

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 the Associate Commissioner for Regulatory Affairs

Effective Date: February 9, 2022

1. Office of the Associate Commissioner for Regulatory Affairs (DCIA).

- A. Advises and assists the Commissioner, Deputy Commissioners, and other key officials on regulations, field operations and compliance-oriented matters that have an impact on strategic direction, policy development and long-range program goals.
- B. Coordinates, interprets, and evaluates the Food and Drug Administration's (FDA) overall field inspections, compliance, import and regulatory science activities; as necessary, works with key FDA officials and the Centers to establish strategic alignment on operational resource management and policy recommendations.
- C. Provides direction and counsel to the Assistant Commissioners and Program Directors in the implementation of policies and operational guidelines that form the framework for the management of FDA field activities.
- D. Evaluates and establishes the overall management and capabilities of the FDA's field organization; initiates action to improve the management of field activities and coordinates the formulation and management of career development plans.
- E. Advises the Commissioner, Deputy Commissioners, and other key officials on policy, programs, and plans for activities between the FDA and other federal, State, territorial, tribal and local regulatory and public health agencies.
- F. Advises the Commissioner and Deputy Commissioners on the management of scientific resources and the operation of field laboratories to assure their coordinated, efficient and effective use; provides coordination between field and Headquarter scientific programs.

- G. Directs and coordinates the field's emergency response to natural, unintentional and intentional disasters and outbreaks related to FDA regulated products or impacting FDA regulated industries, working with the Office of Emergency Management.
- H. Provides direction and counsel to the Director of the Office of Criminal Investigations in the coordination and execution of criminal investigations to align with FDA and Center priorities.
- I. Directs and oversees the Office of Regulatory Affairs (ORA) activities related to planning and evaluation of training and development programs.
- J. Directs and oversees ORA activities regarding planning and evaluation of programs and projects, information technology, communication efforts, and resource utilization.
- K. Directs and oversees the performance of organization and management studies for ORA and directs implementation of study recommendations.
- L. Directs and oversees ORA's partnership and policy activities.
- M. Develops, coordinates, and oversees Office of Regulatory Affairs (ORA) engagement on Government Accountability Office (GAO) studies, Department of Health and Human Services (DHHS) and Office of the Inspector General (OIG) audits.

2. Data Analytics and Program Evaluation Staff (DCIA2).

- A. Analyzes field performance data, evaluates overall field accomplishments in terms of stated goals and resource utilization, establishes ACRA IO Dashboards that convey overall performance of ORA annual priorities and recommends changes in operational program plans and field manpower allocations.
- B. Develops planning and evaluation guidance materials, based on the Food and Drug Administration (FDA) decisions and program evaluation data, for use by the field in program planning and budgeting. Assists the field in evaluating performance and programs.
- C. Analyzes field performance data, evaluates overall field accomplishments in terms of stated goals and resource utilization.
- D. Serves as subject matter experts on the development of information systems related to manpower utilization and data extraction.

3. Authority and Effective Date.

The functional statements for the Program Evaluation 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
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Office of the
Associate Commissioner for
Regulatory Affairs

Data Analytics & Program Evaluation Staff (DCIA)

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

Data Analytics and Program Evaluation Staff