SMG 1121A.44

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 Biologics Inspectorate

Division of Biotechnology Inspectorate

Effective Date: May 13, 2024

1. Division of Biotechnology Inspectorate (DCSDE).

A. Manages field inspection operations within the associated division for products regulated by the Center for Biologics Evaluation and Research (CBER) at the request of and in coordination with Centers and Offices.

B. Manages and evaluates resource use in support of the biologics program in coordination with Centers and Offices.

C. Conducts and monitors investigations and inspection activities related to biological products regulated by CBER.

D. Refers inspections with 483 observations for consideration of regulatory and enforcement action and assists in implementing approved action at the directions of the Centers and Offices, including liaising with United States (U.S.) Attorneys and U.S. Marshals and ensuring court-ordered actions are completed on time and in total fulfillment of the Court's order. Recommends legal action and assists in implementing approved action.

E. Manages and evaluates biologics program activities and manages a quality assurance program in coordination with Centers and Offices.

F. Develops short and long-range work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program in coordination with Centers and Offices.

G. Advises the Office of Biological Products Operations Inspectorate Director of emerging problems, trends, program needs and any local or state issues.

H. Manages program administrative and operational activities, including all phases of personnel management, financial management, property, and supplies for the Division.

I. Participates in regulatory meetings on alleged violations.

J. Collaborates with Centers and Offices on the development and updates to Compliance Programs relevant to CBER regulated products.

K. Develops, reviews, and analyzes, in coordination with Centers and Offices, regulations and policies that apply to the inspection of products regulated by CBER.

L. Decides whether remote regulatory assessment/alternative tool is appropriate for the purposes of oversight of a regulated establishment in coordination with Centers and Offices.

M. Reviews complaints received regarding regulated products and conducts appropriate inspection/investigation follow-up in coordination with Centers and Offices.

2. Biotechnology Investigations Branch 1 (DCSDE1).

A. Performs inspections of biological drug products, such as vaccines, cellular and gene therapies, allergenics, and live biotherapeutic agents' products regulated by CBER and prepares reports for Centers and Offices at the request of the Centers and Offices.

B. Refers inspections and investigations with 483 observations to CBER for consideration of appropriate follow-up.

C. Evaluates and determines effectiveness of corrective actions taken by biologics establishments and provides feedback to Centers and Offices.

D. Prepares and provides evidence of investigational findings.

E. Plans, schedules, and controls biologics inspectional and investigational operations in coordination with Centers and Offices.

F. Supports the development and implementation of domestic and foreign inspectional work plans in collaboration with CBER.

G. Participates as subject matter experts in the design, implementation and presentation of biological drug, device, and vaccine training programs.

H. Monitors emerging issues and advancement in biological drug, device and vaccine product development and manufacturing technology.

I. Plans and evaluates program activities and manages a Quality Assurance Program in coordination with Centers and Offices.

J. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience; and performs pre-market activities of biological products when requested.

K. Performs follow-up activities to assess recall effectiveness and prevent recurrences.

L. Maintains cooperative relationships with State and local counterpart agencies. Collaborates with state and local officials to enable information sharing and to leverage regulatory authorities. Participates as subject matter experts in the design, implementation, and presentation of inspection training programs.

M. Conducts a remote regulatory assessment/alternative tool when appropriate for the purposes of oversight of a regulated establishment in coordination with Centers and Offices.

N. Reviews complaints received regarding regulated products and conducts appropriate inspection/investigation follow-up in coordination with Centers and Offices.

3. Biotechnology Investigations Branch 2 (DCSDE2).

A. Performs inspections of biological drug products, such as vaccines, cellular and gene therapies, allergenics, and live biotherapeutic agents' products regulated by CBER and prepares reports for Centers and Offices at the request of the Centers and Offices.

B. Refers inspections and investigations with 483 observations to CBER for consideration of appropriate follow-up.

C. Evaluates and determines effectiveness of corrective actions taken by biologics establishments and provides feedback to Centers and Offices.

D. Prepares and provides evidence of investigational findings.

E. Plans, schedules, and controls biologics inspectional and investigational operations in coordination with Centers and Offices.

F. Develops Supports the development and implementation of domestic and foreign inspectional work plans in collaboration with CBER.

G. Participates as subject matter experts in the design, implementation and presentation of biological drug, device, and vaccine training programs.

H. Monitors emerging issues and advancement in biological drug, device and vaccine product development and manufacturing technology.

I. Plans and evaluates program activities and manages a Quality Assurance Program in coordination with Centers and Offices.

J. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience; and performs pre-market activities of biological products when requested.

K. Performs follow-up activities to assess recall effectiveness and prevent recurrences.

L. Maintains cooperative relationships with State and local counterpart agencies. Collaborates with state and local officials to enable information sharing and to leverage regulatory authorities. Participates as subject matter experts in the design, implementation, and presentation of inspection training programs.

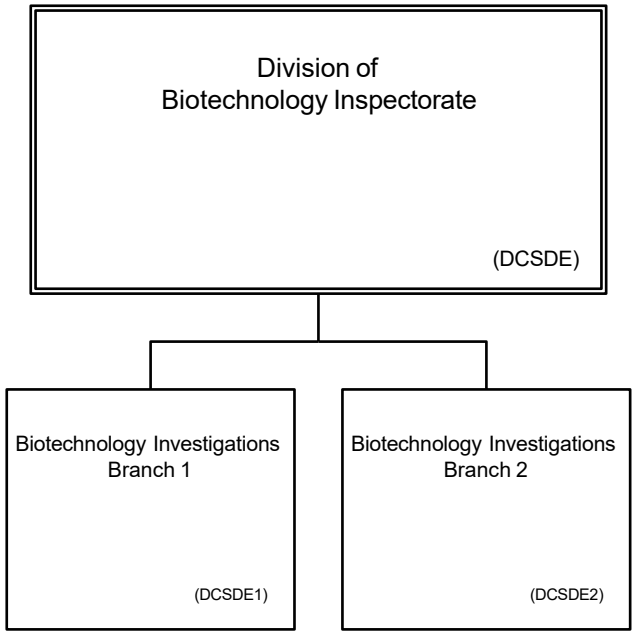
M. Conducts a remote regulatory assessment/alternative tool when appropriate for the purposes of oversight of a regulated establishment in coordination with Centers and Offices.

N. Reviews complaints received regarding regulated products and conducts appropriate inspection/investigation follow-up in coordination with Centers and Offices.

4. Authority and Effective Date.

The functional statements for the Division of Biotechnology Inspectorate were approved by the Secretary for Health and Human Services on March 5, 2024, and effective on May 13, 2024.

Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Biologics Inspectorate
Division of Biotechnology Inspectorate



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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 Biologics Inspectorate, Division of Biotechnology Inspectorate organization structure depicting all the organizational structures reporting to the Director:

Biotechnology Investigations Branch 1 (DCSDE1)
Biotechnology Investigations Branch 2 (DCSDE2)