

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of Enterprise Transformation

Effective Date: May 13, 2024

1. Office of Enterprise Transformation (DCAE)

- A. Leads Food and Drug Administration (FDA) enterprise business change initiatives supporting modernization activities by centralizing planning, implementation, and governance of high-priority cross-cutting business process improvement efforts.
- B. Works with and at the direction of the FDA Executive Committee (EC) to identify and prioritize enterprise change and transformation opportunities in support of FDA strategic priorities.
- C. Leads, coordinates, and manages highly complex and cross-cutting business transformation projects and programs from the concept stage through execution and delivery taking into account relevant project lifecycle guidelines.
- D. Drives business transformation and enterprise change by leading the business analysis, process improvement, and evaluation activities to solve high-priority, multi-center business problems that support data and technology modernization activities.
- E. Elicits, analyzes, specifies, and validates the business needs of OET project stakeholders.
- F. Establishes effective governance of high priority cross-organization business process improvement efforts that include technology, data, and analytics components to ensure that initiatives are successful.
- G. Develops and implements comprehensive change management programs for OET-led initiatives to assist organizations in successful transitions.

- H. Collaborates with FDA stakeholders to determine change and transformation opportunities, project scope and vision, to prioritize requirements, and to determine feasible options and solutions.
- I. Ensures optimal implementation of all OET projects and programs through program evaluation and continuous performance monitoring.
- J. Delivers strategic support to the FDA EC to ensure that program and project work aligns with FDA strategy and meets performance targets.
- K. Provides business, data, and systems analysis to understand the structure, policies, and operations of FDA organizations and programs, and recommends solutions to help the FDA EC achieve its goals.
- L. Utilizes a variety of analytical methods, models, and techniques to advance OET projects.
- M. Communicates changes to policies, business processes, procedures, and underlying IT systems so that new solutions are understood, adopted, and adhered to in support of business transformation.

2. Authority and Effective Date.

The functional statements for the Office of Enterprise Transformation were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024

**Department of Health and Human Services
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Enterprise Transformation organization structure depicting all the organizational structures reporting to the Director: