

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

DIVISION OF PROCESS ASSESSMENT III

Effective Date: September 26, 2014

1. DIVISION OF PROCESS ASSESSMENT III (DKKNVDC).

- A. Oversees the scientific review and quality evaluation of manufacturing process and facilities for Investigational New Drug applications (IND) New Drug applications (NDA), Abbreviated New Drug applications (ANDA) and supplemental NDAs and ANDAs assigned to Division, including liquid products (e.g., parenterals, ophthalmics, oral liquids, nasal sprays) and complex drug substance products and processes.
- B. Advises Center of Drug Evaluation and Research (CDER) and Office of Pharmaceutical Quality (OPQ) on scientific and regulatory issues associated with the manufacturing processes of liquid products and complex drug substances.

2. PROCESS ASSESSMENT BRANCH VII (DKKNVDC1).

- A. Assesses the suitability of manufacturing process data in IND, NDA, and ANDA and supplemental NDAs and ANDAs for liquid drug products.
- B. Assesses the suitability of microbiological data in IND, NDA, ANDA and supplemental NDAs and ANDAs for products with a lower risk of microbial contamination.
- C. Assesses the acceptability of manufacturing facilities for lower risk facilities, through evaluation of facility and pre-approval inspection related documentation.
- D. Participates in or leads pre-approval inspections for NDAs, ANDAs and supplements, as merited.

E. Uses risk-based approach, communicates issues with review and inspection related application team members.

F. Provides clear risk-based recommendation on assessment related activities.

3. PROCESS ASSESSMENT BRANCH VIII (DKKNVDC2).

A. Assesses the suitability of manufacturing process data in IND, NDA, ANDA and supplemental NDA and ANDA for liquid drug products.

B. Assesses the suitability of microbiological data in IND, NDA, ANDA and supplemental NDA and ANDA for products with a lower risk of microbial contamination.

C. Assesses the acceptability of manufacturing facilities for lower risk facilities, through evaluation of facility and pre-approval inspection related documentation.

D. Participates in or leads pre-approval inspections for NDA, ANDA and supplements, as merited.

E. Uses risk-based approach, communicates issues with review and inspection related application team members.

F. Provides clear risk-based recommendation on assessment related activities.

4. PROCESS ASSESSMENT BRANCH IX (DKKNVDC3).

A. Assesses the suitability of manufacturing process data in IND, NDA, ANDA and supplemental NDA and ANDA for drug substances.

B. Assesses the suitability of microbiological data in IND, NDA, ANDA and supplemental NDA and ANDA for products with a lower risk of microbial contamination.

C. Assesses the acceptability of manufacturing facilities for lower risk facilities, through evaluation of facility and pre-approval inspection related documentation.

D. Participates in or leads pre-approval inspections for NDA, ANDA and supplements, as merited.

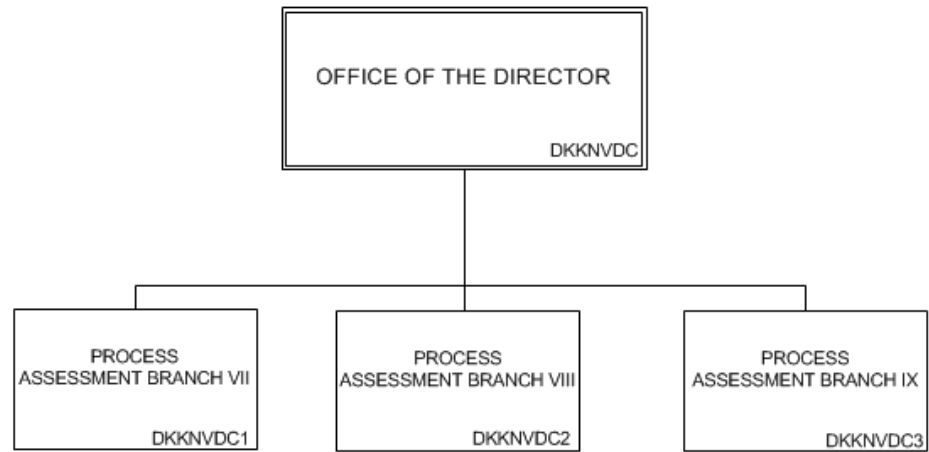
E. Uses risk-based approach, communicates issues with review and inspection related application team members.

F. Provides clear risk-based recommendation on assessment related activities.

5. 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.

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STAFF MANUAL GUIDE 1280.53
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, Division of Process Assessment III organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVDC:

- Process Assessment Branch VII – DKKNVDC1
- Process Assessment Branch VIII – DKKNVDC2
- Process Assessment Branch IX – DKKNVDC3