

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of the Chief Scientist

Effective Date: May 13, 2024

1. Office of the Chief Scientist (DCP).

- A. Provides strategic leadership, coordination, and research expertise to support scientific excellence, innovation, and capacity to achieve the Food and Drug Administration's (FDA) public health mission.
- B. Plans, administers, coordinates, and evaluates office scientific, management, laboratory, and regulatory programs, plans, and policies.
- C. Provides cross-agency scientific coordination to advance and communicate FDA science.
- D. Supports scientific excellence and the professional development of FDA scientists in all areas, including through FDA-wide Fellowship and Traineeship Programs, continuing education, and scientific interactions with universities and others.
- E. Provides support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning FDA regulated products, including their evaluation, quality, safety, and effectiveness.
- F. Leads implementation of FDA's Medical Countermeasures Initiative (MCMi) Regulatory Science Program to help translate emerging science and technology into innovative, safe, and effective medical countermeasures (MCM).
- G. Provides direction and oversees FDA's occupational health and safety program in close collaboration with FDA Centers and Offices.
- H. Leads FDA efforts to protect and enhance scientific integrity, and where substantive scientific differences of opinion arise and require review at the

FDA level, addressing them through appropriate processes intended to protect both FDA's mission and the integrity of its science.

- I. Plans and conducts scientific research related to product safety and toxicology in support of FDA regulatory needs and decision-making.
- J. Provides direction and coordination of cosmetics and color additive programs, including efforts under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).
- K. Plans and conducts regulatory testing and related research for medical products, tobacco, and specialty laboratory analyses.
- L. Ensures consistent operations of FDA's advisory committee program.
- M. Leads FDA in implementation of the Federal Technology Transfer Act and related legislation to foster scientific collaborations and partnerships that promote innovation and to translate FDA inventions into public health solutions through collaboration, patenting, and licensing.
- N. Collaborates with other FDA Centers and Offices, other agencies, global regulatory partners, academia, regulated industry, innovators, and consumers in carrying out scientific activities and functions of OCS.

2. Advisory Committee Oversight and Management Staff (DCP1).

- A. Works in close collaboration with FDA Centers to ensure consistent operations within the FDA's advisory committee program.
- B. Provides guidance and assistance on the establishment, staffing, and management of the FDA's advisory committees to obtain the best possible scientific advice to assist the FDA in meeting its public health mission.
- C. Serves as the FDA liaison with the Office of the Secretary and the Department of Health and Human Services (DHHS) Committee Management Office on matters related to the FDA's advisory committees.
- D. Ensures that all FDA advisory committee activities are consistent with the provisions of the Federal Advisory Committee Act, other applicable Federal laws, FDA and Departmental policies, and related guidance, regulations, and statutes.

3. FDA Technology Transfer Program Staff (DCP2).

- A. Performs FDA-wide responsibility for managing, directing, and implementing the Stevenson-Wydler Technology Innovation Act of 1980 and its amendments, including the Federal Technology Transfer Act of 1986.

- B. Using technology transfer authorities, establishes and maintains the frameworks and tools that FDA relies on to collaborate with external partners and enhance the regulatory science enterprise through innovation.
- C. Provides for the best possible use of FDA inventions by translating these research outcomes into opportunities and products that improve public health.
- D. Works in close collaboration with FDA Centers and Offices to ensure consistent application of HHS and FDA technology transfer policies and processes, in compliance with relevant laws and regulations.
- E. Provides intellectual property guidance for FDA; protects and manages the Agency's intellectual property portfolio.
- F. Serves as FDA's liaison on technology transfer matters to HHS and its components, the Federal Laboratory Consortium, and the Interagency Working Group for Technology Transfer.

4. Administrative Management Staff (DCP3).

- A. Provides guidance and leadership on administrative management policies, guidelines, issues, and concerns that impact office programs and initiatives.
- B. Plans, develops, and implements a wide range of administrative management activities for the office including financial, human capital, and other essential administrative support services, in coordination with OCS subcomponents.
- C. Represents the office and serves as a liaison on administrative management matters.
- D. Conducts special projects and assignments in support of office priorities and management initiatives.

