Continuous Manufacturing Has a Strong Impact on Drug Quality

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If we used a time machine to transport a pharmaceutical scientist from the 1960s into a current pharmaceutical production plant of today, it might be surprising to learn that they would already be very familiar with most of the processes and production techniques being used. That's because not much has changed in pharmaceutical production over the last 50 or so years.

For decades, most drugs have been manufactured using what is known as "batch" technology — a process whereby the ultimate finished product has been made after many stops and starts in a series of steps. Unfortunately each break in the process causes inefficiency and delay, as well as the increased possibility of defects and error.

Today, a new and exciting technology — continuous manufacturing — enables much faster production and more reliable products through an uninterrupted process. How much faster is continuous manufacturing? In some cases, manufacturing that takes a month by batch technology might only take a day using continuous manufacturing techniques.

Of course, speed alone would not matter if continuous manufacturing compromised quality. But by eliminating breaks between steps and reducing opportunities for human errors during the stops and starts in the batch process, continuous manufacturing is more reliable — and safer. That's a powerful combination.

There's the added benefit that more efficient production of quality products can drive down manufacturing costs, possibly resulting in lower drug prices for consumers. Continuous manufacturing also allows manufacturers to respond much quicker to changes in demand, potentially contributing to prevention of drug shortages.

We are seeing a growing number of manufacturers working towards building continuous manufacturing into their processes. One manufacturer, Vertex, the maker of a cystic fibrosis drug

called Orkambi (lumacaftor/ivacaftor) has been using the continuous manufacturing process for this drug since its approval date in July 2015.

Last Friday marked another significant step towards integrating continuous manufacturing into pharmaceutical production. FDA approved, for the first time, a manufacturer's *change* in their production method from "batch" to continuous manufacturing. This new approval is for manufacturing Janssen Products, LP's, medication for the treatment of HIV-1 infection, Prezista (darunavir). The company's efforts in manufacturing advancement were facilitated by the use of FDA's recently-released draft guidance to industry titled, *Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base*, a product of the agency's Emerging Technology Team (ETT) designed to help manufacturers implement a variety of technological advancements.

Although it is not easy for drug manufacturers to transition from batch to continuous manufacturing, there are significant rewards. FDA encourages others in the pharmaceutical industry to consider similar efforts.

Progress comes at an opportune time. The medications we use are changing. We are entering an era of precision medicine, when drugs must be made with unique features and provided more quickly to patients in need. FDA will continue our efforts to encourage the advancement of continuous manufacturing as one of a variety of ways to enhance the quality of the medications used by the American public.

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