

**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 Human and Animal Drug Inspectorate**

**Division of Human and Animal Drug Global Operations**

Effective Date: May 13, 2024

**1. Division of Human and Animal Drug Global Operations (DCSJB).**

- A. Coordinates, directs, and assists the Office of Inspections and Investigations (OII) headquarters and field organizations with domestic and international investigative activities related to pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).
- B. Creates, clears, and/or issues pharmaceutical field assignments, including responses to adverse event reports relative to pharmaceutical products, emergency response activities, and drug shortages. Serves as technical point of contact for these assignments and monitors outcomes.
- C. Implements pharmaceutical program work plans within the Office level organization. Assists other OII offices and divisions in interpretation of work plan implementation.
- D. Plans and evaluates program activities and manages a Quality Assurance Program.
- E. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations, including the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the International Conference on Harmonization (ICH), as appropriate.

## **2. Human and Animal Drug Program Operations Branch (DCSJB1).**

- A. Coordinates, directs, and assists the OII headquarters and field organizations with domestic and international investigative activities related to pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by CDER and CVM.
- B. Manages and coordinates the implementation of new regulations and initiatives within the OII pharmaceutical quality program.
- C. Reviews and evaluates implementation of existing procedures and guidance related to pharmaceutical products.
- D. Performs pharmaceutical quality inspections, as necessary.
- E. Serves as subject matter expert on field operations relative to pharmaceutical quality, to external and internal cross-FDA committees, workgroups, and task forces.
- F. Provides technical and programmatic expertise to the FDA Centers, Offices, and field organizations through national technical and program experts.
- G. Provides inspectional and technical assistance to field and foreign organizations on pharmaceutical inspection and regulatory matters.
- H. Participates as subject matter experts in the design, implementation, and presentation of pharmaceutical training programs.
- I. Provides pharmaceutical program technical assistance and training to other regulatory and public health partners.

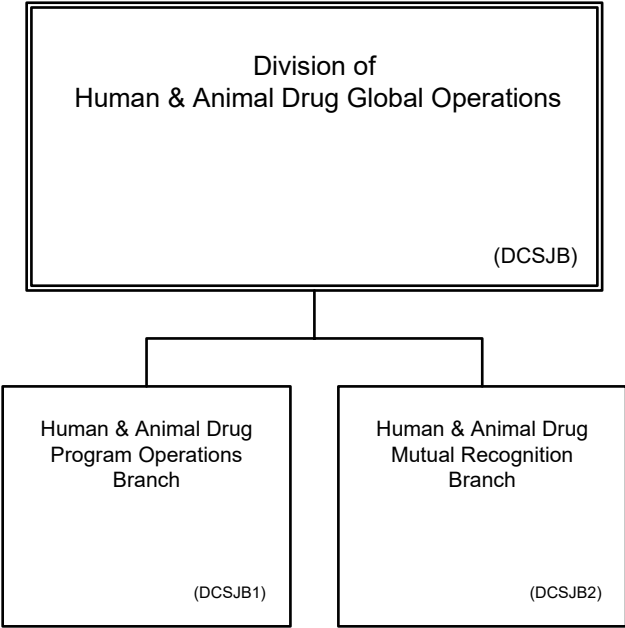
## **3. Human and Animal Drug Mutual Recognition Branch (DCSJB2)**

- A. Reviews and evaluates Foreign Regulatory Authority inspection reports to evaluate the extent of coverage and the extent to which manufacturers are adhering to applicable FDA enforced laws and regulations.
- B. Monitors and responds to Foreign Regulatory Authority inspection inquiries and requests.
- C. Coordinates and participates in meetings, conferences, seminars, workshops, and other technical forums with other national regulatory authorities.
- D. Participates in capability assessments of foreign regulators and makes recommendations on capability decisions.

#### **4. Authority and Effective Date.**

The functional statements for the Division of Human and Animal Drug Global Operations 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 & Investigations  
Office of Human and Animal Drugs Inspectorate  
Division of Human and Animal Drug 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 Human and Animal Drugs Inspectorate, Division of Human and Animal Drug Global Operations organization structure depicting all the organizational structures reporting to the Director:

Human and Animal Drug Program Operations Branch (DCSJB1):  
Human and Animal Drug Mutual Recognition Branch (DCSJB2):