

# **FDA Executive Summary**

## **Meeting of the Device Good Manufacturing Practice Advisory Committee**

On April 11, 2013, the advisory committee will discuss the potential effects of extreme weather events and natural disasters on medical device manufacturing chain processes and marketed medical device safety and quality. Challenges to the medical device industry that may result from an extreme weather event or natural disaster may include, but are not limited to, power interruptions and outages; wireless network interruptions; extreme changes in temperature and humidity; fires, flooding, and inability to access clean water; contamination of water, devices, or packaging; and transport interruptions. These extreme weather conditions may create challenges for the medical device industry to ensure the safety and effectiveness of the medical devices brought to the market and used in health care. The committee will discuss how to optimize the use of FDA's current quality system framework to address these risks and vulnerabilities to the manufacturing chain resulting from extreme weather events. The committee may identify future steps and make recommendations of successful practices to help industry mitigate or better tolerate challenges to the manufacturing chain as a result of extreme weather. The committee may also identify next steps and recommendations for the agency to consider.

### **Federal Notice**

<https://federalregister.gov/a/2013-03963>

### **Meeting Date and Location**

April 11, 2013 from 8 a.m. to 6 p.m.  
Hilton Washington DC North/Gaithersburg  
620 Perry Parkway, Gaithersburg, MD 20877

### **Contact Person**

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**Background:**

The purpose of this Device GMP Advisory Committee meeting is to discuss successful practices and steps that the medical device industry can take to mitigate or better tolerate risks and vulnerabilities to medical device safety and quality resulting from extreme weather events and natural disasters. The advisory committee will be asked to discuss how the current regulatory framework (i.e., the Quality System regulation, 21 CFR Part 820) addresses vulnerabilities of extreme weather to manufacturing chain processes and to the safety and quality of medical devices in the marketplace. The Quality System regulation is a key element of the Food and Drug Administration (FDA) framework that permits manufacturers to assure the safety and quality of marketed medical devices. It is broad in scope and addresses product design and labeling, testing and procurement of materials, manufacturing processes, packaging, sterility, shipping and storage of devices, complaint handling, and corrective and preventive actions. Although the regulation sets expectations for the framework of a quality system, this regulation provides firms with the flexibility to develop procedures and documentation tailored to their particular devices, business size, and facilities. The FDA encourages industry to identify and apply successful practices to bring safe and effective products to market and to assure that devices in the marketplace remain safe and effective.

In the wake of Hurricane Katrina in 2005, CDRH began internal discussions about the effects of extreme weather events on devices and the medical device industry. Extreme weather events and natural disasters may create additional, unforeseen challenges and stresses to medical device manufacturing chains and to the safety and effectiveness of marketed products. Challenges that may result from an extreme weather event include, but are not limited to, power interruptions and outages; wireless network interruptions; extreme changes in temperature and

humidity; fires; flooding and inability to access clean water; contamination of water, devices, or packaging; and transport interruptions.

More recently, Hurricane Sandy affected a large portion of the mid-Atlantic and northeastern parts of the United States. Many firms and warehouses were subject to lengthy power outages, damage, and flooding. To prepare for the results of extreme weather events, the FDA is asking the advisory committee to discuss as part of the meeting the following questions. How can industry's procedures and practices be optimized to be useful during extreme weather events to maintain the quality and safety of devices during transport and storage? What actions are critical for firms to take for prompt return to full production after an extreme weather event? What elements of the Quality System regulation are critical for manufacturers to control production, transport, and storage to ensure safe and effective marketed products during or in the aftermath of extreme weather? Are corrective and preventive action procedures (21 CFR Part 820.100), as currently implemented, the right mechanism to assure the return to safe and effective production after extreme weather? Are they sufficient? What changes might be helpful?

An extreme weather event or natural disaster may have far-reaching effects. For example, raw materials, especially when harvested from natural resources, may become contaminated by flooding resulting from extreme weather or a natural disaster such as the earthquake and resulting tsunami affecting Japan in March of 2011. How can supplier controls be optimally applied by medical manufacturers when component suppliers are affected by extreme weather to minimize risks to safety and device performance?

Hurricanes, tornadoes, earthquakes, and other natural disasters may result in interruptions to routing and transport whether by air, land, or water. Product deliveries and shipping

schedules may be cancelled or adjusted. How might purchasing controls (21 CFR Part 820.50), production and process controls (21 CFR Part 820.70), and labeling and packaging controls (21 CFR Part 820.120) from the Quality System regulation successfully be implemented to ensure the integrity and quality of medical devices that are caught in extreme weather events during manufacture, transport, or storage? What additional steps or successful practices might firms take to mitigate damage to products during storage or shipping from extreme weather?

In recent years, extreme weather events and natural disasters have introduced new, unforeseen conditions and challenges. For example, Hurricane Katrina brought extreme heat, high humidity, and extensive flooding. These conditions left the local public health severely vulnerable. Hurricane Sandy set new records in damage and areas affected. In light of such previous extreme weather events, how can firms efficiently and successfully implement the Quality System regulation to anticipate and address future challenges to medical device manufacturing from extreme weather? Does the Advisory Committee have suggestions to optimize the current regulatory framework or Compliance Program 7382.845 activities to optimally address concerns of extreme weather events and natural disasters? If yes, which parts?

Extreme weather events may create new opportunities for increasing the robustness of a medical device design to withstand extreme and austere environments. How should medical device firms balance resources between anticipating and preparing for risks of extreme weather events compared to key product design issues with immediate potential for public health improvement?

Extreme weather events may require medical device firms to readdress emergency preparedness and planning. Mitigating future vulnerabilities and minimizing the risks affecting device safety and quality resulting from extreme weather conditions and natural disasters

requires knowledge and understanding of both the nature of the environmental threat and methods of coping with it. This advisory committee meeting will discuss and identify successful practices to help the medical device industry prepare for and tolerate challenges from extreme weather events and natural disasters and provide perspective that will help FDA optimize its regulatory activities.