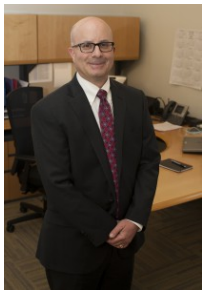
“Continuous Manufacturing” – Common Guiding Principles Can Help Ensure Progress

Posted on September 11, 2017 by FDA Voice

By: Michael Kopcha, Ph.D., R.Ph.

Today, a new and exciting technology – continuous manufacturing (CM) – can truly transform the drug manufacturing process so that it is more reliable and efficient. We discussed in a previous blog how CM enables a much faster and more reliable manufacturing process. In some cases, manufacturing that takes a month to complete with older technology — often called “batch” technology — might only take days using CM. FDA is seeking input, through a public docket open until September 21, from experts in the field about the science, technology, and best practices concerning CM.



As with any new technology, implementing CM presents challenges, such as the initial cost of investing in new equipment. However, the CM production method offers clear benefits for both patients and industry. CM can shorten production times and improve the efficiency of the manufacturing process. CM also allows for more nimble testing and control that can help reduce the likelihood of manufacturing failures. These control strategies could potentially contribute to the prevention of drug shortages. CM technology can be implemented for an entire production process, or for specific operations within the process. Manufacturers can tailor their use of CM based on their particular product and business needs.

Congress has recognized the potential benefits CM can offer for drug manufacturing as well. The 21st Century Cures Act, enacted in December 2016, authorized grants to support studying CM and recommending improvements to the process of continuous manufacturing of drugs and biological products.

FDA encourages adoption of this technology by engaging with firms interested in using CM. FDA’s Emerging Technology Team (ETT) assists companies that want to implement innovative technology, including CM, for manufacturing both new and existing drugs. We have already seen two companies that have implemented CM and benefited from early engagement with the ETT. Vertex has been using a CM process for their cystic fibrosis drug, Orkambi

(lumacaftor/ivacaftor), since its approval in July 2015. In 2016, FDA approved a change in production from batch to continuous manufacturing for Janssen Products' medication to treat HIV-1 infection, Prezista (darunavir).

With many companies now evaluating their operations for potential uses of CM, some have found specific ways to utilize CM techniques in their own production processes. As a result of these individual efforts, we now see a variety of different approaches for implementing CM technology throughout industry.

Given these emerging variations, FDA's goal is to provide a framework of principles that clarify our expectations, while still encouraging companies to innovate and implement CM. We are talking with industry and are also helping lead this conversation on a global level by engaging our foreign regulatory counterparts regarding the development of clear regulatory standards.

To further this effort and gather more input from experts, we have opened the public docket for comment until September 21. FDA is interested in getting public feedback on published documents on this topic, including an industry-coordinated best practices document issued by the public-private consortium Center for Structured Organic Particulate Systems (C-SOPS), and white papers from a 2014 symposium published in the Journal of Pharmaceutical Sciences.

If you have experience and expertise on CM, please submit your comments, which will help us to gather and consolidate the important scientific information being developed in this area.

Assuring the availability of quality, safe and effective medications to the American public is a priority for FDA. CM, and other innovative manufacturing and control strategies, offer ways for the pharmaceutical industry to continue to help support this goal. By drawing upon the experience of FDA, industry, and academia, we will develop common guiding principles to support implementation of CM, building on the great progress made by industry to date.

Michael Kopcha, Ph.D., R.Ph., is FDA's Director, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research