

Pharma-Trends: **Safety**



Safety is a key driver in the pharma industry, both from the perspective of an end-user patient as well as from an operational standpoint.



This article is the second in a series of articles examining the role packaging will play in the key trends impacting the pharma industry. Next issue, our final article will cover automation and efficiency.

Pharmaceuticals, such as oncology drugs, biopharmaceuticals and vaccines are all growth markets, but they also possess highly volatile properties. Cytotoxic agents and hormones have a higher risk of cross-contamination from harmful dust exposure during processing. In addition, certain formulations require minimal doses due to high potency levels. In light of these facts, automation is a key requirement in processing, in that it both protects workers and ensures reproducible, accurate dosage.

Automation and safety technologies made by Bosch

To prevent exposure to harmful products, Bosch has developed automation and safety technologies that can protect operators, such as barrier technology for aseptic filling lines, isolators and containment technology. These technologies have gained wider acceptance in order to meet the demands of the growth markets. In addition, FDA guidelines for aseptic manufacturing strongly recommend their use.

The industry is rapidly adopting isolators and restricted access barrier systems (*RABS*) because verification technologies are much improved. Again, integration in this realm can be key. An integrated isolator and filler offers advantages over two components from two suppliers. In this type of system, controls are integrated, as is the knowledge base behind the system.

Bosch has met this demand with the *GKF HiProTect* capsule filling system. *HiProTect* is a modular capsule filling line with integrated isolators, as well as an automated self-cleaning system. The unit also offers flexibility to expand into liquid capsules for more accurate dosing. Accurate dosing, for obvious health reasons, is also an urgent matter being addressed with greater automation.

High efficiency and quality assurance

To increase accuracy, many of Bosch's packaging and processing applications integrate Process Analytical Technology (PAT). PAT is the FDA's risk-based approach, which enables high efficiency and quality assurance in pharmaceutical manufacturing by introducing inspection and controlling systems throughout the entire process.

Bosch offers equipment that provides in-line analysis and control of critical parameters for filling capsules and liquid pharmaceutical products. For example,

the solid capsule filling process's quality parameters can be monitored and controlled, and capsules of a sub-standard quality can be identified and eliminated. Compressed air and vacuum-monitoring units constantly check operating pressure and stop the system before malfunctions arise. Problems are not just identified; they are fixed along the way in a closed loop, which identifies faults before they can reduce downtime.

These examples of increased automation in the production of pharmaceuticals are vital, not just for operational efficiency but to serve the needs of the growing markets for highly targeted and highly potent treatments.

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