

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Regulatory Management Operations

Effective Date: February 9, 2022

1. Office of Regulatory Management Operations (DCIB).

- A. Provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA), Deputy ACRA and other senior management officials on all matters related to Office of Regulatory Affairs (ORA's) resource management operations and training and employee development plans.
- B. Coordinates regulatory management operations, including resource and administrative activities, and training and development, for the program areas and offices in ORA; supports field regulatory management operations through collaboration with the all ORA offices and the field components.
- C. Evaluates the overall management and capabilities of the Center's field administrative organization; initiates action to improve the management of Headquarters (HQ) and field activities to streamline processes and ensure efficiency.
- D. Provides advice and counsel to the ACRA and other senior Food and Drug Administration (FDA) officials concerning new legislation, executive orders, new regulations or other information that may affect current or proposed FDA policies.
- E. Oversee the management of the strategic training, education and development plan for ORA personnel and where appropriate, state and local regulatory partners, in line with ORA's mission, program priorities and core values.
- F. Provides leadership and guidance to assure compliance with statutes, executive orders and administrative directives on all administrative management operations, and training and development.

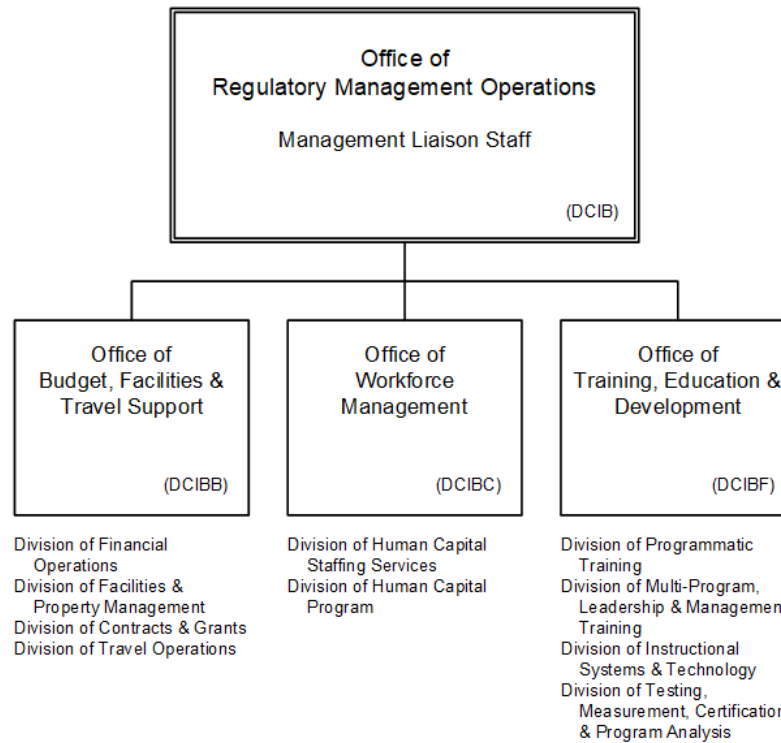
2. Management Liaison Staff (DCIB1)

- A. Provides advice and counsel to the Director of the office and other ORA senior managers and staff on all areas of labor and employee relations.
- B. Provides counsel and support for management and is the administrative interface with the FDA and Department related to labor and employee relations.
- C. Coordinates on behalf of ORA in Departmental labor negotiations.
- D. Develops, reviews, and coordinates implementation of ORA policies and procedures to ensure compliance with applicable contractual, regulatory and statutory governing laws in the areas of employee and labor relations.
- E. Manages ORA employee relations, including but not limited to employee misconduct and Equal Employment Opportunity (EEO) related matters.
- F. Assures compliance with regulations, case law, executive orders, administrative directives, Collective Bargaining Agreements, and statutes such as the Federal Labor Relations Act.
- G. Serves as subject matter experts for ORA training activities related to labor and employee relations.
- H. Provides personnel and administrative support services on all employee and labor relations for all of ORA, ensuring customer needs are identified and met

3. Authority and Effective Date.

The functional statements for the Office of Regulatory Management Operations were approved by the Deputy Secretary of Health and Human Services on December 22, 2021, and effective on February 9, 2022

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Regulatory Management Operations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Management Operations organization structure depicting all the organizational structures reporting to the Assistant Commissioner for Regulatory Management Operations:

Management Liaison Staff

Office of Budget, Facilities, and Travel Support (DCIBB)

Office of Workforce Management (DCIBC)

Office of Training, Education, and Development (DCIBF)

These organizations report to the Office of Budget, Facilities, and Travel Support:

Division of Financial Operations (DCIBBA)

Division of Facilities and Property Management (DCIBBB)

Division of Contracts and Grants (DCIBBC)

Division of Travel Operations (DCIBBD)

These organizations report to the Office of Workforce Management:

Division of Human Capital Staffing Services (DCIBCA)

Division of Human Capital Program (DCIBCB)

These organizations report to the Office of Training, Education, and Development:

Division of Programmatic Training (DCIBFA)

Division of Multi-Program, Leadership, and Management Training (DCIBFB)

Division of Instructional Systems and Technology (DCIBFC)

Division of Test, Measurement, Certification, and Program Analysis (DCIBFD)