

Putting the Pedal to the Metal in Pharmaceutical Manufacturing

PMMI

The United States is the largest manufacturer and exporter of pharmaceuticals and has the highest volume of pharmaceutical consumers on the planet (*BusinessVibes*, Industry Factsheet). Consistent with the level of demand, in 2012, the U.S. Food & Drug Administration approved 39 new drugs – the most in a single year since 1996 (*Reuters*, “FDA New Drug approvals Hit 16-year high in 2012”). The new drugs have included game-changing treatments for cystic fibrosis, the first human cord blood product ever, the first treatments for advanced basal cell carcinoma (the most common skin cancer) and myelofibrosis (bone marrow disease). Even more new drugs are expected to be approved over the next few years and should add about \$100 billion to the pharmaceutical industry.

To remain competitive in the world’s busiest pharmaceutical market, manufacturers must increase their speed, running lines around-the-clock while continuing to adhere to stringent FDA regulations at the research and development, preclinical and clinical work phases. Advancements in equipment for material handling, process flow, automation, product inspection and form-fill-seal (FFS) have enabled manufacturers to speed production like never before while still meeting these rigorous standards.

Fast and Furious Technologies

When looking at the anatomy of a high-speed pharmaceutical line, there are many technologies that can push the limit of production. We’re seeing advancements in the handling of containers, which can cycle up to 400 units per minute containing various bottle shapes and sizes and simultaneous product labeling and packaging.

To help manufacturers rapidly implement new customer projects and streamline changeover efforts, FFS machinery has replaced the once-complex and time consuming manual filling and sealing steps, thus increasing the speed and capacity to which pharmaceutical manufacturers can deliver products. However, more recent developments in FFS extend the machine’s running time and reduce the time needed for die set changing and maintenance. Additional features include Ethernet capabilities for reporting machine status and tracking reliability metrics.

Product Safety Gets Precise

X-ray inspection systems are being integrated into the production line to ensure proper product position, detect seal imperfections and identify contaminants. Improved system hardware allows for inspection at speeds up to 700 feet per minute and also features check weighing capabilities.

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Published on Chem.Info (<http://www.chem.info>)

The technologies on these high-speed lines adhere with current FDA and European Medicines Agency (EMA) standards; like the FDA's Drug Quality and Security Act which looks to oversee small drug manufacturers in the compounding pharmaceutical industry and establish a national track-and-trace system. To further promote good manufacturing practices (GMP), lines can be outfitted with vision, coding and information technology software upgrades to meet serialization standards and the California e-pedigree law expected to be enacted in 2015. This law will require manufacturers to keep detailed electronic records of each transaction resulting in a change of ownership of a given drug to combat counterfeiting.

Pharma Continues to Forge Ahead

Flexible, high-speed production lines will ensure manufacturers can keep up with the demand and ingenuity of the pharmaceutical industry. Such innovations can be found at Pharma EXPO (November 2-5, 2014; McCormick Place, Chicago). Co-located with PACK EXPO International 2014 and produced by PMMI, The Association for Packaging and Processing Technologies, the owner and producer of the PACK EXPO trade shows, in partnership with the International Society for Pharmaceutical Engineering (ISPE), Pharma EXPO will offer packaging, processing and supply chain solutions for pharmaceutical, nutraceutical and medical product manufacturers — along with world-class education from ISPE. Innovations in track and trace, anti-counterfeiting, supply chain management, robotics and more will take center stage at Pharma EXPO.

Visit pharmaexpo.com [1] to learn more and sign-up to be notified when registration opens for the event.

Source URL (retrieved on 11/23/2014 - 2:35am):

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