

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Partnerships and Operational Policy

Effective Date: December 14, 2018

1. Office of Partnerships and Operational Policy (DCIH).

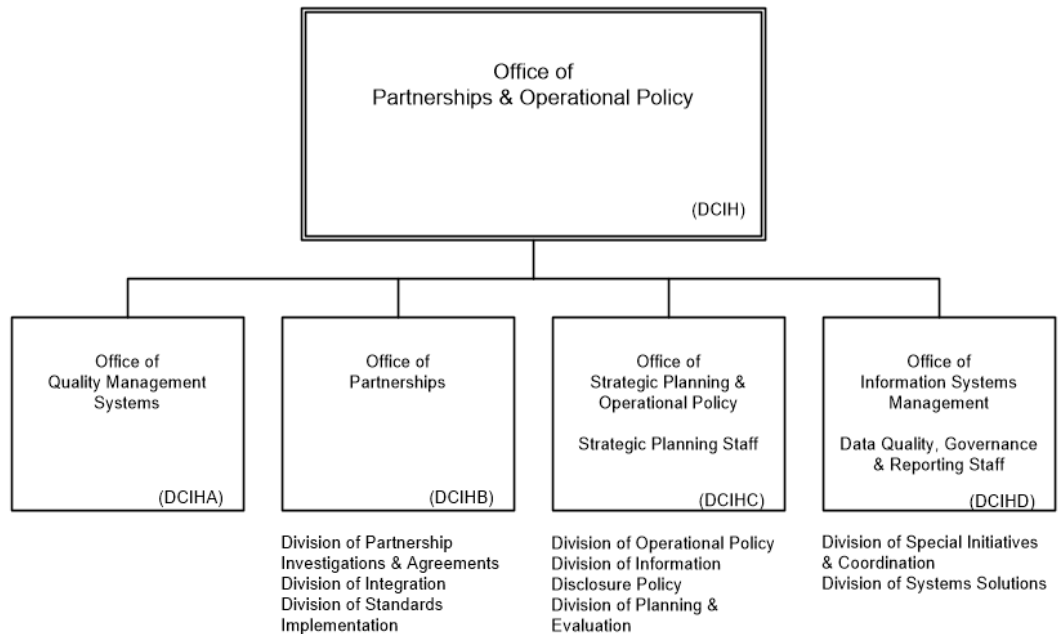
- A. Provides direction and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other senior Office of Regulatory Affairs (ORA) leaders on the implementation of policies and programs in the development, coordination, and evaluation of the Food and Drug Administration (FDA) partnerships with other Federal, state, local, tribal and territorial regulatory agencies and international partners.
- B. Provides overall leadership and guidance in the development, coordination and evaluation of the FDA's Federal, state, local and territorial funding of grants, cooperative agreements, and contracts.
- C. Develops cooperative relationships with external stakeholders such as international, Federal, state, local, tribal and territorial counterparts, as well as awareness of these partnerships and engagement within the FDA to further leverage and collaboration on our shared public health regulatory mission.
- D. Oversees the development of programs and policies that enhance the Integrated National Food Safety System (IFSS).
- E. Provides direction and counsel to the ACRA and other senior FDA officials concerning new legislation, executive orders, new regulations or other information that may affect current or proposed FDA policies.
- F. Oversees the development and coordination of new or modified FDA compliance policies and regulatory procedures for all domestic and imported products regulated by the FDA.

- G. Provides overall leadership and guidance for ORA's Information Disclosure and Freedom of Information Act (FOIA) program.
- H. Leads the development of ORA's strategic management plans and priorities.
- I. Provides direction and counsel to senior ORA managers in the development of strategies for applying quality management to core program areas and business processes.
- J. Directs and oversees ORA activities related to information technology needs, systems development, and budgetary issues.

2. Authority and Effective Date.

The functional statements for the Office of Partnerships and Operational Policy were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Partnerships and Operational Policy**



Staff Manual Guide 1121.60a
Organizations and Functions
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Partnerships and Operational Policy organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Partnerships and Operational Policy (DCIH):

Office of Quality Management Systems (DCIHA)

Office of Partnerships (DCIHB)

Office of Strategic Planning & Operational Policy (DCIHC)

Office of Information Systems Management (DCIHD)

These organizations report to the Office of Partnerships (DCIHB)

Division of Partnership Investigations & Agreements

Division of Integration

Division of Standards Implementation

These organizations report to the Office of Strategic Planning & Operational Policy (DCIHC)

Strategic Planning Staff

Division of Operational Policy

Division of Information Disclosure Policy

Division of Planning & Evaluation

These organizations report to the Office of Information Systems Management (DCIHD)

Data Quality, Governance & Reporting Staff

Division of Special Initiatives & Coordination

Division of Systems Solutions