

SMG 1117A.72

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Information Management and Technology

Office of Informatics and Technology Innovation

Effective Date: December 14, 2018

1. Office of Informatics and Technology Innovation (DCNFB).

- A. Leads and implements enterprise cloud, high performance, and scientific efforts in support of the Food and Drug Administration (FDA) regulatory mission.
- B. Leads, researches and implements enterprise informatics solutions and standards in support of FDA regulatory mission.
- C. Focuses on agile practices to develop enterprise beta applications, hybrid cloud, mobility, tools, and software; conducts business and technical requirements analysis.
- D. Manages FDA's Scientific Computing Board (SCB) and advocates for cloud, scientific, and high-performance computing at the FDA level and advises on the prioritization and governance of major computational science initiatives. Facilitates FDA-wide IT, informatics, standards and scientific governance bodies (IO Council, SCB, FDA Data Standards Council, etc.).
- E. Conducts technical monitoring including accountability of projects.
- F. Supports scientific computing workstations, in the areas of deployment, updates including operating systems, Commercial Off-The-Shelf (COTS) and customized software and hardware and troubleshooting of problems with workstation hardware and software.

2. Informatics Standards Staff (DCNFB1)

- A. Foster, coordinate and sponsor standards-based electronic data submission, brokering, storage, retrieval, analysis, and knowledge dissemination.

- B. Assists in the development of the Knowledge Architecture through standards-based Master Data capability.
- C. Manages the FDA Data Standards Council and assists the Health Informatics leadership and the FDA's CIO Council to determine the Master data components including the use of industry data exchange standards and terminology.
- D. Defines, advocates and implements data exchange standards consistent with health information technology and the industry.
- E. Implements harmonized controlled vocabularies.
- F. Implements Master Data Management for key elements.
- G. Utilizes enterprise information flow processes.
- H. Transforms legacy data to standardized formats.
- I. Develops enterprise standards and messaging, transport data, create and implement enterprise lab strategies.

3. Knowledge Management Staff (DCNFB2)

- A. Plans, directs and coordinates FDA library programs to determine policy and provide oversight for the provision of library services and information with varied formats and purposes to better serve the FDA and the public.
- B. Provides research support to FDA through delivery of information consulting and advisory services, literature searches, and document delivery services for FDA to carry out its public health mission.
- C. Collaborates with FDA researchers on research projects, bibliographies, internal publication databases, copyright issues, digitization, etc. and provide FDA with information to meet its scientific and regulatory mission.
- D. Collects, organizes, maintains and preserves information resources, in multiple formats, in all areas of FDA's research and regulated products, including: biologics, blood products, cosmetics, devices, drugs, food processing and safety, nutrition, pharmacy, pharmacology, radiology, tobacco, toxicology, and veterinary medicine.
- E. Increases awareness of library services, staff expertise, and its research by promoting the library to customers. Provides services and resources to FDA, Health and Human Services (HHS), other Federal employees and the public on a limited basis.

- F. Selects, evaluates, acquires, develops and provides electronic access to scientific and technical databases, publications and other media mechanisms in support of FDA-wide research needs.
- G. Partners with libraries and information centers, publishers, consortia across the Federal Government, health related associations, and other organizations to enhance resource sharing opportunities that provide cost savings, sharing skills and knowledge, benchmarking best practices, and fostering collaborations that have a beneficial impact on the library and FDA's work.

4. Enterprise Architecture and Technology Innovation Staff (DCNFB3)

- A. Strengthen partnerships with all FDA components, HHA Operating Divisions (OPDIVs), departments, academia, industry, international collaborators, law enforcement and the media.
- B. Provides advice, expertise, collaborations and direction in the areas of market research, enterprise architecture, security and privacy, and infrastructure; includes hybrid cloud, and mobility. Liaise with the IT project management organizations and acquisition programs to ensure capital planning and acquisition guidelines are appropriately met for agile development.
- C. Explores healthcare IT solutions (e.g. electronic medical records, data standards, etc.) in collaboration with HHS OPDIVs and other healthcare organizations.
- D. Ensures alignment with FDA and Center-specific priorities for agile innovation and technology.
- E. Conducts studies and analyses to determine appropriate IT hardware, software and infrastructure requirements that includes capacity planning. Ensures FDA infrastructure is kept up to date with FDA technology standards.
- F. Provides technical consultation to FDA IT organizations to identify appropriate IT hardware, software and infrastructure requirements for new IT applications.
- G. Ensures adherence of FDA systems activities to enterprise architecture policies, standards and procedures.
- H. Establishes and implements an Enterprise IT Common Component Framework containing modules/services to be shared across the FDA's information systems and maintains FDA's enterprise applications.
- I. Assists in development and maintenance of FDA's policies and procedures for independent verification and validation of IT systems.

- J. Develops, implements and provides problem management processes for the FDA systems, including trend analysis of problems. Develops standard IT reports.
- K. Coordinates the development and implementation of FDA data administration policies, standards and procedures to ensure design consistency, including review of work products for compliance with standards and enterprise architecture.
- L. Evaluate FDA's new enterprise requirements and solutions, or new enhancements where applicable adherence with Office of Management and Budget (OMB) sanctioned plans such as cloud computing and incremental deliveries.
- M. Validates specifications, requirements, procedures guidelines and design of new enterprise requirements and solutions, new enhancements where applicable, and that system upgrades or modifications are in compliance with enterprise architecture. Performs enterprise systems analyses, develops and implements testing plans.
- N. Assists in the development and implementation of technical specifications and plans for procurement of cloud services, scientific and high-performance computing, and IT equipment (hardware and software) and support resources required for systems integration.
- O. Leads FDA's strategy, development, and implementation of a) cloud, high performance and scientific computing, b) sharing publicly safe information and applications with the public, and c) new innovations.

5. Authority and Effective Date.

The functional statements for the Office of Informatics and Technology Innovation were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Information Management and Technology, Office of Informatics and Technology Innovation organization structure depicting all the organizational structures reporting to the Director.

These organizations below report to the Office of Informatics and Technology Innovation (DCNFB)

Informatics Standards Staff

Knowledge Management Staff

Enterprise Architecture and Technology Innovation Staff