SMG 1280.83a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administrations

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Program & Regulatory Operations

Division of Regulatory & Business Process Management III

Effective Date: September 25, 2019

1. Division of Regulatory & Business Process Management III (DCDLGC).

A. Leads and manages all processes associated with drug quality review and facility inspections for all applications throughout the drug product lifecycle.

B. Coordinates with all Office of Pharmaceutical Quality (OPQ) offices to monitor and track the progress of all internal and cross-functional OPQ projects to ensure completion on time and conformance to the internal processes and procedures.

C. Serves as the external Liaison for quality-related topics, including inspectional scheduling with Office of Regulatory Affairs.

D. Reports performance trends and providing recommendation for continual improvement of the processes.

E. Leads and manages any change initiatives resulting from OPQ's internal change management system.

2. Regulatory & Business Process Management Branch 6 (DCDLGC1).

A. Leads and manages all processes associated with drug quality review and facility inspections for all applications throughout the drug product lifecycle.

B. Establishes, manages and maintains internal review teams associated with drug quality reviews.

C. Establishes and manages timelines associated with drug quality reviews.

D. Serves as an external liaison to regulated industry for quality-related topics.

E. Serves as an internal liaison to offices within OPQ, as well as offices/centers outside of OPQ, who are associated with the drug review process.

F. Manages all correspondences between the Food and Drug Administration (FDA) and drug product applicants.

G. Serves as the regulatory expert within the drug quality review teams.

3. Regulatory & Business Process Management Branch 7 (DCDLGC2).

A. Leads and manages all processes associated with drug quality review and facility inspections for all applications throughout the drug product lifecycle.

B. Establishes, manages and maintains internal review teams associated with drug quality reviews.

C. Establishes and manages timelines associated with drug quality reviews.

D. Serves as an external liaison to regulated industry for quality-related topics.

E. Serves as an internal liaison to offices within OPQ, as well as offices/centers outside of OPQ, who are associated with the drug review process.

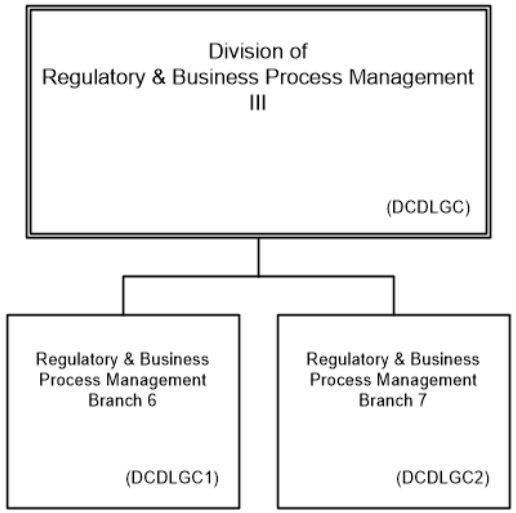
F. Manages all correspondences between the FDA and drug product applicants.

G. Serves as the regulatory expert within the drug quality review teams.

4. Authority and Effective Date.

The functional statements for the Division of Regulatory & Business Process Management III were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
Office of Program & Regulatory Operations
Division of Regulatory & Business Process Management III



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Program and Regulatory Operations, Division of Regulatory & Business Process Management III organizational structures depicting all the organizational structures reporting to the Director.

Division of Regulatory & Business Process Management III (DCDLGC).

These organizations report to the Division of Regulatory & Business Process Management III:

Regulatory & Business Process Management Branch 6 (DCDLGC1)

Regulatory & Business Process Management Branch 7 (DCDLGC2)