

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 Executive Programs

Effective Date: December 14, 2018

1. Office of Executive Programs (DCDI).

- A. Coordinates the operations of the Office of the Center Director, ensuring that the goals and priorities of the Center Director are carried out.
- B. Advises and assists the Center Director and other key officials on center programmatic matters.
- C. Coordinates Ombudsman activities, including managing informal dispute resolution between regulated industry and Center for Drug Evaluation and Research (CDER), managing informal dispute resolution within CDER for scientific and review issues, responding to consumer and industry inquiries and investigating complaints, receiving and assessing feedback on CDER programs and advising CDER Director about problems and proposes solutions.
- D. Coordinates inter-center product jurisdiction activities, including establishing and representing CDER's position on which Food and Drug Administration's (FDA) Center is most appropriate for reviewing a combination product, responding to formal and informal requests for assignment of combination and non-combination products, and serve as the point of contact and information source regarding product jurisdiction.

2. Program Management and Analysis Staff (DCDI1).

- A. Provides leadership, direction, and planning for administrative and contract management programs for the Office of Executive Programs (OEP) and Office of the Center Director (OCD).
- B. Provides guidance and support services for OEP and OCD on all aspects of administrative, budget, facilities management, and human resources activities.
- C. Coordinates, develops, and assesses policies, procedures, and best practices related to office administration and contract management within OEP and OCD.
- D. Provides representation to OEP and OCD on Center and Agency best practices

boards associated with staff responsibilities.

3. Legislative Affairs Staff (DCDI2).

- A. Serves as center liaison to the Department of Health and Human Services, Office of the Inspector General, Government Accounting Office, Federal Communications Commission, Federal Trade Commission, and Securities Exchange Commission.
- B. Advises officials within CDER on policies and principles to assure adequacy for accomplishing program objectives related to legislative activities.

4. Executive Operations Staff (DCDI3).

- A. Provides executive secretariat support to the immediate OCD, including coordinating executive and legislative correspondence and activities; managing the preparation and coordination of meetings; and preparing background material, graphics, and other information for meetings, speeches, and presentations.
- B. Serves as media liaison responsible for all media interactions, in coordination with the Office of Communications.
- C. Serves as point of contact for OCD and OEP in leading communication between the OCD and CDER offices.

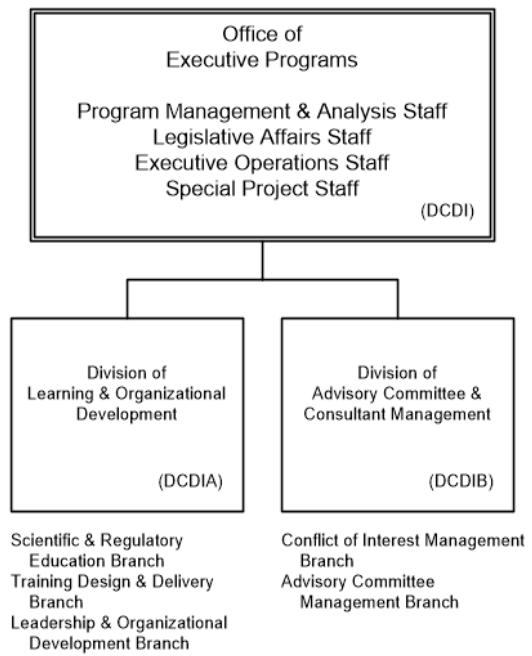
5. Special Projects Staff (DCDI4).

- E. Provides project management support for Center-wide and FDA initiatives to improve the quality and timeliness of regulatory review and improve team-based management practices.
- F. Serves as a major Center-Level focal point for policy issues that require management and coordination between top-level staff officials of FDA.

6. Authority and Effective Date.

The functional statements for the Office of Executive Programs were approved by the Secretary of the Department 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 Executive Programs**



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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 Executive Programs organizational structures depicting all the organizational structures reporting to the Director.

Office of Executive Programs (DCDI).

These organizations report to the Office of Executive Programs:
Division of Learning & Organizational Development (DCDIA)
Division of Advisory Committee & Consultant Management (DCDIB)

These organizations report to the Division of Learning & Organizational Development:
Scientific & Regulatory Education Branch
Training Design & Delivery Branch
Leadership & Organizational Development Branch

These organizations report to the Division of Advisory Committee & Consultant Management:
Conflict of Interest Management Branch
Advisory Committee Management Branch