

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

Effective Date: May 13, 2024

1. Office of Compliance (DCDF).

- A. Plans, develops, and directs compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply.
- B. Advises the Center Director and other officials on the Food and Drug Administration's (FDA) regulatory and enforcement responsibilities and possible risks associated with human drugs.
- C. Implements programs and projects to identify, assess, and prioritize the public health significance and patient risks associated with drug quality and safety concerns presented throughout the drug lifecycle.
- D. Leads and oversees the development of human drug enforcement and compliance policy and standards.
- E. Develops and guides compliance strategies and enforcement action and ensures uniform interpretation of standards.
- F. Oversees the planning and development of compliance and enforcement strategies and actions that are patient-focused and risk-based to secure the safety, efficacy, and quality of the nation's drug supply.
- G. Executes high-level decisions, monitors performance, and directs strategies and operations of component offices to ensure compliance and enforcement decisions and policies are patient-focused and risk-based.
- H. Designs and develops internal procedures and processes to support work quality, and oversight of implementation, monitoring, and continual improvement of the quality system.

- I. Reviews and evaluates inspectional and analytical findings to assess compliance with FDA-enforced laws and regulations; determines the most suitable course of action and, if appropriate, recommends legal action.
- J. Liaises with the United States (U.S.) Department of Justice and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.
- K. Conducts administrative meetings on alleged violations and initiates enforcement action.
- L. Facilitates clearance, if necessary, for administrative and other product detentions, prepares related correspondence, and supports detention hearings.
- M. Advises inspectorate staff on interpretations of the Food, Drug, and Cosmetic Act and its related regulations throughout the inspectional process.
- N. Issues untitled and warning letters to regulated industry.
- O. Plans, organizes, and implements comprehensive outreach, including stakeholder education, training, and technical assistance programs designed to promote voluntary compliance and self-regulation in cooperation with other inspectorate and Headquarters components.
- P. Conducts selected inspections and pre-operational reviews of establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs inspectorate analyses; and prepares reports on findings of each inspection and/or investigation. Maintains cooperative relationships with State and local counterpart agencies and develops work and information sharing agreements.

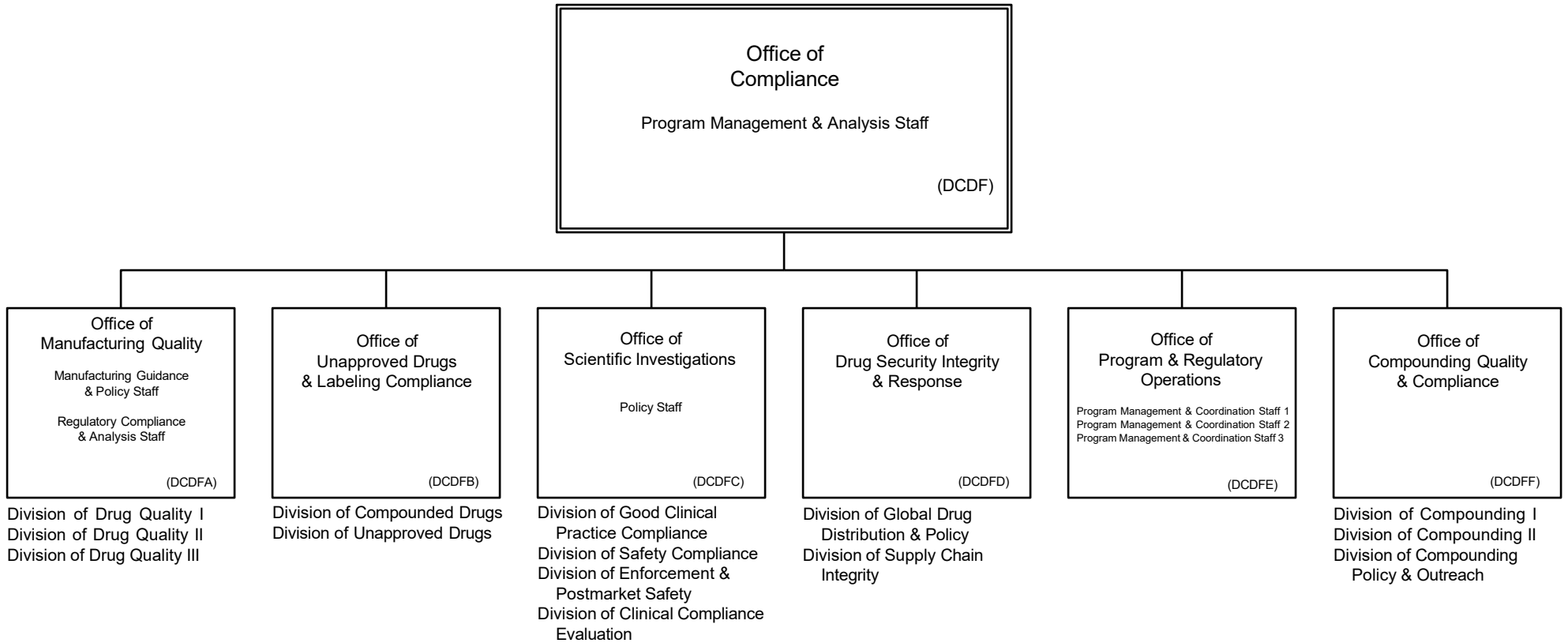
2. Program Management and Analysis Staff (DCDF1)

- A. Provides leadership, guidance and support services to the Office of Compliance on all aspects of administrative, budget, contracts and provides service and support on human resource, personnel operations services and recruitment activities.

3. Authority and Effective Date.

The functional statements for the Office of Compliance 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**



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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Compliance (DCDF)
Program Management and Analysis Staff
Office of Manufacturing Quality (DCDFA)
Office of Unapproved Drugs and Labeling Compliance (DCDFB)
Office of Scientific Investigations (DCDFC)
Office of Drug Security Integrity and Response (DCDFD)
Office of Program and Regulatory Operations (DCDFE)
Office of Compounding Quality and Compliance (DCDFF)

These organizations report to the Office of Manufacturing Quality (DCDFA):

Manufacturing Guidance and Policy Staff
Regulatory Compliance and Analysis Staff
Division of Drug Quality I
Division of Drug Quality II
Division of Drug Quality III

These organizations report to the Office of Unapproved Drugs and Labeling Compliance (DCDFB):

Division of Compounded Drugs
Division of Unapproved Drugs

These organizations report to the Office of Scientific Investigations (DCDFC):

Policy Staff
Division of Good Clinical Practice Compliance
Division of Safety Compliance
Division of Enforcement and Postmarket Safety
Division of Clinical Compliance Evaluation

These organizations report to the Office of Drug Security Integrity and Response (DCDFD):

Division of Global Drug Distribution and Policy
Division of Supply Chain Integrity

These organizations report to the Office of Program and Regulatory Operations (DCDFE):

Program Management and Coordination Staff 1

Program Management and Coordination Staff 2

Program Management and Coordination Staff 3

These organizations report to the Office of Compounding Quality and Compliance (DCDFF):

Division of Compounding I

Division of Compounding II

Division of Compounding Policy and Outreach