

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: May 13, 2024

1. Office of Manufacturing Quality (DCDFA).

- A. Reviews and evaluates inspectional and analytical findings to assess compliance with the Food and Drug Administration (FDA) enforced laws and regulations. Determines the most suitable course of action and, if appropriate, recommends legal action.
- B. 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.
- C. 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.
- D. Develops and guides compliance strategies and enforcement action and ensures uniform interpretation of drug manufacturing quality standards and systems.
- E. Issues untitled and warning letters to regulated industry.
- F. Facilitates clearance, if necessary, for administrative and other detentions, prepares related correspondence, and supports administrative product detention hearings.
- G. Collaborates with foreign regulators in the development and execution of compliance and enforcement strategies related to drug quality standards and systems.

- H. 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 action and assess overall impact on patient access to high-quality, effective drugs.
- I. Collaborates with investigators to ensure the uniform application of risk-based, patient-focused compliance and enforcement policies and actions throughout the inspection process.

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 FDA 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. Regulatory Compliance and Analysis Staff (DCDFA2).

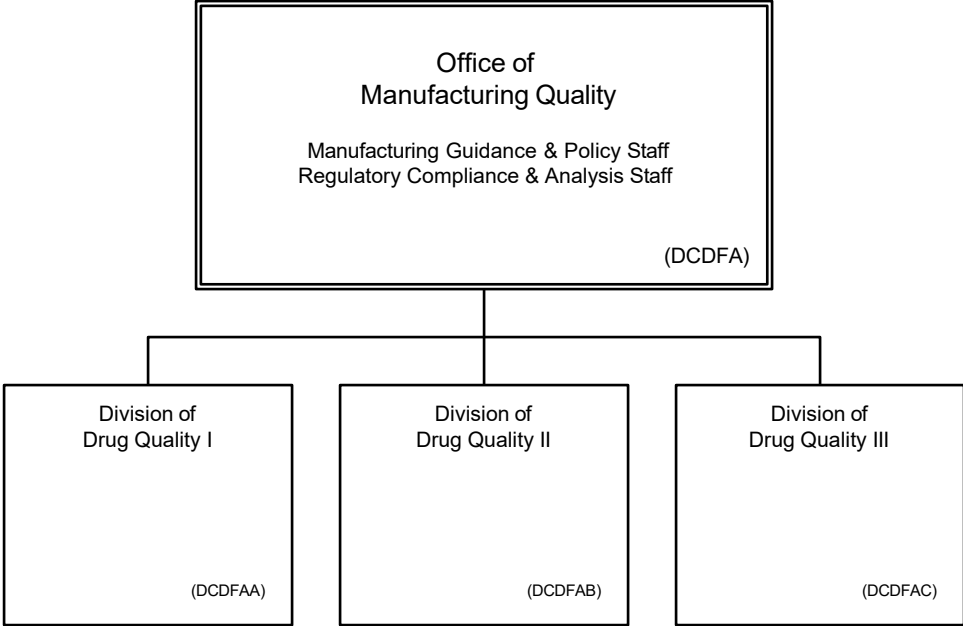
- A. Leads and manages regulatory compliance initiatives associated with manufacturing quality, in collaboration with other functional office leadership.
- B. Collaborates with other appropriate CDER and FDA offices on a portfolio of regulatory compliance programs relating to manufacturing quality, quality management systems, and data science.
- C. Designs and develops internal procedures and processes to support work quality, and oversight of implementation, monitoring, and continual improvement of the quality system.

- D. Serves as the regulatory interface for the Office with other foreign regulatory health authorities on related Current Good Manufacturing Practices (CGMPs) in industry. Collaborates with foreign regulators on strategies and actions related to drug quality standards and systems.
- E. Coordinates cross-functional projects that are led by the Office of Manufacturing Quality and involves other agency components to ensure timelines and deliverables are met.

4. Authority and Effective Date.

The functional statements for the Office of Manufacturing Quality were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Manufacturing Quality**



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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:

Manufacturing Guidance and Policy Staff (DCDFA1)
Regulatory Compliance and Analysis Staff (DCDFA2)
Division of Drug Quality I (DCDFAA)
Division of Drug Quality II (DCDFAB)
Division of Drug Quality III (DCDFAC)