

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF OPERATIONS

OFFICE OF MEDICAL PRODUCTS AND TOBACCO OPERATIONS

DIVISION OF MEDICAL PRODUCTS AND TOBACCO PROGRAM OPERATIONS

Effective Date: 08/07/2012

1. DIVISION OF MEDICAL PRODUCTS AND TOBACCO PROGRAM OPERATIONS (DLLRIDA).

- A. Serves as the Agency focal point for coordinating, directing, and assisting the field and Headquarters with domestic and international medical products and tobacco investigative activities.
- B. Serves as operational medical products and tobacco liaison to FDA's foreign offices; provides inspectional and technical assistance to FDA's field and foreign offices.
- C. Coordinates international medical products and tobacco regulatory activities. Participates in harmonization efforts with other FDA components and national and international governments.
- D. Develops, reviews, and recommends procedures for inclusion in the Agency's various guidance manuals. Reviews policy documents relative to the investigation and evaluation of the compliance of regulated medical product and tobacco facilities with the laws and regulations administered by the Agency.
- E. Serves as subject matter experts on field operations relative to medical products and tobacco on internal cross Agency committees, workgroups and task forces.
- F. Assists with responses to adverse event reports relative to medical products and drug shortages.

2. MEDICAL PRODUCTS AND TOBACCO PROGRAM OPERATIONS BRANCH (DLLRIDA1).

- A. Serves as the Agency focal point coordinating, directing, and assisting the field and headquarters with medical products and tobacco investigative activities.
- B. Develops, reviews, and recommends procedures and guidance manuals for investigating and evaluating the compliance of regulated medical products and tobacco industries with laws and regulations administered by the Agency.
- C. Creates reviews, clears and/or issues field assignments. Serves as technical point of contact for these assignments and monitors outcomes of assignments.
- D. Provides inspectional and technical assistance to FDA field and foreign offices.
- E. Provides technical expertise in investigations operations and manages the Medical Products and Tobacco National Experts Program.
- F. Performs medical product and tobacco inspections.
- G. Identifies and advocates for medical product and tobacco investigator training needs at the district, regional and national level and, as subject matters experts, participate in the design, implementation, and presentation of these training programs.
- H. Monitors emerging issues and advancements in technology and recommends and coordinates implementation into the Agency's medical products and tobacco investigative activities.

3. TEAM BIOLOGICS BRANCH (DLLRIDA2).

- A. Coordinates development of the Agency-wide bioresearch monitoring activities; monitors compliance activities to assure uniform application of compliance policies; serves as liaison with other Federal agencies and outside organizations relative to Agency-wide bioresearch monitoring activities.
- B. Provides policy and program direction to Agency units carrying out the objectives of the Bioresearch Monitoring Program (BMP). Coordinates assignments involving multiple FDA Centers and interagency inspectional assignments. Monitors Agency performance in meeting program accomplishment projections for the BMP.
- C. Evaluates proposed disqualification recommendations of clinical investigators, institutional review boards, and toxicology laboratories.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner of Food and Drugs on August 7, 2012.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
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DIVISION OF MEDICAL PRODUCTS AND TOBACCO PROGRAM
OPERATIONS**

OFFICE OF THE DIRECTOR

Medical Device and Tobacco Program
Operations Branch
Team Biological Branch

STAFF MANUAL GUIDE 1121.832
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: August 7, 2012

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Operations, Office of Medical Products and Tobacco Operations, Division of Medical Products and Tobacco Program Operations organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Medical Products & Tobacco Operations Branch
- Team Biologics Branch