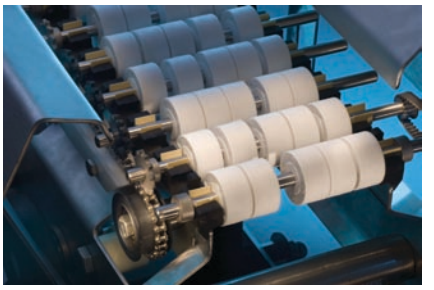
Pharmaceutical syringe handling requires specialized conveyor system applications to keep these products moving through the packaging line smoothly and safely without these difficulties. Several conveyor systems engineered specifically for handling pharmaceutical liquids and particularly syringes have been developed. These systems incorporate some of the latest in smart automation and devices that can streamline any syringe packaging line into high efficiency. One is Slip-Torque technology developed by Shuttleworth Inc., a division of Pro Mach.

Slip-Torque technology can minimize product damage through its low back-pressure accumulation system. The system provides low line-pressure throughout a continuous-motion accumulation conveyor that allows for precise product placement on the conveyor while it continues to take product flow from an upstream line for a period of time, where other convey-

ors would have stopped well before. A low-pressure accumulation buffer absorbs irregularities in the production flow and provides a smooth, even flow on the line. Minimizing line stoppages significantly decreases opportunities for damage. By allowing the process to continue as close as possible to a steady state condition increases line efficiency and throughput.

Slip-Torque utilizes individually powered, stationary rotating roller shafts covered with loose, segmented rollers, which become the conveyor surface. It is powered by a continuous chain to provide the drive force to convey the product. When the syringes stop on the surface of the conveyor, the segmented rollers beneath them also stop, generating low back-pressure accumulation, while minimizing vibration, contaminant transference, abrasion, and product damage. It is the weight of the product being conveyed combined with the coefficient of friction between the shafts and the inside diameter of the rollers that provides the driving force. As the weight of the product increases, there is a corresponding increase in the driving force supplied.

The system allows the same conveyor to be split into multiple, independently-operating lanes if desired. Each lane can act independently, but is powered by only one common motor, reducing energy costs. "Slip-Torque conveyors have the ability to modulate the speed of different sections of the conveyor via a central control PLC and HMI," says Todd Eckert, product manager, Shuttleworth. "As syringes move down the line, the rollers at the back end of the conveyor can be moving faster than the ones at the front end of it. The products can be moving at variable speeds on different sections of the conveyor as dictated by throughput requirements. This controls the product spacing on the conveyor, keeping the syringes and tubs separated and equally spaced from each other to minimize product contact and facilitate infeed into sterilizers, fillers, and wrappers."



For pharmaceutical processing, Slip-Trak conveyors are suitable for Class 10 (per Federal Standard 209E) cleanrooms. The drive components are fully enclosed in an evacuation chamber to eliminate airborne particulate contamination.

Such motorized rollers like Slip-Torque can also be used to minimize product contact while steering syringe tubs with uneven bottoms into desired

locations. Motorized rollers with tapered corners can maintain product orientation through 45° and 90° conveyor turns.

For pharmaceutical processing, a variation of Slip-Torque called Slip-Trak is suitable for Class 10 (per Federal Standard 209E) cleanrooms. Drive components are fully enclosed in an evacuation chamber to eliminate airborne particulates.

Flexible control devices can also provide enhanced syringe movement. More advanced conveyor designs for syringe handling utilize spaces between rollers to allow product steering devices to be mounted below the surface, reaching up between the rollers to effect more precise and flexible product motion control without interfering with the line flow.

Motion control devices can now be more specifically located on pharmaceutical conveyors compared to conventional systems, bringing a much higher level of positioning accuracy (and more positive product handling for less product defects) to the syringe conveying process. Devices like: a) blade stops and brakes that enable on-demand stops and starts of production flow; b) lift-and-transfer, lift-and-rotate, side transfer and turntable devices used to provide a smooth and accurate product transfer at a 90-degree angle to the original transport direction or to change the orientation of products on the conveyor; c) product positioners to accurately position syringes for a particular process; d) pushers to push syringe tubs perpendicular from one conveyor traffic lane to another traveling in the same or the opposite direction into or out of operator workstations or off of the conveyor system completely; and, e) single-row combiners to combine lanes into one single row.

Zone-controlled accumulation for fragile syringes is designed to be compatible with Class 1 (per Federal Standard 209E) cleanroom standards. It is an electronically controlled accumulation conveyor line of modules suited to applications requiring no product-to-product contact. The system is fabricated of ultra clean, non-outgassing components and materials. Every roller on both sides of the conveyor is positively driven. This double-sided positive drive limits product crabbing or skewing, even with distorted syringe tubs. The zoned rollers are active only on demand—when the syringes leave a zone, all rollers turn off. The independent modules allow for easy installation in new or reconfigured syringe material handling lines.

Traditional flat-belt conveyor systems are now giving way to solid-faced rollers for liquid pharmaceutical applications. With no return loop (as found on flat-belt conveyors) there is little or no chance of carrying contamination throughout the system.

IMPROVING PRODUCT INTEGRITY

The automated conveyor systems now available for handling syringes allow a much needed improvement in streamlined throughput and packaging capability. Those pharmaceutical manufacturers that endeavor to make the upgrade to these systems will find reduced product defects, a higher level of product quality, and a more efficiently run and profitable plant.

Robyn Schmitt writes on automation technology.