SMG 1280.55a

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Pharmaceutical Manufacturing Assessment

Division of Microbiology Assessment I

Effective Date**:** September 25, 2019

1. Division of Microbiology Assessment I (DCDLDE).

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), and supplemental NDA/ ANDA, and Drug Master Files (DMF) assigned to Division.

B. Advises Center for Drug Evaluation and Research (CDER) and other Centers on microbial control, and sterility assurance, and microbial product quality aspects of pharmaceutical manufacturing.

2. Microbiology Assessment Branch 1 (DCDLDE1).

A. Assesses the microbiological data in IND, NDA, ANDA, DMF, and supplemental NDA and ANDA, typically for products intended to be sterile or at a higher risk of microbial contamination.

B. Assesses the suitability of process manufacturing data in IND, NDA, and ANDA, and supplemental NDA and ANDA for lower risk manufacturing processes.

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

D. Participates on 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.

3. Microbiology Assessment Branch 2 (DCDLDE2).

A. Assesses the suitability of microbiological data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs, typically for products intended to be sterile or at a higher risk of microbial contamination.

B. Assesses the suitability of process manufacturing data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs for lower risk manufacturing processes.

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

D. Participates on 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.

4. Microbiology Assessment Branch 3 (DCDLDE3).

A. Assesses the suitability of microbiological data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs, typically for products intended to be sterile or at a higher risk of microbial contamination.

B. Assesses the suitability of process manufacturing data in INDs, NDAs, ANDAs and supplemental NDAs and ANDAs for lower risk manufacturing processes.

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

D. Participates on inspections for NDAs, ANDAs and supplements, as merited.

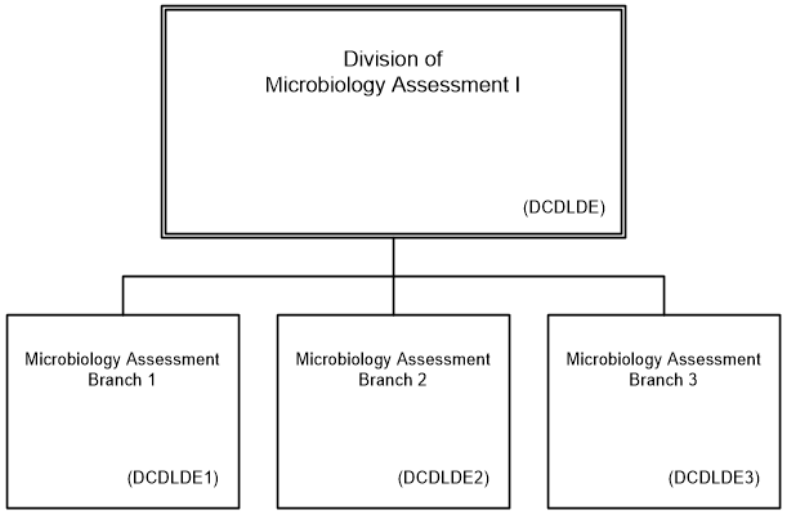
E. Uses a risk-based approach, communicates issues with review and inspection related application team members.

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

5. Authority and Effective Date.

The functional statements for the Division of Microbiology Assessment I were approved by the Secretary of Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
Office of Pharmaceutical Manufacturing Assessment
Division of Microbiology Assessment I



Staff Manual Guide 1280.55a
Organizations and Functions
Effective Date: September 25, 2019

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Pharmaceutical Manufacturing Assessment, Division of Microbiology Assessment I organizational structures depicting all the organizational structures reporting to the Director:

Division of Microbiology Assessment I (DCDLDE).

These organizations report to the Division of Microbiology Assessment I:

Microbiology Assessment Branch 1 (DCDLDE1)

Microbiology Assessment Branch 2 (DCDLDE2)

Microbiology Assessment Branch 3 (DCDLDE3)