

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF OPERATIONS

OFFICE OF INFORMATION MANAGEMENT AND TECHNOLOGY

OFFICE OF INFORMATION MANAGEMENT

OFFICE OF TECHNOLOGY AND DELIVERY

DIVISION OF APPLICATION SERVICES

Effective Date: 01/27/2014

1. DIVISION OF APPLICATION SERVICES (DMMHAAB)

- A. Designs, develops, implements, and maintains Agency software applications, Commercial Off-The-Shelf (COTS) software, Information Technology (IT) systems, systems support and maintenance, and their integration as cloud computing, incremental deliveries, and structured governance principles.
- B. Establishes and implements an Enterprise IT Common Component Framework containing modules/services to be shared across Agency information systems and maintains Agency enterprise applications.
- C. Designs, develops, implements, and maintains standards-based electronic IT data systems and repositories with an integrated and interoperable information environment to receive, track, report, analyze, and disseminate knowledge on Agency business/program activities.
- D. Directs the development and implementation of Agency Data Administration policy standards and procedures to ensure design consistency, including review of work products for compliance with standards.
- E. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of Agency software applications.
- F. Develops and implements a program risk management plan to oversee and mitigate critical risks and vulnerabilities in the execution of the IT systems.

- G. Partners with the Chief Information Officer (CIO) in development and maintenance of Agency's policies and procedures for independent verification and validation of IT systems.
- H. Develops, implements, and provides problem management processes for the Agency applications, including trend analysis of problems experienced.

2. APPLICATION MANAGEMENT SERVICES STAFF (DMMHAAB1)

- A. Establishes and implements an Enterprise IT Common Component Framework for use in application design, development, testing, implementation, operation, and maintenance of Agency applications.
- B. Validates requirements and performs systems analyses to develop and implement quality assurance and testing strategies, procedures and methodologies, especially automated varieties.
- C. Develops and implements system specifications, requirements, procedures and guidelines related to software quality assurance and testing.
- D. Supports Agency through effective evaluation and creation of streamlined application development methodologies, monitoring, testing, and integration of application technologies utilizing interchangeable common components in order to support Agency business process needs and objectives efficiently and effectively.
- E. Develops and implements a program risk management plan to oversee and mitigate critical risks and vulnerabilities in the execution of the systems under its responsibility.
- F. Interfaces with and supports Division of Application Services (DAS) Project Management personnel on standards and implementation processes.
- G. Develops, implements, and provides problem management processes for Agency applications, including trend analysis of problems experienced.
- H. Provides general operational support including asset management, budget control and administrative services in support of DAS.
- I. Develops, implements and manages system specifications, requirements, procedures and guidelines related to software license management including acquisition strategy, procurement, usage reporting and alternative analysis.

3. DATA MANAGEMENT AND OPERATIONS BRANCH (DMMHAAB2)

- A. Designs, develops, implements, and maintains standards-based electronic IT data systems and repositories that provide the Agency with an integrated and interoperable information environment.
- B. Directs the development and implementation of Agency Data Administration policies, standards and procedures to ensure design consistencies, including review of work products for compliance with standards.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of Agency software applications.
- D. Develops, implements, and provides problem management processes for the Agency applications, including trend analysis of problems experienced.

4. MEDICAL PRODUCTS BRANCH (DMMHAAB3)

- A. Designs, develops, implements, and maintains Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH) software applications, COTS, Information Technology (IT) systems, systems support and maintenance, and their integration with other Federal Agencies, State and Foreign Governments; and public and private entities by utilizing OMB sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.
- B. Validates requirements and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the Agency, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of Agency software applications.

5. OFFICE OF THE COMMISSIONER/CENTER FOR VETERINARY MEDICINE/CENTER FOR TOBACCO PRODUCTS BRANCH (DMMHAAB4)

- A. Designs, develops, implements, and maintains all Center for Tobacco Products (CTP), and Center for Veterinary Medicine (CVM) software applications, COTS,

Information Technology (IT) systems, systems support and maintenance, and their integration with other Federal Agencies, State and Foreign Governments; and public and private entities by utilizing OMB sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.

- B. Validates requirements for and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the Agency, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of Agency software applications.

