

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Bioresearch Monitoring Inspectorate

Division of Bioresearch Monitoring Global Operations

Effective Date: May 13, 2024

- 1. Division of Bioresearch Monitoring Global Operations (DCSEA).**
 - A. Coordinates and directs foreign bioresearch monitoring investigative activities in collaboration with Centers and Offices.
 - B. Serves as subject matter experts on foreign operations relative to bioresearch monitoring on internal cross Food and Drug Administration (FDA) committees, workgroups, and task forces.
 - C. Supports bioresearch monitoring-related emergency response activities.
 - D. Serves as operational liaison for foreign bioresearch monitoring inspection programs to FDA's foreign and other offices.
 - E. Manages the foreign bioresearch monitoring inspection cadre.
 - F. Inspects foreign bioresearch monitoring establishments for which the FDA has regulatory responsibilities, collects samples for analysis, performs field examinations and prepares reports for Centers and Offices.
 - G. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up to Centers and Offices.
 - H. Monitors emerging issues and advancements in bioresearch technology.
- 2. Bioresearch Monitoring Foreign Investigations Branch 1 (DCSEA1).**
 - A. Coordinates and directs foreign bioresearch monitoring investigative activities in collaboration with Centers and Offices.

- B. Serves as subject matter experts on foreign operations relative to bioresearch monitoring on internal cross-FDA committees, workgroups, and task forces.
- C. Supports bioresearch monitoring-related emergency response activities.
- D. Serves as operational liaison for foreign bioresearch monitoring inspection programs to FDA's foreign and other offices.
- E. Manages the foreign bioresearch monitoring inspection cadre.
- F. Inspects foreign bioresearch monitoring establishments for which FDA has regulatory responsibilities, collects samples for analysis, performs field examinations and prepares reports for Centers and Offices.
- G. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up to Centers and Offices.
- H. Monitors emerging issues and advancements in bioresearch monitoring technology.

3. Bioresearch Monitoring Foreign Investigations Branch 2 (DCSEA2).

- A. Coordinates and directs foreign bioresearch monitoring investigative activities in collaboration with Centers and Offices.
- B. Serves as subject matter experts on foreign operations relative to bioresearch monitoring on internal cross-FDA committees, workgroups, and task forces.
- C. Supports bioresearch monitoring-related emergency response activities.
- D. Serves as operational liaison for foreign bioresearch monitoring inspection programs to FDA's foreign and other offices.
- E. Manages the foreign bioresearch monitoring inspection cadre.
- F. Inspects foreign bioresearch monitoring establishments for which FDA has regulatory responsibilities, collects samples for analysis, performs field examinations and prepares reports for Centers and Offices.
- G. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up to Centers and Offices.
- H. Monitors emerging issues and advancements in bioresearch monitoring technology.

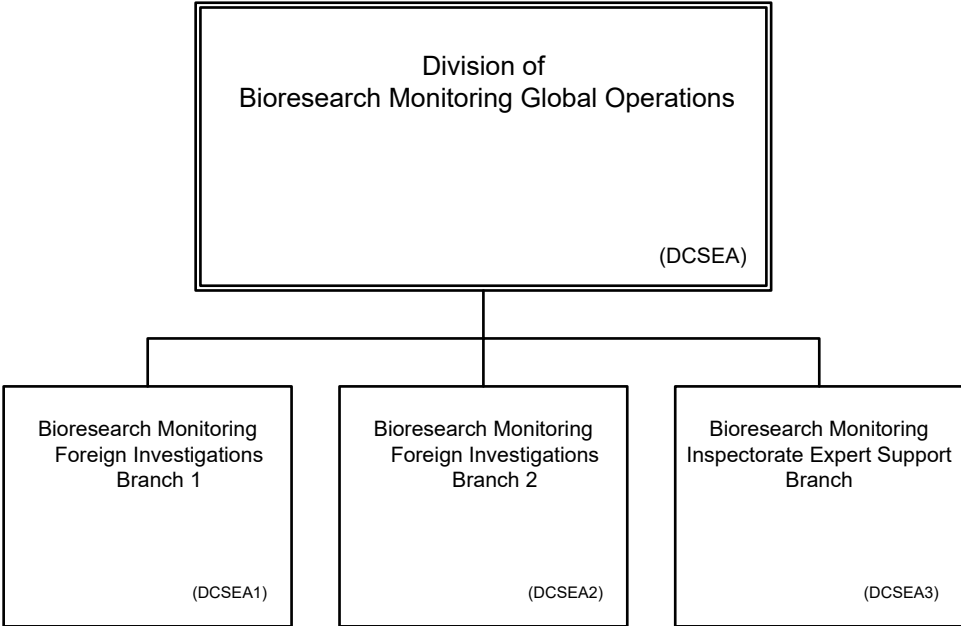
4. Bioresearch Monitoring Inspectorate Expert Support Branch (DCSEA3).

- A. Reviews Center and Office issued bioresearch monitoring inspectional and investigational assignments.
- I. Supports bioresearch monitoring-related emergency response activities.
- J. Supports the development and implementation of domestic bioresearch monitoring inspectional work plans.
- K. Serves as subject matter experts on bioresearch monitoring inspectional operations on internal cross-FDA committees, workgroups, and task forces.
- L. Serves as subject matter experts for developing and delivering training relative to bioresearch monitoring inspections and investigations in consultation with Centers and Offices.
- M. Provides subject matter expertise support to field investigators related to bioresearch monitoring inspections and investigations.
- N. Evaluates domestic inspectional and analytical findings relative to compliance and recommends appropriate follow-up to Centers and Offices.
- O. Serves as subject matter experts and liaison with other BIMO program offices and industry officials to provide guidance on questions related to clinical and nonclinical research in support of marketing applications.

5. Authority and Effective Date.

The functional statements for the Division of Bioresearch Monitoring Global Operations were approved by the Secretary for Health and Human Services and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Bioresearch Monitoring Inspectorate
Division of Bioresearch Monitoring Global Operations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Bioresearch Monitoring Inspectorate, Division of Bioresearch Monitoring Global Operations organization structure depicting all the organizational structures reporting to the Director:

Bioresearch Monitoring Foreign Investigations Branch 1 (DCSEA1)
Bioresearch Monitoring Foreign Investigations Branch 2 (DCSEA2)
Bioresearch Monitoring Inspectorate Expert Support Branch (DCSEA3)