SMG 1280.50

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 PROCESS AND FACILITIES

Effective Date: September 26, 2014

1. OFFICE OF PROCESS AND FACILITIES (DKKNVD).

A. Performs reviews of New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), and Biologic License Applications (BLA) and as appropriate, post-approval supplements, investigational drug applications (INDs), emergency use authorizations (EUA), and other intra-agency applications.

B. Evaluates facilities, process design, and control strategies for certain drug substances and for all drug products to assess the capability of manufacturers to produce quality pharmaceutical and biotechnology products at commercial scale.

C. Manages and evaluates the pre-approval (PAI), pre-license inspection (PLI) programs, and post-approval program, including conducting, leading, or otherwise participating in PAIs, PLIs, post approval inspections and other inspections, as appropriate, and evaluating the results of the inspections.

D. Communicates with investigator, reviewer, and compliance teams, as appropriate, to collaboratively consider manufacturing process and facility related quality issues that may impact approval.

E. Partners with other Offices internal and external to Office of Pharmaceutical Quality to establish standards for Office of Process and Facilities-related review and inspectional activities, including novel and complex manufacturing technologies.

F. Provides technical expertise to other Agency components regarding manufacturing quality issues.

G. Communicates manufacturing quality expectations and standards to industry.

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.

FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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OFFICE OF PHARMACEUTICAL QUALITY
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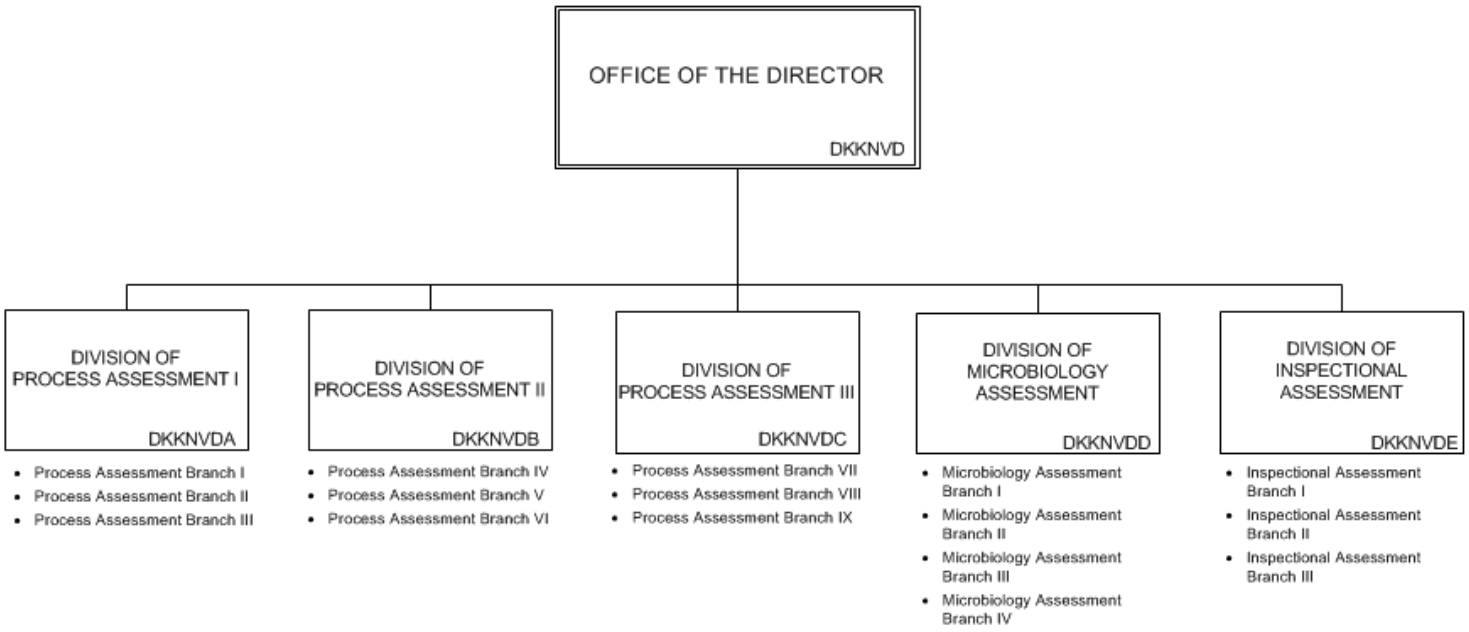

STAFF MANUAL GUIDE 1280.50
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2014

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

OFFICE OF THE DIRECTOR – DKKNVD:

- DIVISION OF PROCESS ASSESSMENT I – DKKNVDA
    - Process Assessment Branch I
    - Process Assessment Branch II
    - Process Assessment Branch III
- DIVISION OF PROCESS ASSESSMENT II – DKKNVDB
    - Process Assessment Branch IV
    - Process Assessment Branch V
    - Process Assessment Branch VI
- DIVISION OF PROCESS ASSESSMENT III – DKKNVDC
    - Process Assessment Branch VII
    - Process Assessment Branch VIII
    - Process Assessment Branch IX
- DIVISION OF MICROBIOLOGY ASSESSMENT – DKKNVDD
    - Microbiology Assessment Branch I
    - Microbiology Assessment Branch II
    - Microbiology Assessment Branch III
    - Microbiology Assessment Branch IV
- DIVISION OF INSPECTIONAL ASSESSMENT – DKKNVDE

- Inspectional Assessment Branch I
- Inspectional Assessment Branch II
- Inspectional Assessment Branch III