

**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: December 14, 2018

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

- A. Leads and manages operational infrastructure support for the entire Office of Compliance (OC) relating to project management, executive communications, workforce development, and drug registration and listing.
- B. Designs and develops internal procedures and processes to support work quality, and oversight of implementation, monitoring, and continual improvement of the quality system.
- C. Coordinates cross-functional projects led by the Center for Drug Evaluation and Research (CDER) OC and involving other agency components to ensure appropriate teaming environments are developed and timelines and deliverables are met.
- D. Assigns, tracks, and ensures timely resolution of all executive communications for the office.
- E. Designs, develops, and implements workforce development programs to continually develop staff competencies and enhance job performance.
- F. Manages drug registration and listing database and policy issues.
- G. Designs and develops internal procedures and processes to support work quality, and oversight of implementation, monitoring, and continual improvement of the quality system.

## **2. Project Management and Coordination Staff 1 (DCDFE1).**

- A. Leads and promotes Office-wide implementation of workforce development activities for the OC.
- B. Designs, develops, and manages processes for identifying, creating, sharing, managing and retaining records and other knowledge within the OC.
- C. Provides the OC strategy for cross-functional quality and planning projects and initiatives within CDER OC.
- D. Coordinates with other CDER OC component offices to ensure on time completion and conformance to internal processes and procedures.
- E. Monitors business processes, identifies improvement needs, and promotes development and implementation of continuous improvements activities.
- F. Manages the assignment and tracking of all executive communications for the office.

## **3. Project Management and Coordination Staff 2 (DCDFE2).**

- A. Provides the OC strategy for cross-functional projects and initiatives.
- B. Leads and manages processes associated with cross-functional or OC-led projects and ensure appropriate program level teaming environments are developed and maintained.
- C. Establishes and manages timelines, milestones, and deliverables for inter-office, high profile or OC-led projects.
- D. Monitors business processes, identifies and designs the development and implementation of continuous improvements activities.
- E. Provides project management support to cross-cutting or complex business informatics working groups and projects or initiatives.

## **4. Drug Registration and Listing Staff (DCDFE3).**

- A. Lead Agency in managing drug registration and listing database and policy issues.
- B. Provides assistance to industry regarding submission of establishment registration and drug product listing data through the management of the electronic drug registration and listing (eDRLS) helpdesk.

- C. Publishes the National Drug Code Directory of all finished drug products available in the United States.
- D. Publishes the Drug Establishment Current Registration Site list of all currently registered drug establishments.
- E. Provides drug registration and/or listing support to the Food and Drug Administration surveillance programs and other Government Agencies.
- F. Assesses and implements regulatory actions concerning violations of drug registration and listing requirements and facility obligations under the Generic Drug User Fee Amendments of 2012.

**5. Authority and Effective Date.**

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

**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  
Project Management & Coordination Staff 1  
Project Management & Coordination staff 2  
Drug Registration & Listing Staff

(DCDFE)

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

Office of Program and Regulatory Operations (DCDFE).

These organizations report to the Office of Program and Regulatory Operations Division of Supply Chain Integrity:

Project Management & Coordination Staff I  
Project Management & Coordination Staff II  
Drug Registration & Listing Staff