

**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**

**Division of Pharmaceutical Quality Program**

Effective Date: December 14, 2018

**1. Division of Pharmaceutical Quality Program (DCIGBA).**

- A. Coordinates, directs, and assists the field and Headquarters with domestic and international investigative activities related to pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).
- B. Creates, clears and/or issues pharmaceutical field assignments, including responses to adverse event reports relative to pharmaceutical products, emergency response activities, and drug shortages. Serves as technical point of contact for these assignments and monitors outcomes.
- C. Implements pharmaceutical program work plans within the Office level organization. Assists other offices and divisions in interpretation of work plan implementation.
- D. Plans and evaluates program activities and manages a Quality Assurance Program.
- E. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations, including the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and International Conference on harmonization (ICH), as appropriate.

## **2. Pharmaceutical Quality Initiatives Branch (DCIGBA1)**

- A. Manages and coordinates the implementation of new regulations and initiatives within the Office of Regulatory Affairs (ORA) pharmaceutical quality program.
- B. Coordinates implementation of user fee programs and collection and analysis of related performance goal data.
- C. Manages Office's Quality Management System. Assesses the quality of the work products, processes, or services to ensure they are fit for use and timely.
- D. Reviews and evaluates implementation of existing procedures and guidance related to pharmaceutical products.

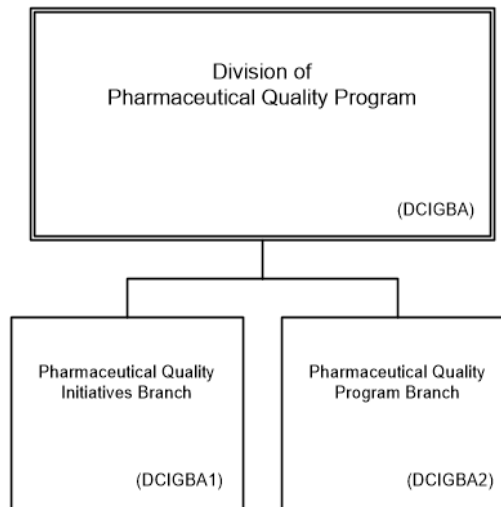
## **3. Pharmaceutical Quality Program Branch (DCIGBA2)**

- A. Coordinates, directs, and assists the field and Headquarters with domestic and international investigative activities related to pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM).
- B. Performs pharmaceutical quality inspections, as necessary.
- C. Serves as subject matter expert on field operations relative to pharmaceutical quality on external and internal cross-Food and Drug Administration (FDA) committees, workgroups and task forces.
- D. Provides technical and programmatic expertise to the field and Centers through national technical and program experts.
- E. Provides inspectional and technical assistance to field and foreign offices on pharmaceutical inspection and regulatory matters.
- F. Participates as subject matter experts in the design, implementation and presentation of pharmaceutical training programs.
- G. Provides pharmaceutical program technical assistance and training to other regulatory and public health partners.

#### **4. Authority and Effective Date.**

The functional statements for the Division of Pharmaceutical Quality Program 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  
Division of Pharmaceutical Quality Program**



Staff Manual Guide 1121.221  
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 Medical Products and Tobacco Operations, Office of Pharmaceutical Quality Operations, Division of Pharmaceutical Quality Program organization structure depicting all the organizational structures reporting to the Director:

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

Pharmaceutical Quality Initiatives Branch (DCIGBA1)

Pharmaceutical Quality Program Branch (DCIGBA2)