SMG 1262.4

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Compliance

Office of Manufacturing Quality

Effective Date: December 14, 2018

1. Office of Manufacturing Quality (DCDFA).

A. Develops and implements compliance and enforcement policies and actions to protect patients from firms whose quality standards and practices may pose a significant risk to public health.

B. Plans, develops, and directs compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety and quality of the nation's drug supply.

C. Develops and guides compliance strategies and enforcement actions, and ensures uniform interpretation of drug manufacturing quality standards and systems.

D. Collaborates with foreign regulators in the development and execution of compliance and enforcement strategies related to drug quality standards and systems.

E. Collaborates with other offices in the Center for Drug Evaluation and Research (CDER), such as Office of Pharmaceutical Quality, Office of Generic Drugs, Office of New Drugs, and the Drug Shortages Staff, as well as other Agency offices, to evaluate compliance and enforcement actions and assess overall impact on patient access to high-quality, effective drugs.

F. Collaborates with investigators to ensure the uniform application of risk-based, patient-focused compliance and enforcement policies and actions.

2. Manufacturing Guidance and Policy Staff (DCDFA1).

A. Leads development of science- and risk-based, patient-focused policies, standards, and guidance related to manufacturing quality that promote effective pharmaceutical quality systems, reliable manufacturing, continual improvement, and conformance to manufacturing quality requirements.

B. Collaborates with Office of Pharmaceutical Quality in the development and prioritization of manufacturing quality policy, standards, and guidance.

C. Collaborates with appropriate CDER and Food and Drug Administration offices concerning industry manufacturing and quality compliance trends, policy changes commensurate with such trends, and-as appropriate-develops, implements, and revises manufacturing quality policies, standards, and guidance.

D. Provides assistance with development of training programs that promote consistent understanding and interpretation of manufacturing quality guidance, policy, and standards.

E. Develops programs and agreements that facilitate coordination of policies and actions with foreign regulatory partners to ensure the best public health outcomes

3. Authority and Effective Date.

The functional statements for the Office of Manufacturing Quality were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
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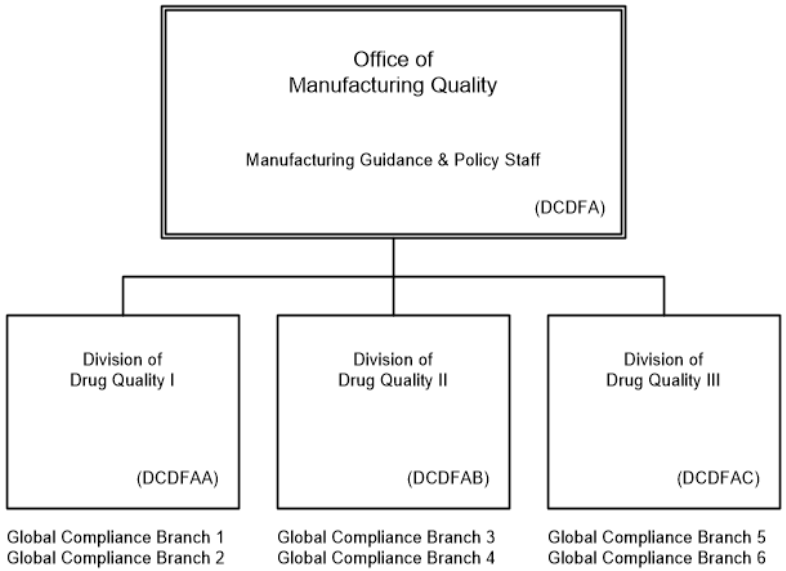

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Manufacturing Quality organization structure depicting all the organizational structures reporting to the Director.

Office of Manufacturing Quality (DCDFA)

These organizations report to the Office of Manufacturing Quality:

Manufacturing Guidance & Policy Staff
Division of Drug Quality I (DCDFAA)
Division of Drug Quality II (DCDFAB)
Division of Drug Quality III (DCDFAC)

These organizations report to the Division of Drug Quality I:

Global Compliance Branch 1 (DCDFAA1)
Global Compliance Branch 2 (DCDFAA2)

These organizations report to the Division of Drug Quality II:

Global Compliance Branch 3 (DCDFAB1)
Global Compliance Branch 4 (DCDFAB2)

These organizations report to the Division of Drug Quality II:

Global Compliance Branch 5 (DCDFAC1)
Global Compliance Branch 6 (DCDFAC2)

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