SMG 1212.5

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Compliance and Biologics Quality

Division of Manufacturing and Product Quality

Effective Date: January 6, 2022

1. Division of Manufacturing and Product Quality (DCBCC).

A. Provides direction, clarification, and interpretation on policy and technical issues for the Division.

B. Manages the overall program responsibilities for the Division, primarily lot release, review of submissions, and inspections.

C. Reviews, evaluates, and takes appropriate action on Investigational New Drug applications (INDs), marketing applications, supplements, and amendments submitted to the Center for Biologics Evaluation and Research (CBER), as part of the managed review process. Performs Chemistry, Manufacturing, and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews for specific CBER-regulated products.

D. Performs quality assurance review of completed submissions for consistency in technical content as well as administrative process requirements.

E. Supports enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by other CBER or field components.

2. Product Release Branch (DCBCC1).

A. Develops and administers the biological products lot release program, in coordination with other CBER components.

B. Reviews manufacturers' submissions for licensed biological product lots.

C. Receives, maintains, and distributes samples of biological products submitted for testing.

D. Provides the final quality review for lot release submissions and prepares release correspondence for company notifications.

E. Receives and controls all protocols submitted to the Center pertaining to biological products subject to license under the biological provisions of the Public Health Service Act, and for the lot-by-lot release system.

3. Manufacturing and Review Branch 1 (DCBCC2).

A. Performs quality control functions to ensure accuracy of review and tracking of application data collected and reported.

B. Monitors the quality assurance and consistency of data collected and reported on CBER review activities.

4. Manufacturing and Review Branch 2 (DCBCC3).

A. Reviews, evaluates, and takes appropriate action on INDs, marketing applications, supplements, and amendments submitted to the CBER, as part of the managed review process. Performs CMC and CGMP reviews.

B. Meets with manufacturers to review facility design/CGMP/new products and technologies.

C. Leads prelicense and preapproval inspections supporting Biologics License Application submissions and supplements, as part of the CBER managed review process. Prepares inspection reports as part of an inspection team and evaluates firms' corrective actions.

D. Supports enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by other CBER or field components.

E. Provides expert technical and regulatory guidance and training to CBER and other Food and Drug Administration (FDA) components, government agencies, and representatives of domestic and foreign biological establishments regarding biological product manufacturing and quality, in coordination with the Office of Communication, Outreach and Development.

5. Manufacturing and Review Branch 3 (DCBCC5).

A. Reviews evaluates, and takes appropriate action on INDs, Marketing applications, supplements, and amendments submitted to CBER, as part of the managed review process.

B. Performs CMC and CGMP reviews.

C. Meets with manufacturers to review facility design/CGMP/new products and technologies.

D. Leads pre-license and preapproval inspections supporting Biologics License Application submissions and supplements, as part of the CBER managed review process.

E. Prepares inspection reports as part of an inspection team and evaluates firms' corrective actions.

6. Applications Review Branch (DCBCC4).

A. Performs administrative processing of all submissions chaired by the Office.

B. Prepares review packages and correspondence for final action on supplements.

C. Schedules and coordinates meetings with industry as well as finalizes meeting minutes for distribution.

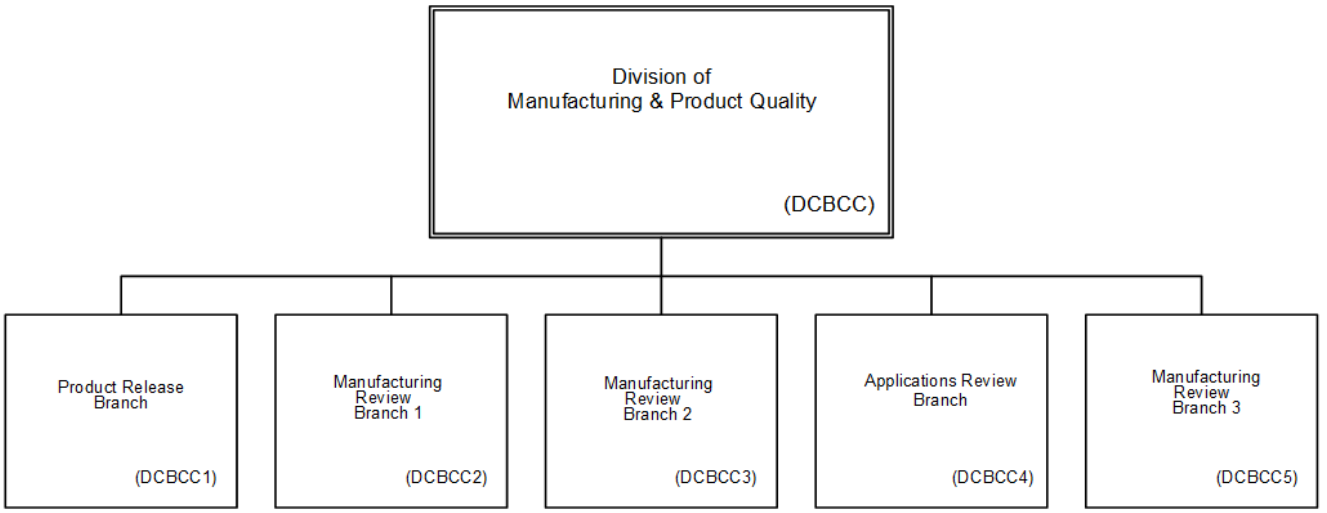
D. Performs all data entry for assignment and tracking of submissions and also generates workload reports in order to maintain operations within the designated Prescription Drug User Fee Act and Medical Device User Fee and Modernization Act time frames.

E. Issues and reissues U.S. and biologics licenses.

7. Authority and Effective Date.

The functional statements for the Division of Manufacturing and Product Quality were approved by the Deputy Secretary of Health and Human Services and effective on January 6, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Manufacturing and Product Quality



Staff Manual Guide 1212.5
Organizations and Functions
Effective Date: January 6, 2022

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, Division of Manufacturing and Product Quality organization structure depicting all the organizational structures reporting to the Director:

Division of Manufacturing and Product (DCBCC)

These organizations report to the Division of Manufacturing and Product Quality:

Applications Review Branch (DCBCC4)

Manufacturing Review Branch 1 (DCBCC2)

Manufacturing Review Branch 2 (DCBCC3)

Manufacturing Review Branch 3 (DCBCC5)

Product Release Branch (DCBCC1)