6. OFFICE OF REGULATORY AFFAIRS/CENTER FOR FOOD SAFETY AND NUTRITION BRANCH (DMMHAAB5)

- A. Designs, develops, implements, and maintains the Office of Regulatory Affairs (ORA) and the Center for Food Safety and Applied Nutrition (CFSAN) software applications, COTS, Information Technology (IT) systems, systems support and maintenance, and their integration with other Federal Agencies, State and Foreign Governments; and public and private entities by utilizing OMB sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.
- B. Validates requirements and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the Agency, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of Agency software applications.

7. ENTERPRISE APPLICATIONS BRANCH (DMMHAAB6)

- A. Designs, develops, implements, and maintains the Agency-Wide software applications, COTS, Information Technology (IT) systems, systems support and maintenance, and their integration with other Federal Agencies, State and Foreign Governments; and public and private entities by utilizing OMB

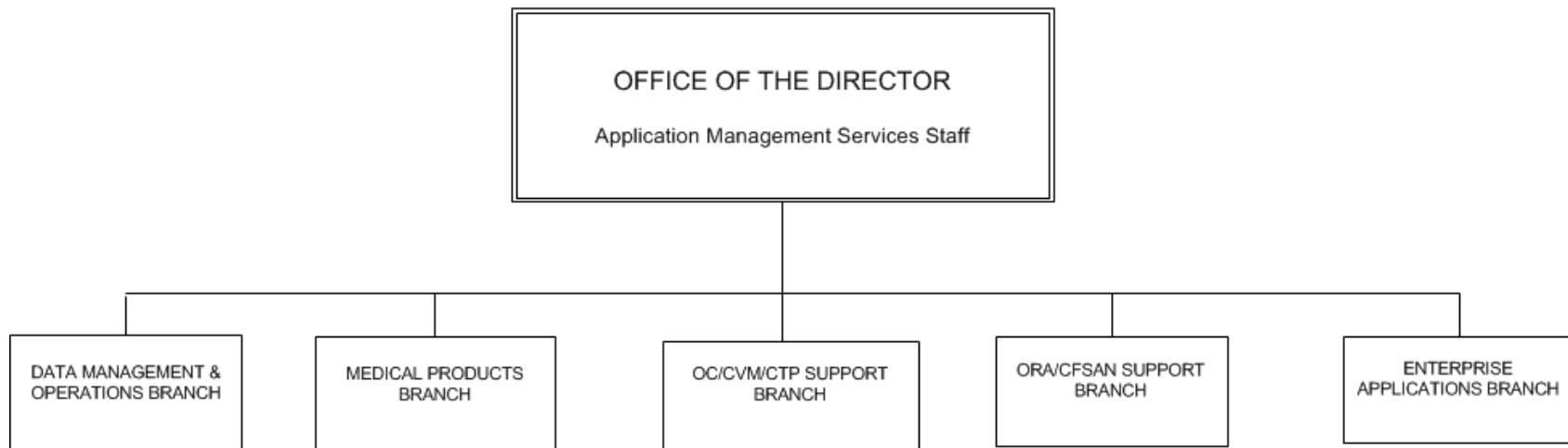
sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.

- B. Validates requirements and directs the design, development and implementation of new system requirements, system enhancements and system maintenance changes for the OC and Agency-wide applications, performs systems analyses to develop and implement testing strategies, procedures and methodologies, especially automated varieties, and develops and implements system specifications, requirements, procedures and guidelines.
- C. Partners in the development and implementation of technical specifications and plans for procurement of IT equipment (hardware and software) and support resources required for the integration and operation of Agency software applications.

8. AUTHORITY AND EFFECTIVE DATE

The functional statements for this office were approved by the Deputy Commissioner for Operations and Chief Operating Officer, effective January 27, 2014.

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DIVISION OF APPLICATIONS SERVICES



STAFF MANUAL GUIDE 1117.2112
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: January 27, 2014

The following is the Food and Drug Administration, Office of Operations, Office of Information Management and Technology, Office of Information Management, Office of Technology and Delivery, Division of Application Services organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- APPLICATION MANAGEMENT SERVICES STAFF
- DATA MANAGEMENT AND OPERATIONS BRANCH
- MEDICAL PRODUCTS BRANCH
- OFFICE OF THE COMMISSIONER/CENTER FOR VETERINARY MEDICINE/CENTER FOR TOBACCO PRODUCTS BRANCH
- OFFICE OF REGULATORY AFFAIRS/CENTER FOR FOOD SAFETY AND APPLIED NUTRITION BRANCH
- ENTERPRISE APPLICATIONS BRANCH