

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 Biotechnology Manufacturing

Effective Date: September 25, 2019

1. Division of Biotechnology Manufacturing (DCDLDG).

- A. Oversees the scientific review and quality evaluation of the manufacturing process and facilities for Biologic License Applications (BLA), Investigational New Drugs (IND), supplemental BLA, and Drug Master Files (DMF) assigned to Division.
- B. Advises the Center for Drug Evaluation and Research and other Centers on the assessment of microbial control, sterility assurance, microbial product quality aspects, and on inspectional and facilities activities related to pre-license, pre-approval and post-approval inspections, and other post-marketing/compliance activities.

2. Biotechnology Manufacturing Branch 1 (DCDLDG1).

- A. Assesses the microbiological and manufacturing process data in IND, BLA, DMF, and BLA supplements.
- B. Assesses other Chemistry, Manufacturing and Control (CMC) data and information relevant to manufacturing processes and controls, container closure integrity, cross-contamination controls, microbial controls, microbiology product quality and sterility assurance and labeling.
- C. Assesses the manufacturing processes facilities and Current Good Manufacturing Practices (CGMP), through evaluation of facility and inspection related documentation.

- D. Leads or participates on inspections for BLA, and their supplements, as merited.
- E. Uses risk-based approaches and communicates review and inspection issues with application team members.
- F. Provides clear, science and risk-based recommendation on assessment related activities.

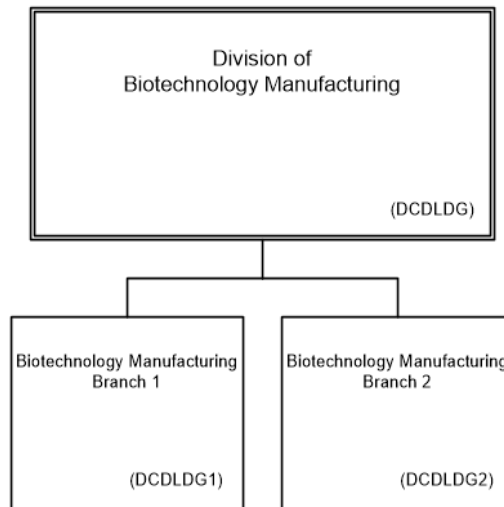
3. Biotechnology Manufacturing Branch 2 (DCDLDG2).

- A. Assesses the microbiological and manufacturing process data in IND, BLA, DMF, and BLA supplements.
- B. Assesses other CMC data and information relevant to manufacturing processes and controls, container closure integrity, cross-contamination controls, microbial controls, microbiology product quality and sterility assurance and labeling.
- C. Assesses the manufacturing processes facilities and CGMPs, through evaluation of facility and inspection related documentation.
- D. Leads or participates on inspections for BLA, and their supplements, as merited.
- E. Uses risk-based approaches and communicates review and inspection issues with application team members.
- F. Provides clear, science and risk-based recommendation on assessment related activities.

4. Authority and Effective Date.

The functional statement for the Division of Biotechnology Manufacturing 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 Biotechnology Manufacturing**



Staff Manual Guide 1280.57
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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 Biotechnology Manufacturing organizational structures depicting all the organizational structures reporting to the Director:

Division of Biotechnology Manufacturing (DCDLDG).

These organizations report to the Division of Biotechnology Manufacturing:

Biotechnology Manufacturing Branch 4 (DCDLDF1)

Biotechnology Manufacturing Branch 5 (DCDLDF2)

Biotechnology Manufacturing Branch 6 (DCDLDF3)