

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

Office of Regulatory and Emerging Science

Effective Date: May 13, 2024

1. Office of Regulatory and Emerging Science (DCPH).

- A. Provides strategic leadership, coordination, and support for innovation in the Food and Drug Administration (FDA) regulatory science and preparedness research to advance FDA's ability to protect and promote public health.
- B. Promotes the goals and needs with respect to regulatory science, preparedness research, and emerging science in the FDA budgeting and priority-setting processes.
- C. Supports high quality, collaborative scientific activities to address important public health and regulatory issues concerning FDA regulated products, including their evaluation, quality, safety, and effectiveness.
- D. Foster and support high quality, mission targeted FDA collaborative and extramural research to enhance product evaluation tools.
- E. Supports administrative functions for the office including budget execution, travel, and human resources, in coordination with the Office of the Chief Scientist (OCS).

2. Regulatory Science Staff (DCPH1).

- A. Advances intramural and extramural regulatory science research through management of FDA-wide programs for research and development activities to support regulatory science and innovation and address scientific and public health priorities.
- B. Leads the FDA Standards Program and Committee, per Staff Manual Guide (SMG) 9100.1, to facilitate internal coordination of FDA's participation in

standards development organizations and interagency engagement on and recognition of regulatory standards.

- C. Provides overarching support and guidance for FDA's animal research activities.
- D. Supports the FDA One Health initiative to coordinate FDA-wide and Federal agencies communication and cooperation on public health issues requiring an FDA-wide focus in the One Health arena.

3. Preparedness Research Staff (DCPH2).

- A. Leads the implementation of FDA's Medical Countermeasures Initiative (MCMi) Regulatory Science Program to develop the tools, standards, and approaches to assess medical countermeasures (MCM) safety, efficacy, quality, and performance and to help translate emerging science and technology into innovative, safe, and effective MCMs.
- B. Fosters the adoption of cross-cutting, emerging science technologies to advance medical product development through the development of regulatory science tools, building FDA expertise with emerging technologies, and facilitating consistent approaches to regulation.

4. Communication and Outreach Staff (DCPH3).

- A. Facilitates communication within FDA and with external partners on matters related to regulatory science, preparedness research, and emerging science on behalf of OCS.
- B. Supports FDA-wide professional development to help ensure that FDA meets the regulatory challenges posed by emerging science and technology developments.
- C. Seeks input from FDA programs, stakeholders, and outside advisors, to help define, review, and meet FDA scientific needs and priorities to support our public health mission.
- D. Supports scientific outreach and collaboration with respect to regulatory science, preparedness research, and emerging science to engage stakeholders including other United States Government Agencies, global regulatory partners, academia, product developers, and consumers in the furtherance of the FDA mission.
- E. Strengthens core scientific capacity and scientific infrastructure through leading and managing scientific working groups, comprised of scientists across FDA, to promote cross-cutting scientific coordination and collaboration.

5. Authority and Effective Date.

The functional statements for the Office of Regulatory and Emerging Science 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
Office of Regulatory and Emerging Science**

Office of
Regulatory and Emerging Science

Regulatory Science Staff
Preparedness Research Staff
Communications and Outreach Staff (DCPH)

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

Regulatory Science Staff (DCPH1)

Preparedness Research Staff (DCPH2)

Communications and Outreach Staff (DCPH3)