SMG 1121A.4

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

Effective Date: May 13, 2024

1. Office of Biologics Inspectorate (DCSD).

A. Provides direction and guidance to the Office of Inspections and Investigations (OII) senior leaders and other Food and Drug Administration (FDA) leaders relative to biological products, field operations, and emergency response activities, including all biological and biopharmaceutical products regulated by the Center for Biologics Evaluation and Research (CBER) and the animal cells, tissues, and cell- and tissue-based products (ACTPs) and intentional genomic alterations (IGA) in animals regulated by the Center for Veterinary Medicine (CVM) in coordination with Centers and Offices.

B. Conducts investigations and inspections of biological products regulated b CBER and ACTPs and IGA in animals regulated by CVM as directed by Centers and Offices.

C. Coordinates, directs, and assists with investigative activities for biological products regulated by CBER and ACTPs and IGA in animals regulated by CVM in collaboration with Centers and Offices.

D. In collaboration with the Centers and Offices, establish inspection goals that align with the resource capacity of OII.

E. Supports the development of inspectorate policy and guidance for investigations for biological products regulated by CBER and ACTPs and IGA in animals regulated by CVM at the direction of the center.

F. Participates, as needed, in systems recognition efforts with FDA Centers and Offices and national and international governments.

G. Facilitates and leads the design, implementation, and presentation of biologics and ACTP and IGA in animals training programs in coordination with Centers and Offices.

H. Monitors emerging issues and advancements in technology and initiates program improvements as necessary in coordination with Centers and Offices.

I. Serves as subject matter expert on field operations relative to external and internal cross-FDA biologics and ACTP and IGA in animals program committees, workgroups and task forces.

J. Coordinates issuance of field assignments with CBER for biologics programs and CVM for ACTPs and IGA in animals in collaboration with Centers and Offices.

K. Leads cooperative relationships with State, local and other Federal agencies; serves on interagency councils, encourages improved State and local consumer protection programs pertinent to FDA-enforced laws and regulations related to biologics regulated by CBER and ACTPs and IGAs in animals regulated by CVM.

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

M. Coordinates emergency activities across the FDA and provides assistance to Department of Health and Human Services components and other external stakeholders in the event of a natural disaster or other emergencies.

N. Provides technical assistance for investigational operations regarding biological product and ACTP and IGA in animals.

O. Directs and coordinates OII response to reports of adverse events relative to potential product shortages in collaboration with the Centers and Offices.

2. Biologics Global Operations Staff (DCSD1).

A. Coordinates and clears and/or issues biological products and ACTP/IGA in animals field assignments, including responses to adverse event reports, emergency response activities, and product shortages in collaboration with Centers and Offices. Serves as technical point of contact for these assignments and monitors outcomes.

B. Provides technical and programmatic expertise to the field, Centers, and Offices through national technical and program experts.

C. Coordinates the design, implementation, and presentation of biologics and ACTP and IGA in animals training programs in collaboration with Centers and Offices.

D. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations, including the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and International Conference on Harmonization (ICH), as appropriate.

E. Monitors emerging issues and advancements in the biologics program and ACTPs and IGA in animals regulated by CVM.

F. Maintains official establishment inventory for biologics regulated by CBER and ACTPs and IGA in animals regulated by CVM.

G. Coordinates and monitors follow-up activities to recalls and complaints related to biologics regulated by CBER and ACTPs and IGA in animals regulated by CVM.

H. Coordinates foreign inspection program for biologics regulated by CBER and ACTPs and IGAs in animals regulated by CVM.

I. Coordinates, directs, and assists the Divisions and OII Headquarters with domestic and international investigative activities related to biological and biopharmaceutical products regulated by CBER and ACTPs and IGA in animals regulated by CVM in coordination with Centers and Offices.

J. Provides expert inspectional and technical assistance to divisions and foreign offices on biological product and ACTP and IGA in animals inspection and regulatory matters.

K. Participates as subject matter experts in the design, implementation, and presentation of biologics and ACTP and IGA in animals training programs.

L. Serves as subject matter expert on field operations relative to the biologics program and ACTPs and IGA in animals on external and internal cross-FDA committees, workgroups, and task forces.

M. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations, including the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and International Conference on Harmonization (ICH), as appropriate.

N. Provides biologics program and ACTP/IGA in animals technical assistance and training to other regulatory and public health partners.

O. Creates, clears and/or issues biological products field assignments, including responses to adverse event reports relative to biological products, emergency response activities, and product shortages in coordination with Centers and Offices. Serves as technical point of contact for these assignments and monitors outcomes.

P. Coordinates implementation of user fee programs and collection and analysis of related performance goal data for OII activities.

Q. Implements biological program work plans within the Office in coordination with Centers and Offices. Assists other offices and divisions in interpretation of work plan implementation.

R. Reviews and evaluates implementation of existing procedures and guidance related to biological products and ACTPs and IGAs in animals.

S. Participates as subject matter experts in the design, implementation, and presentation of biologics and ACTP and IGA in animals training programs.

T. Plans and evaluates program activities and manages a Quality Assurance Program.

U. Serves as subject matter expert on field operations relative to the biologics program and ACTPs and IGA in animals on external and internal cross-FDA committees, workgroups, and task forces.

V. Performs biologics and ACTP/IGA inspections, as necessary.

W. Provides biologics program and ACTP/IGA technical assistance and training to other regulatory and public health partners.

