

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Finance, Budget, Acquisitions, and Planning

Office of Planning, Evaluation, and Risk Management

Division of Evaluation and Analytics

Effective: February 9, 2022

1. Division of Evaluation and Analytics (DCNEDB).

- A. Leads, performs, and coordinates the FDA's program evaluation function.
- B. Prepares annual User Fee performance reports to Congress.
- C. Performs FDA program and policy evaluations and analytical studies. Recommends alternative courses of action to increase effectiveness of FDA allocation of resources and to improve program and project performance.
- D. Performs analyses of significantly broad FDA issues identified in the planning process. Recommends and/or implements steps to resolve these issues.
- E. Coordinates information gathering and reporting for the FDA's annual Evaluation Plan; coordinates the annual Evaluation Plan with DHHS.
- F. Conducts special evaluation and analytical studies in support of FDA policy development and in resolution of broad FDA problems.
- G. Evaluates the impact of external factors on FDA programs, including consumer expectations and prospective legislation.
- H. Evaluates the impact of FDA operations and policies on regulated industries and other FDA constituents.
- I. Provides process expertise to FDA components in designing consensus sessions with internal and external stakeholders.
- J. Assists and consults with FDA components on the design and execution of key program and process re-inventions.
- K. Assists and consults with FDA scientific review components to enhance transparency, consistency, accountability, and continuous improvement of review processes.

- L. Facilitates cross-organizational sharing of key program and process improvements.
- M. Leads, performs, and coordinates the FDA's business process design function.
- N. Coordinates the FDA's business process design function in support of business process improvement and automation efforts.
- O. Provides business process design, operations analysis, and project management support to FDA information management programs.
- P. Provides business process design, modeling, and analysis services to FDA programs and initiatives.
- Q. Leads, performs, and coordinates audit-related tasks.
- R. Prioritizes program, project, and process audit and evaluation requirements based on criteria such as risk and available resources.
- S. Schedules and performs program, project, and process audits and evaluations.
- T. Aids audited/evaluated organizations address areas identified as needing improvement.

2. Authority and Effective Date.

The functional statements for the Division of Evaluation and Analytics were approved by the Acting Commissioner of Food and Drugs on December 7, 2021, and effective on February 9, 2022.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Operations, Office of Finance, Budget, Acquisitions, and Planning, Office of Planning, Evaluation, and Risk Management, Division of Evaluation and Analytics organization structure depicting all the organizational structures reporting to the Director:

Division of Evaluation and Analytics (DCNEDB)