

SMG 1219.3

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 Communication, Outreach and Development

Division of Manufacturers Assistance and Training

Effective Date: January 6, 2022

1. Division of Manufacturers Assistance and Training (DCBHB).

- A. Provides assistance and training to industry, including large and small manufacturers and trade associations, and responds to requests for information regarding the Center for Biologics Evaluation and Research (CBER) policies and procedures.
- B. Informs industry and trade associations of the status of the CBER policies and initiatives through regular information mailings and training.
- C. Communicates regularly with Center staff to insure they are kept informed of current CBER policies, procedures, initiatives, and accomplishments.
- D. Serves as the CBER focal point for industry and trade associations to provide meeting support and coordinates external meetings with other Food and Drug Administration (FDA) Centers.
- E. Directs, manages, coordinates, and develops the Center's overall professional and management training program, a formal career development program, a new employee orientation program, and related policies.
- F. Coordinates and develops in-service and automated data processing training programs pertinent and unique to the Center.
- G. Coordinates with external organizations to develop and implement training, professional, and technical development programs.
- H. Interacts with other FDA Centers and the Office of Regulatory Affairs in the development and implementation of scientific and professional training programs.

- I. Participates as an active member of the CBER Curriculum Committees in the development and implementation of Centerwide scientific and professional training programs.

2. Career Development and Directed Training Branch (DCBHB1).

- A. Provides oversight for the Center's directed training and professional and management development programs, including recommendations on appropriate programs and mechanisms for training and educating CBER employees.
- B. Directs the development and formulation of Center training philosophy and policy, providing significant influence on the conduct of CBER training and development programs, ensuring comprehensive approach to staff development and training.
- C. Establish programs directed towards the Center population at all levels, including development and implementation of training programs in specialized areas.
- D. Coordinates CBER Competency Model and integrating it with the Center's curriculum, recruitment and retention, succession planning, performance management and other programs to ensure a highly competent CBER workforce.
- E. Develops comprehensive employee orientation, career and professional development programs and courses at all levels in organization.
- F. Coordinate measurement strategies to assess the impact of CBER program curricula and course offerings.
- G. Deliver cost effective training and development solutions including, but not limited to, distance learning, satellite broadcasts, blended learning approaches, web-based, classroom, etc.
- H. Develop and formulate CBER's distance learning programs which impact the Center, Agency, and other target populations outside the government such as private industry, trade organizations, and academia.
- I. Advise on use of Learning Management System by CBER Staff.
- J. Directs continuing education requirements for accreditation of training from appropriate professional, educational, and scientific organizations with awards of approved Continuing Education Units (CEU) to CBER staff.

3. Manufacturers Assistance and Technical Training Branch (DCBHB2).

- A. Oversight of communication initiatives with manufacturers, both large and small, regarding the general approval process, statutory authority, agency regulation and Center policies and procedures for biological products, including those

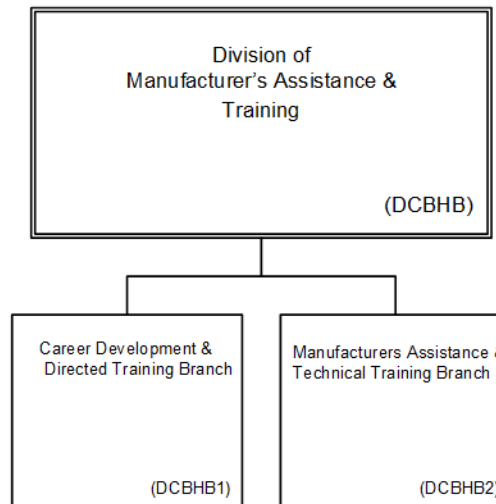
produced by biotechnology, to promote their understanding and compliance with regulatory requirements and enhance product development activities.

- B. Develop policy and procedures to coordinate requests for industry/scientific association liaison meetings with Center.
- C. Assure minutes of liaison meeting are written and circulated for comment and maintained in OCOD.
- D. Articulate current regulatory policies, guidelines, points to consider, and pertinent memoranda to manufacturers and inform trade associations of the status of CBER policies and initiatives by participating in industry/scientific association conferences, and through mailings and multi-media mechanisms.
- E. Oversees requests for CBER staff to participate in events such as scientific workshops, panel discussions and regulatory conferences to assure presentations conform to Agency and Center policy.
- F. Manage CBER speaker database.
- G. Participate on Industry/scientific association educational committees to provide guidance for educational and regulatory conferences on topics relevant to mission and responsibilities of Agency and Center.
- H. Serve as CBER Representative on Agency-level task forces, working groups and standing ad-hoc committees.
- I. Manage development and coordination of scientific technical training for Center including new reviewer and investigator training.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for the Division of Manufacturers Assistance and Training 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 Communication, Outreach and Development
Division of Manufacturer's Assistance and Training**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Center for Biologics Evaluation and Research, Office of Communications, Outreach and Development, Division of Manufacturer's Assistance and Training organization structure depicting all the organizational structures reporting to the Office Director.

Division of Manufacturer's Assistance and Training (DCBHB):

- Career Development and Directed Training Branch (DCBHB1)
- Manufacturers Assistance and Technical Training Branch (DCBHB2)