X. Assists with responses to adverse event reports relative to biological products and ACTP/IGA in animals.

Y. Maintains official establishment inventory for biologics regulated by CBER and ACTPs and IGA in animals regulated by CVM, including updates to firm registration data.

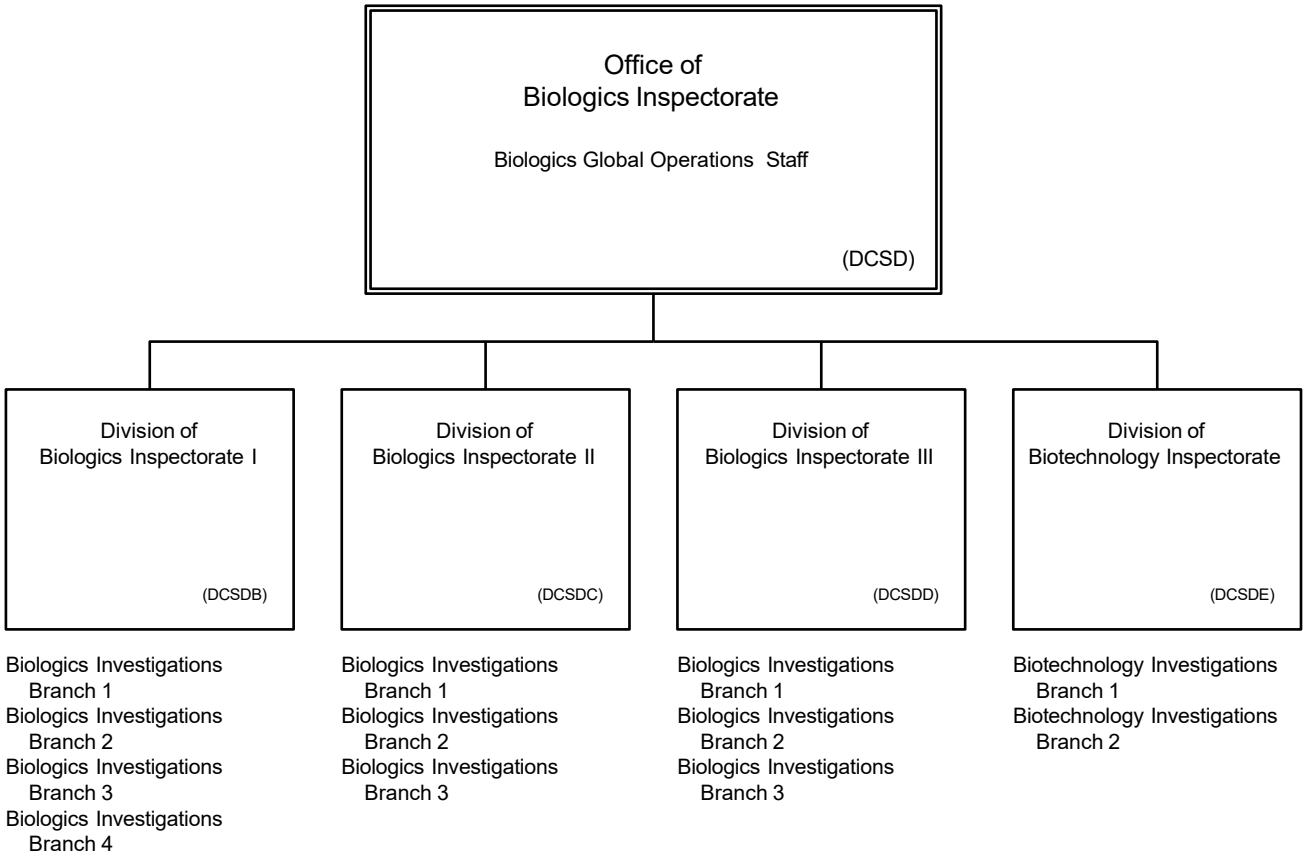
Z. Coordinates and monitors follow-up activities to recalls and complaints related to biologics regulated by CBER and ACTPs and IGA in animals regulated by CVM.

AA. Develops the foreign workplan for the biologics program and ACTPs and IGAs in animals regulated by CVM in collaboration with CBER and CVM and issues the inspection assignments.

3. Authority and Effective Date.

The functional statements for the Office of Biologics Inspectorate were approved by the Secretary of 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



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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 organization structure depicting all the organizational structures reporting to the Director:

Biologics Global Operations Staff
Division of Biologics Inspectorate I (DCSDB)
Division of Biologics Inspectorate II (DCSDC)
Division of Biologics Inspectorate III (DCSDD)
Division of Biotechnology Inspectorate (DCSDE)

These organizations report to the Division of Biologics Inspectorate I (DCSDB):

Biologics Investigations Branch 1
Biologics Investigations Branch 2
Biologics Investigations Branch 3
Biologics Investigations Branch 4

These organizations report to the Division of Biologics Inspectorate II (DCSDC):
Biologics Investigations Branch 1
Biologics Investigations Branch 2
Biologics Investigations Branch 3

These organizations report to the Division of Biologics Inspectorate III (DCSDD):
Biologics Investigations Branch 1
Biologics Investigations Branch 2
Biologics Investigations Branch 3

These organizations report to the Division of Biotechnology Inspectorate (DCSDE):
Biotechnology Investigations Branch 1
Biotechnology Investigations Branch 2