

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 Medical Products and Tobacco Operations

Office of Pharmaceutical Quality Operations

Effective Date: December 14, 2018

1. Office of Pharmaceutical Quality Operations (DCIGB).

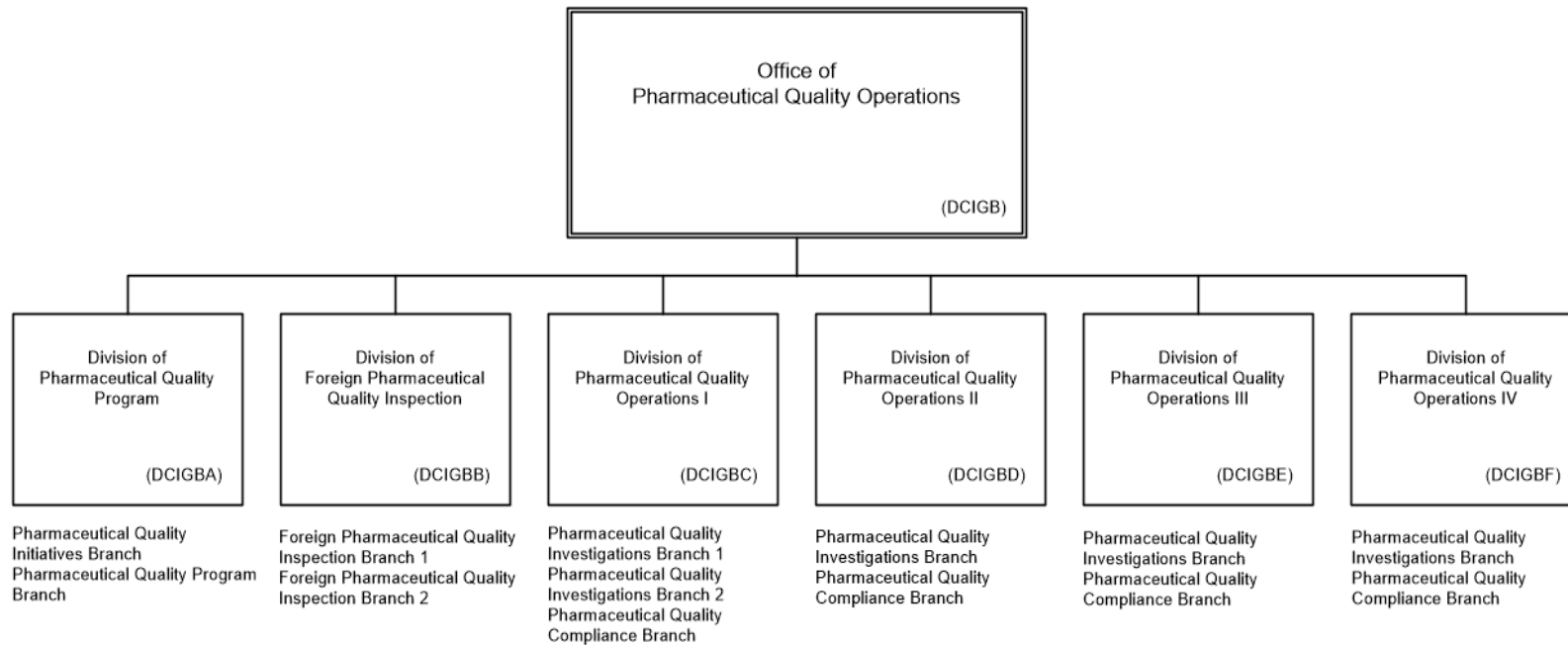
- A. Provides direction and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other Food and Drug Administration (FDA) leaders relative to pharmaceutical products field operations and emergency response activities, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).
- B. Coordinates, directs and assists with pharmaceutical product investigative activities.
- C. Supports the development of policy and guidance for investigations and compliance for pharmaceutical products.
- D. As needed, participates in systems recognition efforts with other FDA components and national and international governments.
- E. Participates as subject matter experts in the design, implementation and presentation of pharmaceutical training programs.
- F. Monitors emerging issues and advancements in technology and recommends program improvements as necessary.
- G. Serves as a subject matter expert on field operations relative to external and internal cross-FDA pharmaceutical product committees, workgroups and task forces.

- H. Creates, reviews, and/or facilitates the issuance of field assignments with the Centers for pharmaceutical programs. Monitors and serves as technical point of contact for these assignments.
- I. Develops and maintains cooperative relationships with State, local and other Federal agencies; serves on interagency councils; and encourages improved State and local consumer protection programs pertinent to FDA-enforced laws and regulations.
- J. Plans and evaluates program activities and manages a Quality Assurance Program.
- K. Coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency.
- L. Conducts investigations and inspections of pharmaceutical products, and other CDER and CVM-regulated commodities.
- M. Provides technical assistance regarding pharmaceutical investigational operations.
- N. Directs and coordinates the Office of Regulatory Affairs response to reports of adverse events relative to pharmaceutical products and potential drug shortages in collaboration with the Centers.

2. Authority and Effective Date.

The functional statements for the Office of Pharmaceutical Quality Operations 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 Medical Products and Tobacco Operations
Office of Pharmaceutical Quality Operations**



Staff Manual Guide 1121.22a
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Pharmaceutical Quality Operations organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Pharmaceutical Quality Operations (DCIGB):

Division of Pharmaceutical Quality Program (DCIGBA)

Division of Foreign Pharmaceutical Quality Inspection (DCIGBB)

Division of Pharmaceutical Quality Operations I (DCIGBC)

Division of Pharmaceutical Quality Operations II (DCIGBD)

Division of Pharmaceutical Quality Operations III (DCIGBE)

Division of Pharmaceutical Quality Operations IV (DCIGBF)

These organizations report to the Division of Pharmaceutical Quality Program (DCIGBA):

Pharmaceutical Quality Initiatives Branch

Pharmaceutical Quality Program Branch

These organizations report to the Division of Foreign Pharmaceutical Quality Inspection (DCIGBB):

Foreign Pharmaceutical Quality Inspection Branch 1

Foreign Pharmaceutical Quality Inspection Branch 2

These organizations report to the Division of Pharmaceutical Quality Operations I (DCIGBC):

Pharmaceutical Quality Investigations Branch 1

Pharmaceutical Quality Investigations Branch 2

Pharmaceutical Quality Compliance Branch

These organizations report to the Division of Pharmaceutical Quality Operations II (DCIGBD):

Pharmaceutical Quality Investigations Branch

Pharmaceutical Quality Compliance Branch

These organizations report to the Division of Pharmaceutical Quality Operations III (DCIGBE)

Pharmaceutical Quality Investigations Branch

Pharmaceutical Quality Compliance Branch

These organizations report to the Division of Pharmaceutical Quality Operations IV (DCIGBF)

Pharmaceutical Quality Investigations Branch

Pharmaceutical Quality Compliance Branch

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