

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 Analytical Regulatory Laboratories

Effective Date: May 13, 2024

1. Office of Analytical Regulatory Laboratories (DCPJ).

- A. Advises the Office of the Chief Scientist (OCS) on scientific issues and laboratory activities related to tobacco, pharmaceuticals, nanotechnology, and cosmetics.
- B. Provides strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues concerning the Food and Drug Administration (FDA) regulated products, including their evaluation, quality, safety, and effectiveness.
- C. Plans and conducts laboratory testing and fosters development and use of innovative technologies to meet public health needs.
- D. Coordinates with FDA Centers and Offices on analytical regulatory laboratory scientific resources, including subject matter experts, to assure a cohesive, efficient, and effective approach to public health protection.
- E. Provides administrative functions for laboratory operations, including budget execution, travel, and human resources, in coordination with OCS.

2. Analytical and Regulatory Laboratories Staff (DCPJ1).

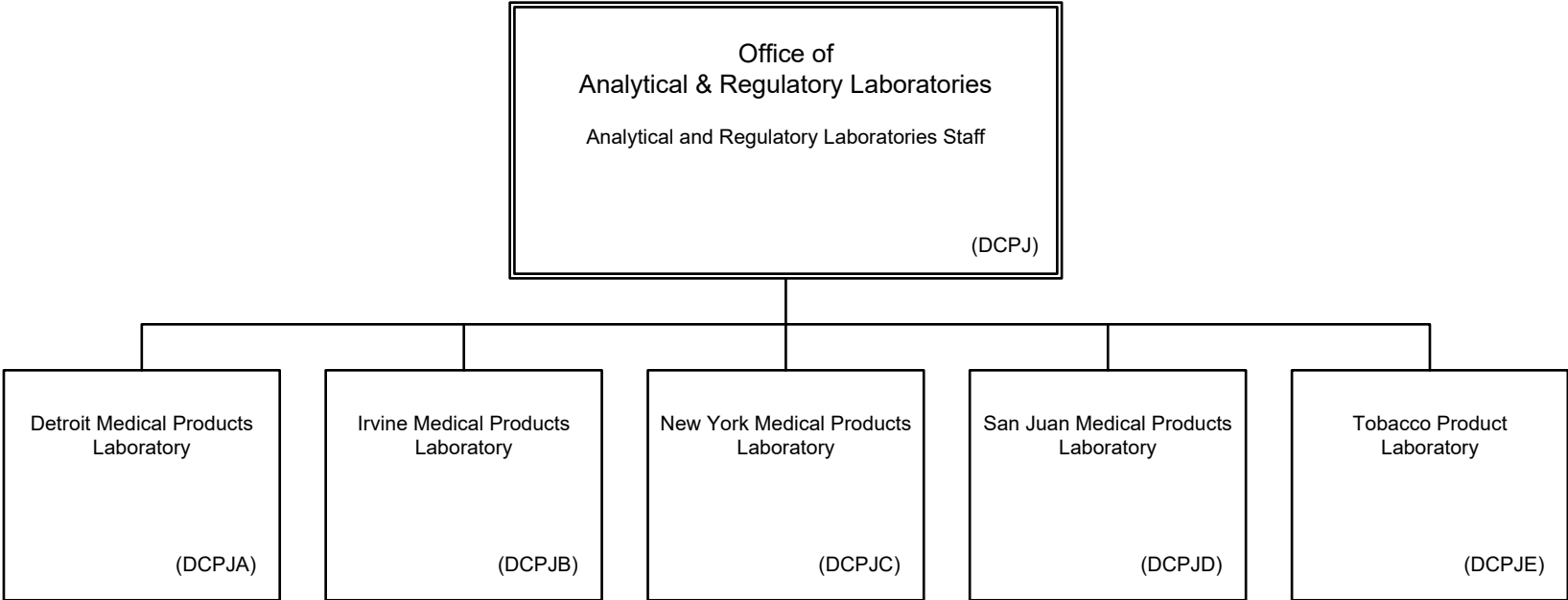
- A. Works with appropriate Centers and Offices to establish and execute strategic and tactical plans for the effective use of laboratory resources relative to pharmaceuticals, tobacco, nanotechnology, and cosmetics.

- B. Provides and coordinates day to day subject matter expertise and technical support and service to laboratories relative to pharmaceuticals, tobacco, nanotechnology, and cosmetics.
- C. Coordinates with OCS and appropriate Centers and Offices to identify and execute applied research based on data gaps, product risk, and emerging public health issues.
- D. Serves as subject matter experts in the development of new or modified scientific and analytical regulatory procedures relevant to pharmaceuticals, tobacco, nanotechnology, and cosmetics.
- E. Coordinates with the FDA's inspections and investigations program and FDA's scientific professional development program to develop and implement training programs relative to pharmaceuticals, tobacco, nanotechnology, and cosmetics based analytical methods.
- F. Leads in the implementation and maintenance of relevant laboratory accreditation standards and oversight programs.
- G. Represents OCS on internal and external working groups, committees, taskforces, etc., in area of program and product responsibility.

3. Authority and Effective Date.

The functional statements for the Office of Analytical Regulatory Laboratories 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 Analytical and Regulatory Laboratories**



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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 Analytical and Regulatory Laboratories organization structure depicting all the organizational structures reporting to the Director:

Analytical and Regulatory Laboratories Staff

Detroit Medical Products Laboratory

Irvine Medical Products Laboratory

New York Medical Products Laboratory

San Juan Medical Products Laboratory

Tobacco Products Laboratory