**SMG 1212.6**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Compliance and Biologics Quality**

**Division of Biological Standards and Quality Control**

Effective Date: January 6, 2022

## 1. Division of Biological Standards and Quality Control (DCBCD).

A. Develops product testing programs in a secured and controlled environment using appropriately qualified and validated methods for generating data supportive of Center regulatory activities.

B. Maintains product testing programs in a manner that meets internationally recognized standards.

C. Participates in lot release activities by performing testing of submitted samples and review of lot release protocols according to approved testing programs.

D. Participates in regulatory review activities by contributing expertise to the evaluation of test methods, assessment of acceptability of assay method validation packages, and evaluation of appropriateness of product specifications.

E. Provides expert scientific and technical advice and assistance to industry, other Food and Drug Administration (FDA) components, and international and academic organizations on issues related to biologics product testing and methods validation.

F. Prepares, calibrates, holds and distributes official U.S. reference preparations used in the control testing of biological products.

G. Collaborates with national and international health agencies on evaluation studies of International Reference Preparations and functions as a World Health Organization/ Pan American Health Organization Essential Regulatory Laboratory.

H. Develops and maintains scientific programs for the evaluation and standardization of reagent test kits and related devices in cooperation with other Center components.

I. Participates, as appropriate, in development and improvement of procedures used to evaluate safety, efficacy and purity in biological products.

J. Oversees the staff of biochemistry, virology and immunochemistry laboratories for in-support testing, lot release testing, review activities and calibration of reference standards.

**2. Lab of Analytical Chemistry Branch (DCBCD4).**

A. Operates laboratory in compliance with appropriate quality standards.

B. Evaluates product samples submitted in support of Investigational New Drugs (INDs), License applications and supplements for evaluation and lot release, or for special post marketing surveillance.

C. Performs review of manufacturer's lot release protocols.

D. Coordinates the technology transfer of significant new testing capabilities into the unit from both internal and external sources and completes required qualification and validation studies.

E. Facilitates the development of post license product lot release Testing Plans, and guides the form and content of lot release protocols.

F. Performs review of INDs, Biologics License Applications (BLAs) and supplements as necessary to support other Center components.

G. Evaluates and develops new assay technologies that relate directly to the Division of Biological Standards and Quality Control (DBSQC) mission.

H. Facilitates the procurement and/or preparation and calibration of physical standards and references significant to Center for Biologics Evaluation and Research's (CBER) scientific mission.

I. Facilitates the preparation and calibration of research materials significant to CBER's scientific mission in support to other Center components.

**3. Lab of Biochemistry, Virology, and Immunochemistry Branch (DCBCD5).**

A. Evaluate product samples submitted in support of INDs, license applications and supplements for evaluation and lot release, or for special post-marketing surveillance.

B. Performs review of manufacturer's lot release protocols.

C. Coordinates the technology transfer of significant new testing capabilities into the unit from both internal and external sources and completes required qualification and validation studies.

D. Facilitates the development of post license product lot release Testing Plans and guides the form and content of lot release protocols.

E. Performs review of INDs, BLAs and supplements as necessary to support other Center components.

F. Evaluates and develops new assay technologies that relate directly to the DBSQC mission.

**4. Lab of Blood Related Products Branch (DCBCD6).**

A. Operates laboratory in compliance with appropriate quality standards.

B. Evaluates product samples submitted in support of Investigational New Drugs (INDs), license applications and supplements for evaluation and lot release, or for special post-marketing surveillance.

C. Performs review of manufacturer's lot release protocols.

D. Coordinates the technology transfer of significant new testing capabilities into the unit from both internal and external sources and completes required qualification and validation studies.

E. Facilitates the development of post license product lot release Testing Plans and guides the form and content of lot release protocols.

F. Cooperates with other FDA components in the review of medical devices related to infectious disease testing when such products have label indications for use in blood establishments and evaluates and validates lot release Serum panels.

G. Evaluates and develops new assay technologies that relate directly to the Division of Biological Standards and Quality Control (DBSQC) mission.

H. Facilitates the procurement and/or preparation and calibration of physical standards and references significant to Center for Biologics Evaluation and Research's (CBER) scientific mission.

I. Facilitates the preparation and calibration of research materials significant to CBER's scientific mission in support to other Center components.

**5. Quality Assurance Branch (DCBCD2).**

A. Provides support for development and maintenance of programs proscribed by the elements of DBSQC's Quality Program and as required by appropriate quality standard(s).

