

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Laboratory Operations and Applied Science

Office of Scientific Coordination and Computational Sciences

Effective Date: May 13, 2024

1. Office of Scientific Coordination and Computational Sciences (DCRMD).

- A. Leads, directs, and coordinates all Human Foods Program (HFP) applied science and laboratory regulatory science activities as well as for collaborations with other Food and Drug Administration (FDA) offices, Department components, and other governmental and external groups. Coordinates among the HFP laboratory, surveillance, and policy offices on decisions involving emerging scientific issues and knowledge.
- B. Evaluates and promulgates overall Office of Laboratory Operations and Applied Science (OLOAS) scientific programs and plans and monitors the scientific portfolio to ensure a cohesive, mission-relevant Human Foods laboratory program, including applied scientific activities, inquiries, and strategic plans. Fosters the development of novel methods to respond to unmet public health needs and to improve existing regulatory methods.
- C. Leads, directs, and coordinates the dissemination of expert scientific and technical advice to the OLOAS Director, to the overall HFP, and to other key officials on highly complex scientific issues and cross-cutting applied science activities.
- D. Represents the HFP in scientific advisory boards and other professional forums, including international forums, on issues related to science and policy.
- E. Provides leadership and coordination, fostering collaborations and effective communication, with internal and external laboratory partners (e.g., Centers of Excellence, domestic and international governmental agencies) to support

an informed, cohesive applied science workplan focused on the highest strategic priorities.

- F. Leads the program overseeing validation and implementation of new/novel regulatory methods in collaboration with the HFP laboratory, surveillance, and policy offices.
- G. Coordinates between HFP laboratories and HFP statistical, bioinformatic, and computational components to facilitate method development, and method validation for chemical and microbial hazards.
- H. Identifies emerging needs and provides technical support pertaining to scientific computing; including the development and application of scientific data standards, bioinformatics and statistical programming, high-performance computing, and scientific data management for OLOAS and coordinates approaches to address them.
- I. Provides scientific and administrative leadership for FDA's GenomeTrakr network, overseeing database curation, enhancing data standards, integrating new technologies, and facilitating capacity building.
- J. Promotes collaboration and data-sharing between FDA's GenomeTrakr network and other national and international food safety genomics programs, ensuring that collected data are interoperable and meet quality control standards necessary for regulatory applications.
- K. Coordinates with appropriate HFP and FDA information technology organizations on the implementation of laboratory knowledge management systems. In addition, serves as business subject matter experts in the development of information technology systems relevant to laboratory operations.

2. Senior Science Advisor Staff (DCRMD1).

- A. Leads, directs, and coordinates the dissemination of expert scientific and technical advice to the OLOAS Director, to the overall HFP and to other key officials, on highly complex scientific issues and cross-cutting applied science activities.
- B. Represents the HFP in scientific advisory boards and other professional forums, including international forums, on issues related to science and policy.
- C. Leads, directs, and coordinates collaborations/partnerships with other governmental and external groups.

- D. Advances cohesive, mission-relevant laboratory and computational research programs that support sound, science-based regulatory action in HFP priority areas.
- E. Creates, oversees, and provides project management of contracts and procurements in support of HFP applied science and laboratory regulatory science needs.

3. Research Coordination Staff (DCRMD2).

- A. Provides leadership and coordination, fostering collaborations and effective communication, with internal and external laboratory partners (e.g., Centers of Excellence, domestic and international governmental agencies) to support an informed, cohesive applied science workplan focused on the highest strategic priorities.
- B. Provides project management, leadership, and oversight of the validation and implementation of new/novel regulatory methods in collaboration with the HFP laboratories (both applied science and regulatory) and policy Offices.
- C. Originates, plans, and conducts laboratory investigations, including the development of methods and production of data, in support of policy needs in the broad areas of staff expertise.
- D. Provides scientific and technical review, advice, and assistance in the broad areas of staff expertise.
- E. Provides scientific and administrative leadership on the development and execution of systems/databases for tracking applied scientific activities.

4. GenomeTrakr and Computational Science Staff (DCRMD3).

- A. Provides scientific and administrative leadership for FDA's GenomeTrakr network, overseeing database curation, enhancing data standards, integrating new technologies, and facilitating capacity building.
- B. Promotes collaboration and data-sharing between FDA's GenomeTrakr network and other national and international food safety genomics programs, ensuring that collected data are interoperable and meet quality control standards necessary for regulatory applications.
- C. Coordinates between HFP laboratories and HFP statistical, bioinformatic, and computational components to facilitate method development, and method validation for chemical and microbial hazards.
- D. Coordinates with appropriate HFP and FDA Information Technology (IT) staff on the implementation of laboratory knowledge management systems. In

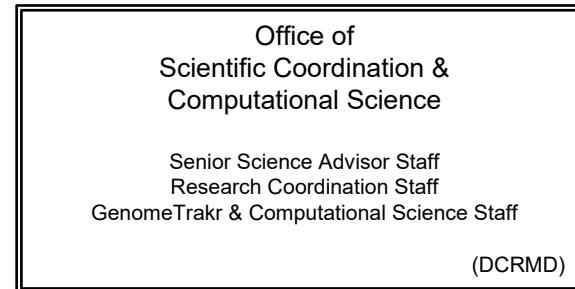
addition, serves as business subject matter experts in the development of information technology systems relevant to laboratory operations.

- E. Provides support to HFP laboratories and state-operated laboratory partners on information technology issues related to analysis of big scientific data using high-performance computing and cloud computing, including genomic analysis of microbial pathogen and other DNA-sequencing methods to characterize adulterants and food ingredients.

5. Authority and Effective Date.

The functional statements for the Office of Scientific Coordination and Computational Sciences 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
Human Foods Program
Office of Laboratory Operations and Applied Science
Office of Scientific Coordination and Computational Sciences**



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The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Laboratory Operations and Applied Science, Office of Scientific Coordination and Computational Sciences organization structure depicting all the organizational structures reporting to the Director:

Senior Science Advisor Staff (DCRMD1)

Research Coordination Staff (DCRMD2)

GenomeTrakr and Computational Science Staff (DCRMD3)