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# Drug Makers Receive FDA Guidance For Return-To-Normal Production Efforts

By **IVT Staff  Sep 16, 2020 7:00 am EDT**

New guidance for industry was just released in an effort to guide drug and biologic manufacturers as they begin to return to normal production efforts as we continue to navigate the COVID pandemic. Specifically, the guidance, "Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency," is meant to assist in the evaluation and prioritization of the renewal of CGMP activities delayed, reduced, or otherwise modified during the public health emergency, as a result of employee illness, site closures, travel restrictions and supply chain interruptions.

According to the FDA announcement the guidance provides recommendations to help manufacturers prioritize production of certain products, described as medically necessary products activities as they resume normal operations. A risk-based approach with a focus on the categories of drug which include, human drugs that are life-supporting, life-sustaining, intended for use in the prevention or treatment of a debilitating disease or condition (including any such drug used in emergency medical care or during surgery), or any such drug that is critical to the public health during a public health emergency.

Manufacturers of drugs and biologics whose production activities deviated from CGMP during the pandemic (based on temporary guidances issued during the pandemic, or otherwise) are expected to include an assessment of such actions as part of their risk management approach, according to the guidance. Manufacturers should give highest priority to those drugs or biologics that are in shortage, or that might be vulnerable to shortage.

The FDA also refers, for procedural purposes, to the guidance for industry "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products" issued in 2011, which encourages manufacturers of medically necessary drug products (MNPs) and components to develop production plans in the event of an emergency that results in high absenteeism at one or more production facilities. The purpose of the guidance is to provide to industry considerations for developing plans for these types of emergencies, as well as to discuss the Center for Drug Evaluation and Research's (CDER's) intended approach to assist in avoiding drug product shortages that may have a negative impact on the national public health during such emergencies. The newest guidance provides additional detail and COVID specific recommendations in order to maintain production and the drug supply.

There is a detailed list of areas and remediation examples provide in the document. Highlights include:

- Suggested line of questions for completing an investigation of unresolved discrepancies and deviations
- Guidelines for determining assessing whether additional measures are needed for a batch to determine suitability in the case of delayed or reduced testing
- Assessing whether additional measure are needed to proactively obtain information from suppliers about the impact of the COVID-19 public health emergency on their operations

- Evaluating the extent to which facilities and equipment have been changed or have not been maintained on schedule

Comprehensive guidance is also included around risk-management and other critical elements for consideration in developing a plan to resume normal drug manufacture. The FDA urges drug manufacturers to develop a resumption plan, in conjunction with an emergency plan, to include any identified remediations and their subsequent activities. “The plan should state that the risk management approach prioritizes the manufacture of drugs at risk of shortage and activities related to restarting batch production (e.g., performance of equipment maintenance prior to restarting production lines) in addition to activities that were delayed, reduced in frequency, or otherwise modified.”

FDA outlines these elements to be considered in developing a plan to resume normal drug manufacturing:

1. Risk management approach that identifies, evaluates, and mitigates factors that may impact product quality
2. Timeline for implementing priorities
3. Specifications which include:
    1. Changes be reviewed and approved by the drug manufacturer’s quality unit
    2. Drug manufacturers submit the required FARs, BPDRs, and animal drug product/manufacturing defect and adverse drug experience reports
    3. If a drug manufacturer decides that a recall is needed, they should notify FDA as recommended in the guidance for industry Product Recall, Including Removals and Corrections
4. Notify FDA of a permanent discontinuance in the manufacture of certain products or an interruption in the manufacture of certain products that is likely to lead to a meaningful disruption in supply of that product

Returning to normal operations should be a fluid process. As production priorities change or new information impacting priorities becomes available updates to the resumption plan should be made in real-time, allowing for reprioritization of activities as appropriate.

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