SMG 1280.81

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF PHARMACEUTICAL QUALITY

OFFICE OF PROGRAM AND REGULATORY OPERATIONS

DIVISION OF REGULATORY AND BUSINESS PROCESS MANAGEMENT I

Effective Date: September 26, 2014

1. DIVISION OF REGULATORY AND BUSINESS PROCESS MANAGEMENT I (DKKNVGA).

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 (ORA).

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 AND BUSINESS PROCESS MANAGEMENT BRANCH I (DKKNVGA1).

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 agency and drug product applicants.

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

3. REGULATORY AND BUSINESS PROCESS MANAGEMENT BRANCH II (DKKNVGA2).

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 agency 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 this Division were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

FOOD AND DRUG ADMINISTRATION
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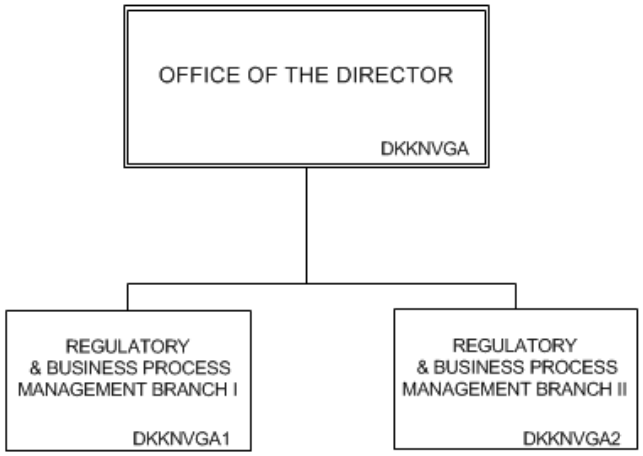

STAFF MANUAL GUIDE 1280.81
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Program and Regulatory Operations, Division of Regulatory and Business Process Management I organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVGA:

- Regulatory & Business Process Management Branch I – DKKNVGA1

- Regulatory & Business Process Management Branch II – DKKNVGA2