SMG 1280.40

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 PHARMACEUTIAL QUALITY

OFFICE OF POLICY FOR PHARMACEUTICAL QUALITY

Effective Date: September 26, 2014

1. OFFICE OF POLICY FOR PHARMACEUTICAL QUALITY (DKKNVC).

A. Develops, implements, and updates science- and risk-based policies, standards, guidance documents, and internal policies, such as Manual of Policies and Procedures (MAPPs), related to the assessment of drug product and drug-containing combination product quality, including chemistry, manufacturing and controls (CMC) review policy and Current Good Manufacturing Practices (CGMP) inspection policy and standards. Evaluates Agency findings such as deficiencies and inspectional citations for conformance to established regulations, policies, standards, and MAPPs.

B. Leads and coordinates development of regulations, guidance documents, standards, and MAPPs with stakeholders (e.g., internal Office of Pharmaceutical Quality (OPQ) reviewers, Office of Compliance, Center for Drug Evaluation and Research (CDER) and Office of Global Regulatory Operations and Policy (OGROP) investigators, and CDER management) that address drug product quality assessment from application review through market availability for all human drugs (Human drugs include biotechnology drugs, over-the-counter and prescription drugs, and application- and non-application-based drugs.). Ensures that assessments are based on a thorough understanding of the product, process, dosage form, and clinically relevant risk factors, and that regulatory policies and standards incorporate benefit-risk considerations.

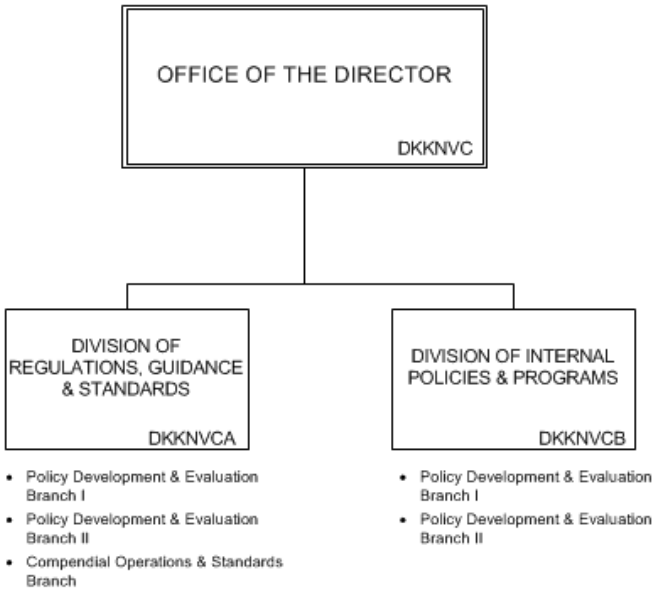
C. Provides executive leadership of the Internal Council of Pharmaceutical Quality. With input from Council members, develops strategic product quality plans and initiates policy projects to address specific unmet needs. Collaborates with the Agency-level Council of Pharmaceutical Quality to address emerging drug product quality trends and establish strategic policy objectives in cooperation with OPQ.

D. Collaborates with OPQ laboratories and helps prioritize research to support policy development and regulatory decision-making. Ensures that the research and scientific knowledge is identified, developed, if necessary, and appropriately used in policy development.

2. AUTHORITY AND EFFECTIVE DATE.

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

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF PHARMACEUTICAL QUALITY
OFFICE OF POLICY FOR PHARMACEUTICAL QUALITY



STAFF MANUAL GUIDE 1280.40
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 Policy for Pharmaceutical Quality organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR – DKKNVC:

- DIVISION OF REGULATIONS, GUIDANCE AND STANDARDS – DKKNVCA
    - Policy Development & Evaluation Branch I
    - Policy Development & Evaluation Branch II
    - Compendial Operations & Standards Branch
- DIVISION OF INTERNAL POLICIES AND PROGRAM – DKKNVCB
    - Policy Development & Evaluation Branch I
    - Policy Development & Evaluation Branch II