

SMG 1220.4

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 Regulatory Operations

Division of Information Technology

Effective Date: September 30, 2022

1. Division of Information Technology (DCBIC)

- A. Develops and manages CBER's Information Technology Investments in review, scientific, and administrative areas.
- B. Leads the CBER Information Technology Governance function.
- C. Responsible for the modernization and digital transformation of CBER's Information Technology architecture, infrastructure and automated services.
- D. Coordinate CBER's Information Technology strategy with CBER management, other FDA Center's, other HHS Operating Divisions and FDA's Office of Digital Transformation.

2. Program Management and Analysis Branch (DCBIC1)

- A. Responsible for IT program management, contract management and oversight, Contractor's Officer Representative (COR), IT contracts creation, and procurement evaluations.
- B. Leads Capital Planning and Investment Control (CPIC), IT budget and investment, IT funds control, and FDA intra-center cost allocations.
- C. Acquires IT products (cloud, software, hardware, network), manages the product life cycle, and vendor relationships.
- D. Provides governance support for the CBER central IT governance, functional areas, and integrated project teams.

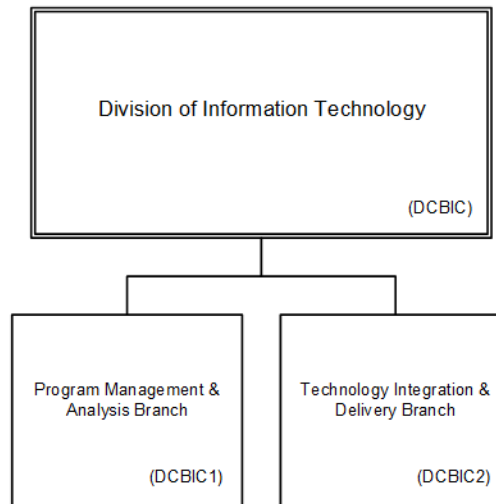
3. Technology Integration and Delivery Branch (DCBIC2)

- A. Establishes a Development, Security and Operations (DevSecOps) environment, culture, and platform to integrate development, security, and operations priorities throughout the entire IT lifecycle.
- B. Implements a cloud-ready technical architecture and manages the delivery of modernized functional services across CBER and integrated throughout the FDA and HHS systems environment.
- C. Supports the IT updates and modernization responsibilities laid out by the Prescription Drug (PDUFA), Medical Device (MDUFA), and Biosimilar (BsUFA) User Fee Agreement commitment letters and other legislative and department mandates.
- D. Operates and maintains legacy IT systems until they can be replaced by modernized functionality.

4. Authority and Effective Date.

The functional statements for the Office of Regulatory Operations, Division of Information Technology, were approved by the Commissioner of Food and Drugs and effective on September 30, 2022.

**Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluations and Research
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Division of Information Technology**



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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 Regulatory Operations, Division of Information Technology organization structure depicting all the organizational structures reporting to the Director:

Division of Information Technology (DCBIC)

These organizations report to the Division of Information Technology:

Program Management & Analysis Branch (DCBIC1)

Technology Integration & Delivery Branch (DCBIC2)