SMG 1121.225

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 Operations III

Effective Date: December 14, 2018

1. Division of Pharmaceutical Quality Operations III (DCIGBE).

A. Manages field inspection and compliance operations within the associated division for pharmaceutical products, including all pharmaceutical and biopharmaceutical products regulated by the Center for Drug Evaluation (CDER) and Center for Veterinary Medicine (CVM).

B. Manages and evaluates resource use in support of the pharmaceutical quality program.

C. Conducts investigations and inspections related to pharmaceutical products.

D. Recommends legal action and assists in implementing approved action.

E. Manages and evaluates pharmaceutical program activities and manages a quality assurance program.

F. Develops short and long-range work plans, staffing needs, and budgetary proposals for the Division's assigned portion of the nationwide program.

G. Advises the Pharmaceutical Quality Program Director of emerging problems, trends, program needs and any local or state issues.

H. Manages program and operational activities, including all phases of personnel management, financial management, property and supplies for the Division.

2. Pharmaceutical Quality Investigations Branch (DCIGBE1)

A. Inspects pharmaceutical establishments, collects samples for analysis, performs field examinations, and prepares reports.

B. Evaluates inspectional and analytical findings relative to compliance and recommends appropriate follow-up.

C. Evaluates corrective actions taken by pharmaceutical establishments and provides feedback.

D. Prepares and provides evidence of investigational findings.

E. Performs special investigations, including division responsibilities under the Government-wide Quality Assurance Program; investigates reports of adverse experience with any Food and Drug Administration (FDA)–regulated pharmaceutical products; and performs pre-market clearance activities of pharmaceutical products.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness and prevent recurrences.

G. Provides inspectional and investigational support to Office of Regulatory Affairs (ORA) headquarters, CDER, CVM and other divisions, as needed.

H. Plans, schedules and controls pharmaceutical inspectional operations.

I. Supports the development and implementation of domestic and foreign inspectional work plans.

J. Provides counsel and training regarding inspectional techniques and technical developments to other Federal, State, local agencies and foreign counterpart agencies and to industry, as appropriate.

K. Assists in managing, evaluating and auditing the program aspects of federal-state contracts.

L. Detains pharmaceutical products after appropriate clearance has been obtained.

M. Maintains cooperative relationships with State and local counterpart agencies and assists in development of work and information sharing agreements.

3. Pharmaceutical Quality Compliance Branch (DCIGBE2)

A. Reviews and evaluates inspectional and analytical findings to assess compliance with FDA-enforced laws and regulations; determines the most suitable course of action and, if appropriate, recommends legal action.

B. Liaises with the United States (U.S.) attorneys and U.S. Marshals, as appropriate, in implementing approved legal actions or orders.

C. Ensures court-ordered actions are completed on time and in total fulfillment of the Court's order.

D. Conducts administrative meetings on alleged violations and initiates enforcement action.

E. Obtains clearance for administrative and other detentions, prepares related correspondence, and supports detention hearings.

F. Monitors recalls and performs follow-up activities to assess recall effectiveness.

G. Issues untitled and warning letters to regulated industry.

H. Answers inquiries from other Federal agencies, foreign missions and industry regarding interpretations of FDA-enforced laws and regulations, case status and enforcement policies, as appropriate.

I. Works with State and local officials to develop uniform legislation, codes and regulations; advises state and local officials on interpretation of federal laws, regulations and enforcement policies and provides consultation relative to joint regulatory approaches.

J. Plans, organizes and implements comprehensive industry education, training and technical assistance programs designed to promote voluntary compliance and self-regulation in cooperation with other field and Headquarters components.

K. Inspects establishments subject to laws and regulations enforced by the FDA; conducts special investigations; collects samples for analysis; performs field analyses; and prepares reports on findings of each inspection and/or investigation. Maintains cooperative relationships with State and local counterpart agencies, and develops work and information sharing agreements. Presents public education and information programs to various external stakeholders and organizations.

4. Authority and Effective Date.

The functional statements for the Division of Pharmaceutical Quality Operations III 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
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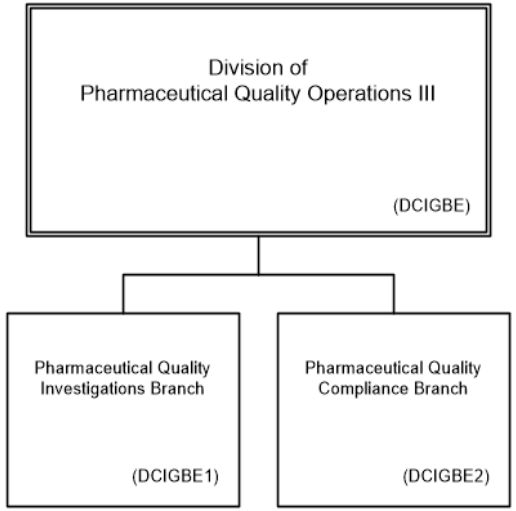

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Pharmaceutical Quality Operations, Division of Pharmaceutical Quality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

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

Pharmaceutical Quality Investigations Branch (DCIGBE1)

Pharmaceutical Quality Compliance Branch (DCIGBE2)