

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 Program and Regulatory Operations

Effective Date: October 9, 2020

1. Office of Program and Regulatory Operations (DCDFE).

- A. Leads and manages operational infrastructure for the Center for Drug Evaluation and Research (CDER), Office of Compliance (OC), relating to project management, process management, controlled correspondence management, and informatics oversight.
- B. Provides project management leadership and technical expertise for cross-functional initiatives led by OC and involving other Food and Drug Administration components to ensure collaborative environments are developed, timelines and deliverables are met.
- C. Designs and develops internal procedures and processes to advance work quality, and oversees implementation, monitoring, and continual improvement of the quality systems.
- D. Triages, assigns, tracks, and ensures timely resolution of all controlled correspondence for the OC.
- E. Manages governance of information technology initiatives of the OC.

2. Program and Regulatory Operations Staff 1 (DCDFE1).

- A. Provides the OC strategy for cross-functional quality and planning projects and regulatory initiatives.
- B. Coordinates with other OC component offices to ensure timely completion of established goals and conformance to internal processes and procedures.

- C. Develops and applies operational strategies, resourcing, and regulatory procedures to ensure that requirements of applicable laws, regulations, and policies are implemented.
- D. Implements quality assurance processes, leads project reviews, monitors project activities and implements strategies to mitigate risk.
- E. Facilitates the OC strategy for engaging stakeholders of the public and private sectors.

3. Program and Regulatory Operations Staff 2 (DCDFE2).

- A. Provides the OC strategy for cross-functional projects and regulatory initiatives.
- B. Leads and manages processes associated with cross-functional activities of OC-led projects and ensures that collaborative environments are developed and maintained.
- C. Leads and manages timelines, milestones, and deliverables for inter-office initiatives, and implementation of continuous improvements activities.
- D. Develops operating criteria and standard regulatory procedures to implement new legislation, regulations, and government mandates.
- E. Monitors operational processes, identifies and designs the development and implementation of continuous improvements activities.

4. Program and Regulatory Operations Staff 3 (DCDFE4).

- A. Evaluates operational processes, identifies improvement needs, and promotes development and implementation of continuous improvements activities.
- B. Manages the triage, assignment and tracking of all controlled correspondence for the office.
- C. Manages information technology initiatives, ensuring that activities are aligned with CDER informatics operational and regulatory policies.
- D. Provides project management leadership for cross-cutting or complex business informatics working groups and projects or regulatory initiatives.
- E. Designs, develops, and manages processes for identifying, creating, sharing, managing and retaining records and other knowledge within the Office of Compliance.

5. Authority and Effective Date.

The functional statements for the Office of Program and Regulatory Operations were approved by the Commissioner of Food and Drugs and effective on September 8, 2020, and effective on October 9, 2020.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Program and Regulatory Operations**

Office of
Program & Regulatory Operations

Program & Regulatory Operations Staff 1
Program & Regulatory Operations Staff 2
Program & Regulatory Operations Staff 3

(DCDFE)

Staff Manual Guide 1262.7
Organizations and Functions
Effective Date: October 9, 2020

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 Program and Regulatory Operations organization structure depicting all the organizational structures reporting to the Director:

Office of Program and Regulatory Operations (DCDFE)
Program and Regulatory Operations Staff 1
Program and Regulatory Operations Staff 2
Program and Regulatory Operations Staff 3