

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF SURVEILLANCE AND BIOMETRICS

Effective Date: January 7, 2015

1. OFFICE OF SURVEILLANCE AND BIOMETRICS (DKKWH).

- A. Provides statistical, epidemiological, and biometric services, and conducts research in support of the operating and scientific programs of the Center.
- B. Represents the Center with other governmental agencies (Federal, State, and International), industry, and consumer organizations on issues related to the activities of the Office including postmarket management activities.
- C. Plans, develops, and implements office administrative support and services including program planning, financial management, extramural and collaborative efforts, procurement, travel, personnel administration, employee development and training, employee evaluations, recognition programs, property management, and facility space management.
- D. Develops target knowledge management initiatives to capture knowledge embedded in databases, with subject matter experts and knowledge created in social interactions. Engages staff in developing and implementing knowledge management tools and processes that support a broad, sustained knowledge management program.

2. PROGRAM MANAGEMENT STAFF (DKKWH2).

- A. Provides leadership and support to the Office of the Director and Division Directors on all administrative and management issues.
- B. Plans, develops, and implements Center and the Office of Surveillance Biometrics (OSB) programmatic matters concerning financial management, personnel, procurement, contracts, inter-agency agreements, employee training, and facilities

- C. Manages and administrates OSB resources designed to support ongoing programs.
- D. Ensures proper distribution of operating and payroll dollars, facility plans, procurement and property, travel requests and automatic data processing needs.
- E. Advises the Office of the Director on potential issues that may affect resources, staffing, and management issues to comply with policies and avoid potential conflicts.
- F. Directs and conducts special assignments or projects for the Center as well as the Office Director.

3. INFORMATICS STAFF (DKKWH3).

- A. Oversees the coordination of the Informatics program in the Center, supports the Data Management Work Group, with responsibilities in data sharing, data standards, data stewardship, and the roadmap for implementation, which affect all premarket and postmarket efforts. Advises and supports the Office Director and key Agency officials concerning the Center's business informatics activities.
- B. Supports regulatory authority around Unique Device Identification (UDI) through development and implementation of the UDI proposed rule, UDI guidance, UDI database, and support of UDI integration into existing Center databases and external data sources.
- C. Provides interpretation of regulatory requirements and establishes policies and procedures relating to those requirements through issuance of guidance and related documents.
- D. Develops and advocates for Center Data Standards and Master Data Management Strategy, including development of a roadmap for implementing the strategy. Promotes visibility of Center's participation in standards development within the existing framework of the Center Standards Program (i.e., CDISC, SNOMED, NCI, ISO, HL7, AAMI, AHRQ, ONC, NIST).
- E. Coordinates with other Agency data standards boards on projects related to the development of data exchange and vocabulary standards affecting medical devices and establishes relationships with external stakeholders to maintain knowledge of current standards and educate the Center staff to keep them abreast on new standards initiatives both within and outside the Agency.

4. SIGNAL MANAGEMENT STAFF (DKKWH4).

- A. Plans, develops and implements the policies, procedures, and processes associated with the evaluation and development of mitigation strategies, and

medical device-related safety signals detected by Center staff or outside stakeholders.

- B. Maintains, coordinates, and manages the Center's Signal Management Governance Board composed of management representatives from each programmatic Office in the Center in order to maintain cross-center processes and integration.
- C. Provides leadership of multi-disciplinary cross-Center teams assembled for the evaluation and mitigation of newly identified device safety signals.
- D. Assists in the gathering, analysis, and presentation of data intended to assist Center subject matter experts in understanding and addressing device-related safety signals.
- E. Tracks and documents the progress and outcomes of safety signals evaluated within the Program and/or assigned out to other Offices for action.
- F. Provides education for Center staff regarding the Signal Management goals, processes.

9. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health and effective on January 7, 2015.

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OFFICE OF THE DIRECTOR

Program Management Staff
Informatics Staff
Signal Management Staff

STAFF MANUAL GUIDE 1256.1
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: January 7, 2015

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Surveillance and Biometrics organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- PROGRAM MANAGEMENT STAFF
- INFORMATICS STAFF
- SIGNAL MANAGEMENT STAFF