FDA Executive Summary

Devices Good Manufacturing Practice
Advisory Panel

Meeting: March 2, 2022

General Issues Panel

21 CFR 820 Quality System Regulation Amendment Proposed Rule

List of Acronyms:

CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practices
DGMP	Devices Good Manufacturing Practice
FDA	Food and Drug Administration
FD&C Act	Food, Drug, and Cosmetic Act
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
MDSAP	Medical Device Single Audit Program
QMS	Quality Management System
QS	Quality System

Purpose of Meeting:

On March 2, 2022, the advisory committee will discuss the proposed rule outlining amendments to the medical device current good manufacturing practices (cGMP) requirements under 21 CFR 820, the Quality System (QS) regulation. The Food and Drug Administration (FDA) is proposing to converge its requirements with quality management system (QMS) requirements used by other regulatory authorities by incorporating the requirements of ISO 13485:2016 (ISO 13485) -- harmonizing cGMP requirements for medical devices globally. Over time, ISO 13485 has become more closely aligned with, and similar to, the requirements of 21 CFR 820. For over two decades, the medical device cGMP requirements for the United States have been the QS regulation; and fundamentally unchanged. This proposed change will require both the agency, and industry to prepare for a transition to meet the newly proposed requirements. The committee may discuss the impact of this proposed regulation on the medical device industry. The committee may provide comments on specific subject areas related to this proposed rule that FDA should consider in seeking to converge U.S. requirements with requirements used by other jurisdictions. The committee may discuss the differences within the proposed regulation that are modifications from ISO 13485, identifying potential challenges expected for transition. The committee may identify future steps and make recommendations of successful practices to help industry prepare their organizations for the transition. The committee may also identify next steps and recommendations for the agency to consider.

Background:

The purpose of this Devices Good Manufacturing Practice (DGMP) Advisory Committee meeting is to discuss the QMS requirements in the proposed amendment of the QS regulation, 21 CFR 820. The advisory committee will be asked to discuss the agency's proposal to incorporate the requirements of ISO 13485, Medical Devices--Quality Management System Requirements for Regulatory Purposes with the current regulatory framework addressing the specific requirements, differences, impacts to the medical device industry, and recommendations for successful implementation of the proposed requirements. The cGMP requirements listed in 21 CFR 820, currently the QS regulation, is a key element of the FDA framework that permits manufacturers to assure the safety and quality of marketed medical devices. For more than two decades, the FDA's cGMP requirements for medical devices have been the benchmark for quality management system requirements in the United States. The QS regulation has been effective, providing assurance that devices are safe and effective. FDA has not undertaken a significant revision of 21 CFR 820 since the publishing of the 1996 Final Rule. Also, in 1996, the International Organization for Standardization (ISO) issued the first version of ISO 13485, "Quality systems--Medical devices--Particular requirements for the application of ISO 9001", as a voluntary consensus standard to specify, in conjunction with the application of ISO 9001, the QMS requirements for the design/development and, when relevant, installation and servicing of medical devices. Over time ISO 13485 has evolved into a stand-alone standard outlining QMS requirements for devices and has become more closely aligned to the requirements of 21 CFR 820, particularly true for the 2016 version. With that progression, FDA sees an opportunity for regulatory harmonization by proposing to amend 21 CFR 820, to include and incorporate the requirements of ISO 13485.

While the QS regulation effectively addresses the requirements for a QMS, FDA has long recognized the value of, and has been exploring ways to effect, global harmonization for the regulation of devices. FDA has gained experience with ISO 13485 and determined that it provides a comprehensive and effective approach to establish a QMS for devices, through our participation in and development of programs that utilize international QMS standards for devices as foundational QMS requirements, such as the 2012 voluntary audit report submission pilot program and the Medical Device Single Audit Program (MDSAP). FDA also participates in the International Medical Device Regulators Forum (IMDRF), a

voluntary group of medical device regulators from around the world focused on regulatory harmonization and convergence.

FDA believes that globally harmonizing the regulation of devices will help provide consistent, safe, and effective devices, contributing to public health through timelier access for patients. Harmonizing differing regulations would remove unnecessary duplicative regulatory requirements and impediments to market access and remove barriers to patient access and costs. The more flexible approach to quality, based on risk management, found within ISO 13485 will meet the needs of patients to have access to quality devices in consonance with the progress of science and technology. Incorporating the requirements of ISO 13485 would further the agency's goals for regulatory simplicity and global harmonization, providing more efficient access to medical devices. Harmonizing 21 CFR 820 with ISO 13485 would have benefits for manufacturers because many firms producing devices for sale within the United States and abroad must comply with both standards. Aligning these standards would mean those firms would need to comply with only a single set of requirements instead of two different ones.