B. Manages document and record control.

C. Manages tracking of submitted regulatory samples within the laboratory.

D. Audits laboratory reports.

E. Audits laboratory functions as required to assure compliance with requirements of operating quality system.

F. Contributes to Center-wide internal audit program and periodic management review.

**6. Laboratory of Microbiology, In-Vivo Testing and Standards Branch (DCBCD3).**

A. Operates laboratory and Standard and Reagent manufacturing and storage facility in compliance with appropriate quality standards.

B. Evaluates product samples submitted in support of INDs, license applications and supplements for evaluation and lot release, or for special post-marketing surveillance.

C. Performs review of manufacturer's lot release protocols.

D. Coordinates the technology transfer of significant new testing capabilities into the unit from both internal and external sources and completes required qualification and validation studies.

E. Facilitates the development of post license product lot release Testing Plans and guides the form and content of lot release protocols.

F. Performs review of INDs, BLAs and supplements as necessary to support other Center components.

G. Evaluates and develops new assay technologies that relate directly to the DBSQC mission.

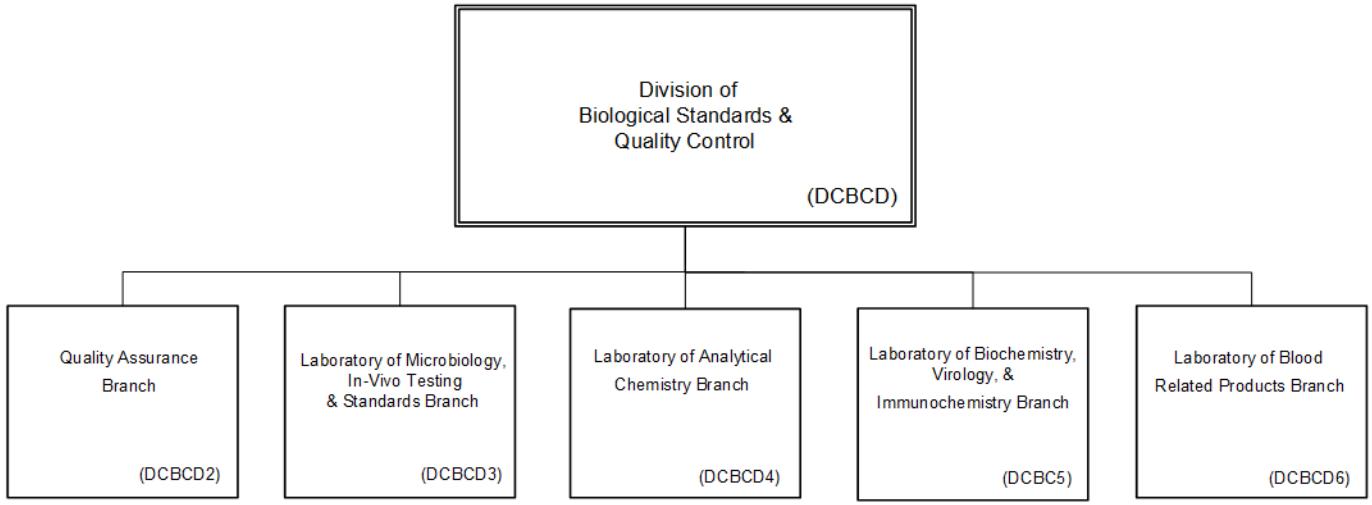
H. Facilitates the procurement and/or preparation, calibration, storage and distribution of physical standards and references significant to CBER's scientific mission.

I. Facilitates the preparation, calibration, storage and distribution of research materials significant to CBER's scientific mission in support to other Center components.

**7. Authority and Effective Date.**

The functional statements for the Division of Biological Standards and Quality Control 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 Biological Standards and Quality Control**



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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 Biological Standards and Quality Control organization structure depicting all the organizational structures reporting to the Director:

Division of Biological Standards and Quality Control (DCBCD)

These organizations report to the Division of Biological Standards and Quality Control:

Lab of Analytical Chemistry Branch (DCBCD4)

Lab of Biochemistry, Virology, and Immunochemistry Branch (DCBCD5)

Lab of Blood Related Products Branch (DCBCD6)

Lab of Microbiology, In-Vivo Testing and Standards Branch (DCBCD3)

Quality Assurance Branch (DCBCD2)