5. Informatics and Business Operations Staff (DCP4).

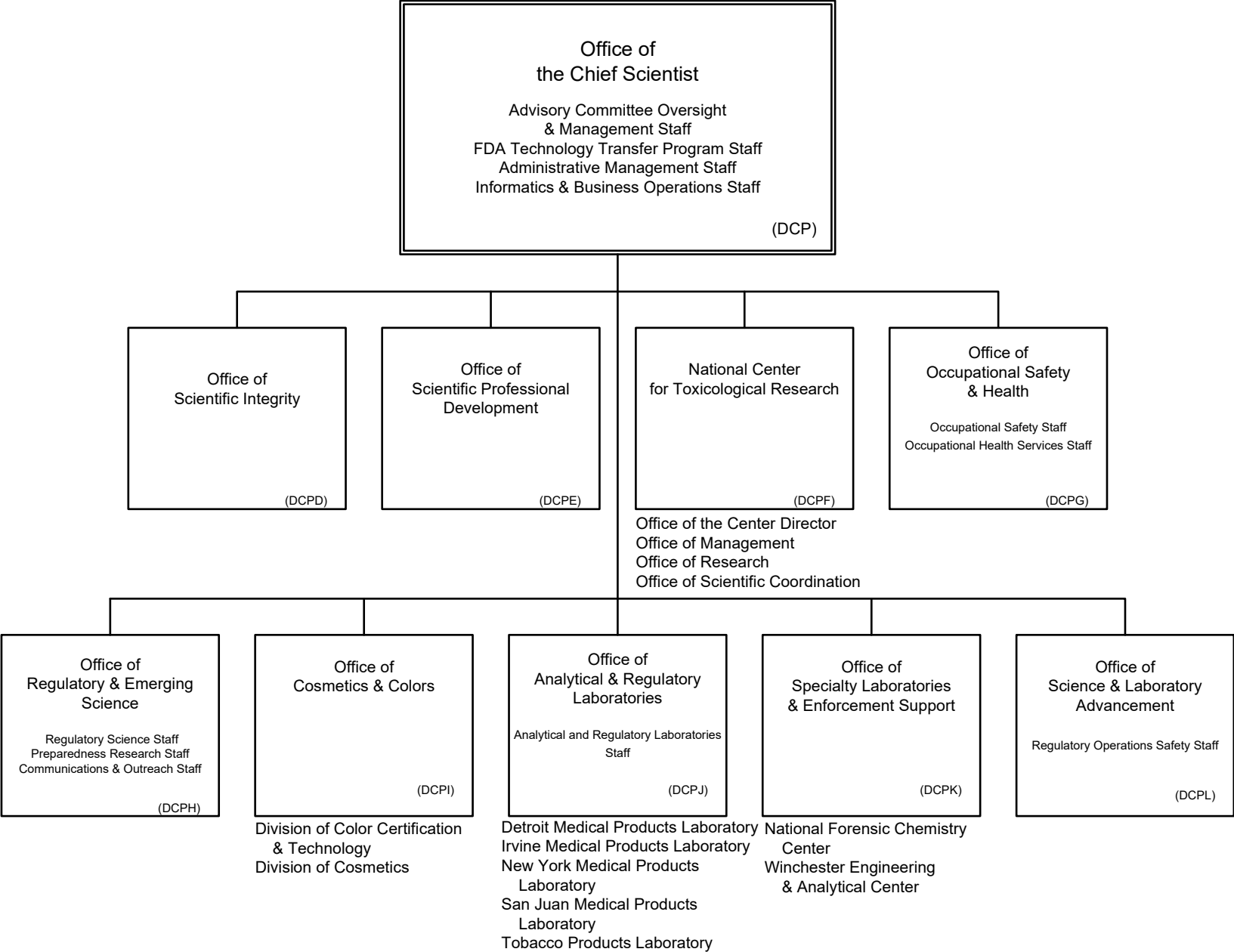
- A. Manages and assesses OCS information technology (IT) portfolio and IT needs across OCS program areas, in collaboration with OCS subcomponents.
- B. Liaises with appropriate FDA IT staff to implement and oversee regulatory testing and specialty laboratory scientific computing and knowledge management needs; serves as business subject matter experts in the development of IT systems relevant to regulatory testing and specialty laboratories, including the Human Foods Program, and for IT system needs across OCS subcomponents.

- C. Tracks and reports work plan obligations and performance metrics for regulatory testing and specialty laboratories; collaborates with work planning partners to ensure up to date and accurate planning data.
- D. Provides outreach and technical support for laboratory training related to business program management and IT system training.
- E. Assists in sampling/analytical program evaluation including data aggregation and trending.
- F. Provides project management support for continuous improvement projects for IT business operations and coordinates related information requests, as assigned.

6. Authority and Effective Date.

The functional statements for the Office of the Chief Scientist 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 the Chief Scientist



Staff Manual Guide 1119A.1
Organizations and Functions
Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist organization structure depicting all the organizational structures reporting to the Director:

Advisory Committee Oversight and Management Staff

FDA Technology Transfer Program Staff

Administrative Management Staff

Informatics and Business Operations Staff

Office of Scientific Integrity (DCPD)

Office of Scientific Professional Development (DCPE)

National Center for Toxicological Research (DCPF)

Office of Occupational Safety and Health (DCPG)

Office of Regulatory and Emerging Science (DCPH)

Office of Cosmetics and Colors (DCPI)

Office of Analytical and Regulatory Laboratories (DCPJ)

Office of Specialty Laboratories and Enforcement Support (DCPK)

Office of Science and Laboratory Advancement (DCPL)

These organizations report to the Office of Scientific Integrity (DCPD):

These organizations report to the Office of Scientific Professional Development (DCPE):

These organizations report to the National Center for Toxicological Research (DCPF):

Office of the Center Director

Office of Management

Office of Research

Office of Scientific Coordination

These organizations report to the Office of Occupational Safety and Health (DCPG):

Occupational Safety Staff

Occupational Health Services Staff

These organizations report to the Office of Regulatory and Emerging Science (DCPH):

Regulatory Science Staff

Preparedness Research Staff

Communications and Outreach Staff

These organizations report to the Office of Cosmetics and Colors (DCPI):

Division of Color Certification and Technology

Division of Cosmetics

These organizations report to the Office of Analytical and Regulatory Laboratories (DCPJ):

Detroit Medical Products Laboratory

Irvine Medical Products Laboratory

New York Medical Products Laboratory

San Juan Medical Products Laboratory

Tobacco Products Laboratory

These organizations report to the Office of Specialty Laboratories and Enforcement Support (DCPK):

National Forensic Chemistry Center

Winchester Engineering and Analytical Center

These organizations report to the Office of Science and Laboratory Advancement (DCPL):

Regulatory Operations Safety Staff