

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Planning and Evaluation

Effective Date: December 14, 2018

1. Office of Planning and Evaluation (DCND).

- A. Leads Food and Drug Administration (FDA)-wide strategic planning initiatives.
- B. Advises and assists the Commissioner and other key FDA officials concerning the performance of FDA planning, evaluation and process improvement activities.
- C. Develops program and planning strategy through analysis and evaluation of issues affecting program operations and performance.
- D. Develops, installs, and monitors the FDA wide planning system including the long-term plans, strategic action plans, and program implementation plans.
- E. Leads the FDA Strategic Planning Council.
- F. Consults with and supports the FDA preparation of legislative proposals, budget proposals, and technical assistance to Congress.
- G. Conducts operations research, management science, program evaluation, and special studies as a basis for forecasting trends, needs, and major problems requiring solutions, and provides assistance and consultation in these areas to operating units.
- H. Develops FDA evaluation programs and systems to evaluate overall FDA program accomplishments against objectives and priorities, recommending changes as necessary.
- I. Estimates marginal impact of funding changes on FDA performance and ability to protect and promote public health.

- J. Leads effort to analyze FDA business processes for process improvement and automation.
- K. Coordinates the development of public health and program outcome measures and monitors and reports on the status of those measures. Develops logic models that link FDA activities and outputs to outcomes.
- L. Coordinates and performs user fee program evaluations and analyses. Leads and coordinates various user fee program initiatives related to performance improvement, program management, and quality systems studies.
- M. Leads, performs, and coordinates FDA's organizational change management function. Helps programs assess and define the need for change, develop effective communications, align the organization to the change initiative, and apply evidence-based best practices.
- N. Leads FDA resource capacity planning and modernized time reporting as well as other management science analytical capabilities to ensure that quality information is available to inform operational and strategic decision making.
- O. Performs and coordinates analytics projects and programs
- P. Supports and performs descriptive, prescriptive, exploratory, and predictive analytics projects at the FDA and in the Centers and FDA entities.
- Q. Provides analytics-related subject matter expertise and support such as examples, case studies, and training to other FDA groups performing analytics projects.
- R. Develops and implements governance for data-related and analytics-related processes in collaboration with FDA offices.
- S. Assists with the design and development of data analyses to support business decisions, including data visualizations and recommendations for appropriate display and analytics technologies.
- T. Supports the development of data source documentation as needed for valid and verifiable data analyses.

2. Planning Staff (DCND1).

- A. Performs and coordinates the FDA's performance planning functions with the Department of Health and Human Services (DHHS) and external stakeholders.
- B. Represents the FDA in DHHS and the Office of Management and Budget (OMB)

performance planning reporting and other activities.

- C. Develops, coordinates and responsible for the FDA's performance planning and achievements in accordance with the Government Performance and Results Modernization Act.
- D. Partners and collaborates with the Office of Budget and FDA components in preparing and reporting the performance goals and results in the FDA's budget.
- E. Coordinates the FDA long range strategic and performance planning in line with the DHHS strategic plan, and other DHHS Operational Divisions.
- F. Maintains, analyzes and reports FDA-wide performance information and achievements to external stakeholders.
- G. Performs and coordinates the FDA's performance planning functions with internal stakeholders:
- H. Responsible for the development and improvement of the FDA's program performance measures, data and goals on a continuous basis to ensure alignment to FDA's (and User Fees') missions and objectives.
- I. Leads and aligns the FDA short- and long-range performance planning objectives and processes.
- J. Assists and consults with FDA components in their performance planning for data, trends, targets and achievements.
- K. Creates and provides performance data dashboards and reports to external and internal stakeholders.
- L. Performs and coordinates program advisory, planning, and analysis services.
- M. Assists FDA components in analyzing and improving their planning processes, performance objectives and goals.
- N. Collaborates with FDA components as requested to identify and implement internal and external best practices to improve overall performance.
- O. Analyzes information by applying mathematical disciplines and principles to make available data and facilitate improved decision- making.
- P. Conducts special operational analysis and planning related studies to improve performance.

- Q. Conducts analysis of resource requests submitted by FDA components and develops recommendations for the Commissioner, to fulfill FDA, DHHS, and OMB requirements.
- R. Provides operations analysis and project management support to the FDA committees and initiatives as needed.
- S. Represents the performance and planning aspects of the FDA's program integrity and enterprise risk management functions.

3. Program Evaluation and Process Improvement Staff (DCND2).

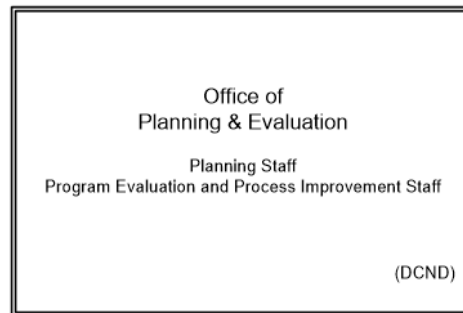
- A. Leads, performs, and coordinates the FDA's program evaluation function.
- B. Prepares annual User Fee performance reports to Congress.
- C. Performs FDA program and policy evaluations and analytical studies. Recommends alternative courses of action to increase effectiveness of FDA allocation of 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. Reports results of audits and evaluations to relevant stakeholders.
- U. Helps audited/evaluated groups address areas identified as needing improvement.

4. Authority and Effective Date.

The functional statements for this Office of Planning and Evaluation 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
Office of Operations
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Planning and Evaluation organization structure depicting all the organizational structures reporting to the Director.

These organizations below report to the Office of Planning and Evaluation (DCND)

Planning Staff

Program Evaluation and Process Improvement Staff