

SMG 1280.80

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

Effective Date: September 26, 2014

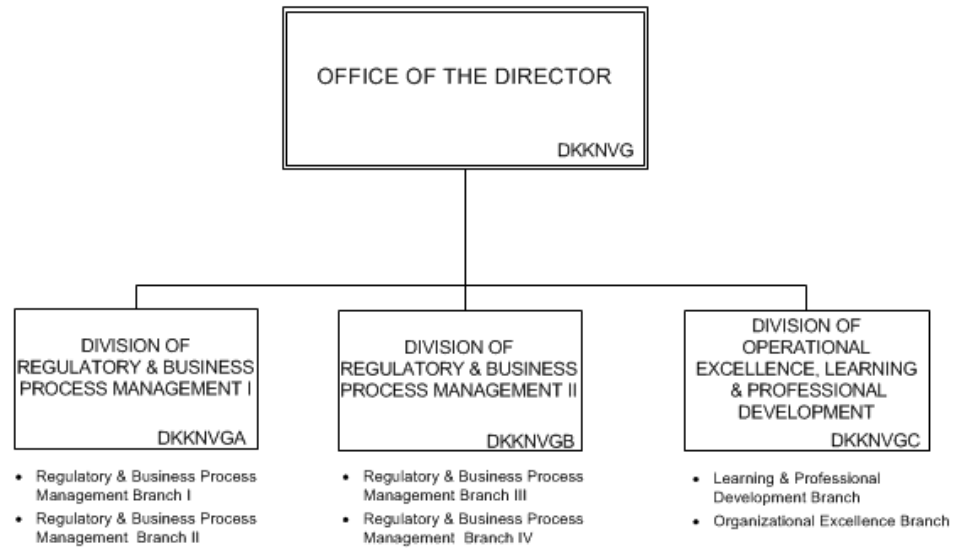
1. OFFICE OF PROGRAM AND REGULATORY OPERATIONS (DKKNVG).

- A. Leads and manages the business processes, quality management system, and training and development system within the Office of Pharmaceutical Quality (OPQ).
- B. Leads and manages all processes associated with drug quality reviews and facility inspections, in collaboration with OPQ functional office leadership.
- C. Designs, develops, and implements internal processes to support the drug quality reviews and inspections.
- D. Monitors, reports and leads corrective and preventive actions relating to the performance of internal processes, as defined by standard procedures.
- E. Designs, develops, and implements OPQ-specific training and developmental programs to ensure the skill sets and competencies of staff are maintained and continually improved.

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Office were approved by the Commissioner of Food and Drugs, and effective on September 26, 2014.

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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 organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNVG:

- DIVISION OF REGULATORY & BUSINESS PROCESS MANAGEMENT I – DKKNVGA
 - Regulatory & Business Process Management Branch I-DKKNVGA1
 - Regulatory & Business Process Management Branch II-DKKNVGA2
- DIVISION OF REGULATORY & BUSINESS PROCESS MANAGEMENT II – DKKNVGB
 - Regulatory & Business Process Management Branch III-DKKNVGB1
 - Regulatory & Business Process Management Branch IV-DKKNVGB2
- DIVISION OF OPERATIONAL EXCELLENCE, TRAINING AND DEVELOPMENT – DKKNVGC
 - Learning & Professional Development Branch-DKKNVGC1
 - Organizational Excellence Branch-DKKNVGC2