SMG 1121A.91

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 Training, Education and Development

Division of Programmatic Training

Effective Date: May 13, 2024

1. Division of Programmatic Training (DCSIA).

- A. Designs, develops, and delivers training and educational programs in consultation with Centers, Offices, and the Human Foods Program (HFP) to Office of Inspections and Investigations (OII) staff and other regulatory partners in the program areas of Human and Animal Food, Pharmaceutical Quality, Biologics, Bioresearch Monitoring, Medical Device and Radiological Health, and Tobacco.
- B. Collaborates with Centers, Offices, and OII subject matter experts to develop course content for training, education, and development programs in Human and Animal Food, Biologics, Bioresearch Monitoring, Medical Device and Radiological Health, Pharmaceutical Quality and Tobacco.
- C. Leads the establishment of national curriculum standards to provide consistency and uniformity in training development and delivery.
- D. Coordinates the establishment of national curriculum standards for all food training programs in consultation with Centers, Offices, and HFP.
- E. Collaborates on training initiatives in consultation with Centers, Offices, and HFP with OII, Centers, Offices, and other regulatory partners in support of the Integrated Food Safety System's mission, vision, and goals.

2. Programmatic Training Branch 1 (DCSIA1).

A. Coordinates, maintains, and carries out the design, development, and delivery of training in the Biologics, Bioresearch Monitoring, Human and Animal Food, Medical Device and Radiological Health, Pharmaceutical

- Quality and Tobacco consistent in consultation with Centers, Offices, and HFP with established national curriculum standards.
- B. Coordinates related course advisory group (CAG) activities for all Food and Drug Administration (FDA) program area training courses (Biologics, Bioresearch Monitoring, Human and Animal Food, Medical Device and Radiological Health, Pharmaceutical Quality and Tobacco).
- C. Coordinates the establishment of national curriculum standards for all human and animal food training programs in consultation with Centers, Offices, and HFP in collaboration with FDA state, local, tribal, territorial partners.
- D. Collaborates on training initiatives with OII, Centers, Offices, and other regulatory partners in consultation with Centers, Offices, and HFP in support of the Integrated Food Safety System's mission, vision, and goals.
- E. Leverages resources for the design, development, and delivery of training products in consultation with Centers, Offices, and HFP in support of the Integrated Food Safety System.

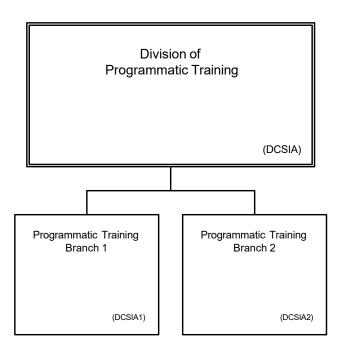
3. Programmatic Training Branch 2 (DCSIA2).

- A. Coordinates, maintains, and carries out the design, development, and delivery of training in the Biologics, Bioresearch Monitoring, Human and Animal Food, Medical Device and Radiological Health, Pharmaceutical Quality and Tobacco in consultation with Centers, Offices, and HFP consistent with established national curriculum standards.
- B. Coordinates related course advisory group (CAG) activities for all FDA program area training courses (Biologics, Bioresearch Monitoring, Human and Animal Food, Medical Device and Radiological Health, Pharmaceutical Quality and Tobacco).
- C. Coordinates the establishment of national curriculum standards for all human and animal food training programs in consultation with Centers, Offices, and HFP in collaboration with FDA state, local, tribal, territorial partners.
- D. Collaborates on training initiatives with OII, Centers, Offices, HFP, and other regulatory partners in support of the Integrated Food Safety System's mission, vision, and goal.

4. Authority and Effective Date.

The functional statements for the Division of Programmatic Training 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 Training, Education, and Development Division of Programmatic Training



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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 Training, Education, and Development, Division of Programmatic Training organization structure depicting all the organizational structures reporting to the Director:

Programmatic Training Branch 1 (DCSIA1) Programmatic Training Branch 2 (DCSIA2)