

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Medical Products and Tobacco Operations

Office of Bioresearch Monitoring Operations

Division of Bioresearch Monitoring Operations II

Effective Date: December 14, 2018

1. Division of Bioresearch Monitoring Operations II (DCIGAB).

- A. Manages field inspection and compliance operations within the Division for the Bioresearch Monitoring Operations (BIMO) program.
- B. Manages and evaluates resource use, operational activities, and all phases of personnel management, financial management, property and supplies for the Division in support of the BIMO program.
- C. Conducts inspections and investigations, collects samples for analysis, and prepares reports in the BIMO program.
- D. Recommends legal action and assists in implementing approved action.
- E. Manages and evaluates BIMO program activities and manages a quality assurance program.
- F. Develops short and long-range work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program.
- G. Advises the BIMO Program Director of emerging problems, trends, program needs and any local or state issues.
- H. Prepares and provides evidence of investigational findings.
- I. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow up, including regulatory or legal action to Food

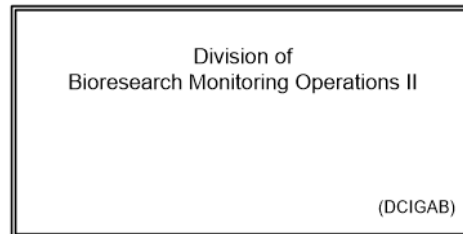
and Drug Administration (FDA) Center Offices when indicated. Assists in implementing approved action.

- J. Performs special investigations; investigates reports of adverse experience with any FDA-regulated products used in clinical or nonclinical research; and conducts inspections and investigations related to any emergencies associated with FDA-regulated products.
- K. Provides inspectional and investigational support to ORA Headquarters, the Centers, and other Divisions as needed.
- L. Provides counsel and training regarding inspectional techniques and technical developments to other Federal agencies, State, local, and foreign counterpart agencies, and industry as appropriate.
- M. Maintains cooperative relationships with other Federal agencies and develops work and information sharing agreements.
- N. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Maintains cooperative relationships with State and local counterpart agencies, and develops work and information sharing agreements. Presents public education and information programs to various external stakeholders and organizations.

2. Authority and Effective Date.

The functional statements for the Division of Bioresearch Monitoring Operations II were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Products and Tobacco Operations
Office of Bioresearch Monitoring
Division of Bioresearch Monitoring Operations II**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Bioresearch Monitoring, Division of Bioresearch Monitoring Operations II organization structure depicting all the organizational structures reporting to the Director:

Division of Bioresearch Monitoring Operations II (DCIGAB)