

**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 INSPECTIONAL ASSESSMENT**

Effective Date: September 26, 2014

**1. DIVISION OF INSPECTIONAL ASSESSMENT (DKKNVDE).**

- A. Oversees the scientific review and quality evaluation of the manufacturing process and facilities for Investigational New Drugs (IND), New Drug applications (NDA), Abbreviated New Drug applications (ANDA), Biologic License Applications (BLA) and supplements assigned to Division.
- B. Advises the Center for Drug Evaluation and Research (CDER) and other Centers on inspectional and facilities issues related to pre-approval and post-approval inspections.

**2. INSPECTIONAL ASSESSMENT BRANCH I (DKKNVDE1).**

- A. Assesses the acceptability of manufacturing facilities, through evaluation of facility and pre-approval inspection related documentation.
- B. Assesses the suitability of manufacturing process data in IND, NDA, ANDA, and BLA and supplemental NDA, ANDA and BLA for products with lower manufacturing risks.
- C. Assesses the suitability of microbiological data in NDA and ANDA and supplemental NDA and ANDA for products with a lower risk of microbial contamination.
- D. Participates in or leads pre-approval inspections for NDA, ANDA, and BLA 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 for NDA, ANDA, and BLA on assessment related activities.

**3. INSPECTIONAL ASSESSMENT BRANCH II (DKKNVDE2).**

- A. Assesses the acceptability of manufacturing facilities, through evaluation of facility and pre-approval inspection related documentation.
- B. Assesses the suitability of manufacturing process data in INDs, NDAs, ANDAs, BIAs and supplemental NDAs, ANDA, and BLAs for products with lower manufacturing risks.
- C. Assesses the suitability of microbiological data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs for products with a lower risk of microbial contamination.
- D. Participates in or leads pre-approval inspections for NDAs, ANDAs, BLAs and supplements, as merited.
- E. Using a risk-based approach, communicates issues with review and inspection related application team members.
- F. Provides clear risk-based recommended New Drug Application on assessment related activities.

**4. INSPECTIONAL ASSESSMENT BRANCH III (DKKNVDE3).**

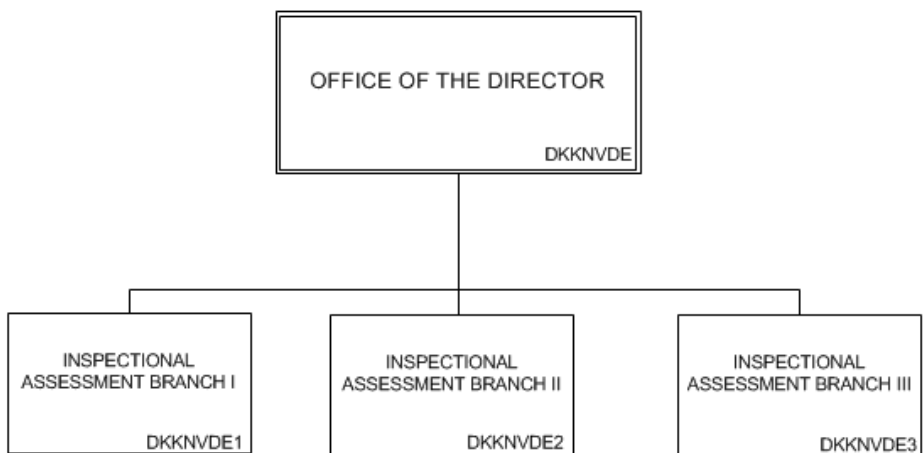
- A. Assesses the acceptability of manufacturing facilities, through evaluation of facility and pre-approval inspection related documentation.
- B. Assesses the suitability of manufacturing process data in INDs, NDAs, ANDAs, BLAs and supplements for products with lower manufacturing risks.
- C. Assesses the suitability of microbiological data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs for products with a lower risk of microbial contamination.
- D. Participates in or leads pre-approval inspections for NDAs, ANDAs, BLAs and supplements, as merited.
- E. Using a risk-based approach, communicates issues with review and inspection related application team members.

F. Provides clear risk-based recommend NDA 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 1280.55  
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 Inspectional Assessment organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR – DKKNVDE:

- Inspectional Assessment Branch I – DKKNVDE1
- Inspectional Assessment Branch II – DKKNVDE2
- Inspectional Assessment Branch III – DKKNVDE3