

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Food and Drug Administration**

**Office of the Commissioner**

**Office of Digital Transformation**

**Office of Information Management and Technology**

Effective: August 24, 2021

**1. Office of Information Management and Technology (DCADA).**

- A. Works in full partnership with the Chief Information Officer (CIO), Office of Digital Transformation (ODT) Senior Leadership, and FDA business areas to develop and communicate the overall vision, mission, values, and roadmap for the FDA's Information Technology (IT) program.
- B. Develops the architecture standards, policies, governance, best practices and technology road map that support the business priorities of the Food and Drug Administration (FDA) including managing information technology infrastructure, telecommunications, security, strategic planning, capital planning and investment control, enterprise architecture, and applications development and management.
- C. Provides consultation to the CIO, ODT Senior Leadership, and other key FDA officials on IT resources and programs, including activities that affect FDA-wide information technology programs, projects, and initiatives.
- D. Manages and executes strategic initiatives and special projects under the direction of the CIO and Chief Technology Officer (CTO) in alignment with ODT's and FDA's information technology goals, priorities, strategies, and activities.
- E. Responsible for the implementation of the FDA's IT policy and governance, procedures and processes to bring the FDA in conformance with the Clinger/Cohen Act and the Paperwork Reduction Act.
- F. Represents the FDA IT programs on internal and external meetings and workgroups on FDA information technology programs and issues.
- G. Establishes policies and procedures for system risk assessments and system business continuity and contingency planning.
- H. Provides expert technical evaluations and recommendations for new and secure emerging technologies to ensure the FDA's IT program can proactively adjust to dynamic business needs, change in mandates, and relevant external drivers.
- I. Manages and oversees special acquisition related services and support for large, complex, and ODT-wide acquisition programs, including guidance to the CIO and

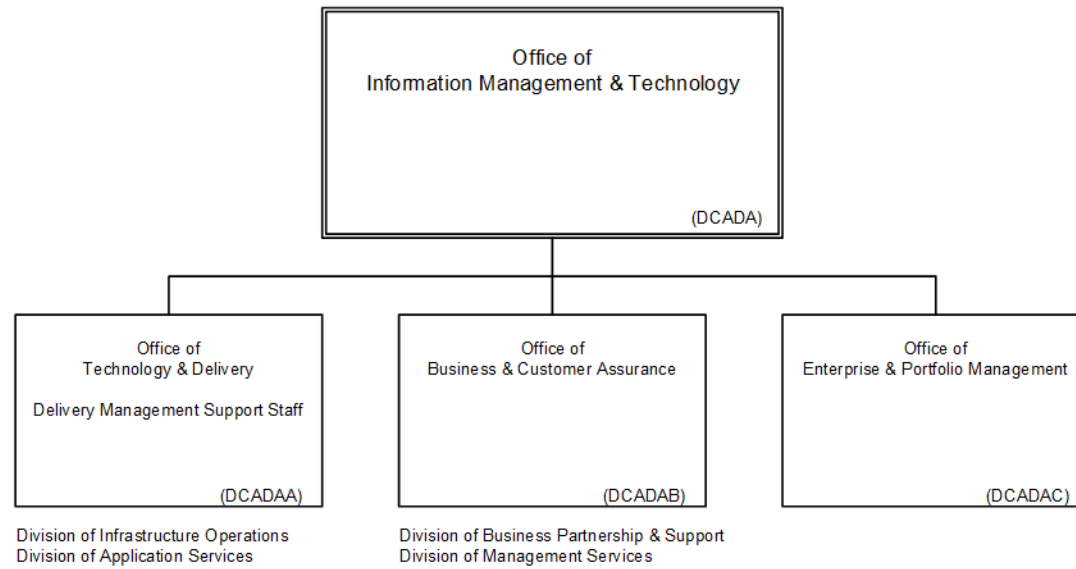
senior leaders on all aspects of contract administration and management, as well as serving as the leadership liaison with the Office of Acquisition and Grants Services (OAGS).

- J. Facilitates cross-FDA and HHS collaboration by leveraging business and technical subject matter expertise to recommend delivery efficiencies and reduce system, data and resource redundancy.
- K. Leads FDA's strategy, development, implementation, and procurement of cloud computing and scientific computing services.
- L. Develops the Food and Drug Administration's (FDA) Enterprise Architecture (EA) standards, policies, governance, and technology framework to support business priorities of the agency in accordance with Office of Management and Budget (OMB) Federal Enterprise Architecture Framework, Federal Information Security Modernization Act of 2014(FISMA), National Institute of Standards and Technology (NIST) Enterprise Architecture Model and HHS Enterprise Architecture guidelines.
- M. Works in complete partnership with the CIO, ODT Senior Leadership, and FDA business leaders to establish a best-in-class Solutions Architecture (SA) practice that services the FDA to enable its mission strategically, and efficiently by promoting and protecting public health.
- N. Leads, manages and oversees FDA's Enterprise Architecture Technology Advisory Board as a governing body to maximize use of IT resources with business and budget acuity across the FDA.

## **2. Authority and Effective Date**

The functional statements for the Office were approved by the Acting Commissioner of Food and Drugs on July 22, 2021 and effective on August 24, 2021.

**Department of Health and Human Services  
Food and Drug Administration  
Office of the Commissioner  
Office of Digital Transformation  
Office of Information Management & Technology**



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

The organizations below report to the Office of Information Management and Technology (DCADA):

Office of Technology and Delivery (DCADAA)

Office of Business and Customer Assurance (DCADAB)

Office of Enterprise Portfolio Management (DCADAC)

The organizations below report to the Office of Technology and Delivery (DCADAA):

Delivery Management Support Staff

Division of Infrastructure Operations

Division of Application Services

The organizations below report to the Office of Business and Customer Assurance (DCADAB):

Division of Business Partnership and Support

Division of Management Services