

What you need to know about "Automation"

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Groundbreakers: Tomorrow's Drug Manufacturing Facilities

Modular construction and disposable process equipment are maximizing agility and minimizing risk

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Groundbreakers: Tomorrow's Drug Manufacturing Facilities

2012 marks what some analysts are already expecting to be the most challenging year in the pharmaceutical industry's history. As patent expirations and global competition step up, and the mantra changes from blockbuster to nichebuster, manufacturers are chipping away, wherever they can, at the years and millions of dollars required to launch each new product. If they must fail, more pharmaceutical manufacturers acknowledge, they'll need to fail fast and move on quickly.



Pharma's older infrastructure has not always allowed this to happen. Over the past few years, the pace of pharma plant consolidations and closures has increased. In the U.S. alone, 38 drug manufacturing facilities were shut down last year, and 65 the year before. However, 106 New Plants and laboratories, worth an estimated \$4.3 billion in contracts, are now planned or under construction



Biopharm companies will be increasing production capacity by 25%, globally, over the next few years. Biosimilars promise to intensify the competition, and companies are gearing up for production in flexible facilities throughout the world. Enabling pharma facilities' transformation are modular construction, which has been around for decades but is now possible in shippingcontainer-sized units, as well as disposable bioprocessing equipment, standardized solutions allowing for continuous operation and quick validation.



At the same time, modeling and simulation tools are becoming more important, particularly for training and startup, as are standard templates for IT and process control. For MedImmune's new biopharmaceutical manufacturing facility in Frederick, Maryland, which won ISPE's Facility of the Year competition last year, best IT and automation practices not always seen in traditional pharma led to improved results.



Some Topics

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Costs twice as much and takes twice as long as you think.

When automating processes, the inclination is to look at the big components like robots or electrical control systems, add up their costs, and then factor in some engineering hours. What is forgotten, however, are important items like light curtains, safety guarding, brackets, pneumatic valves, hoses, cables or rails to move the robot back and forth as well as the items that are required to make all components work together. Lead times on robots can be 16-18 weeks, with most lead times on major items averaging around 8 weeks. With the lead-time on components being so long, a project can take twice as long as you are anticipating it will.



A full automation effort will require maintenance and spare parts to sustain reliability and a high uptime.

All machines need to have routine preventative maintenance performed on them. Spare parts need to be maintained to replace those parts that wear out. Sensors and vision systems need to be adjusted and tightened back into place to maintain the reliability of the machine.



Technologies are constantly changing.

Just because you bought something 5 years ago, and it works well, it doesn't mean that it's still the best technology on the market. Think about how many updates and upgrades there are with the typical computer; there is always some upgrade or new version that makes it function better. The same holds true for automation, products are improving and new technologies are constantly emerging.

