SMG 1258.90

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

Office of Health Technology VII

Effective Date: January 6, 2022

1. Office of Health Technology VII (DCCFI).

A. Responsible for executing end-to-end device review programs and activities.

B. Works closely with other offices on classification and reclassification activities, and the development of guidance documents.

C. Provides initial support for questions related to regulatory programs in response to specific requests from medical device and health technology industries, trade associations, other Federal agencies, other countries, State agencies, and the general public.

D. Advises, coordinates, and provides consultation to the Super Office Director and other Food and Drug Administration (FDA) officials on Office programs and policies concerning premarket review activities, postmarked market surveillance, and quality.

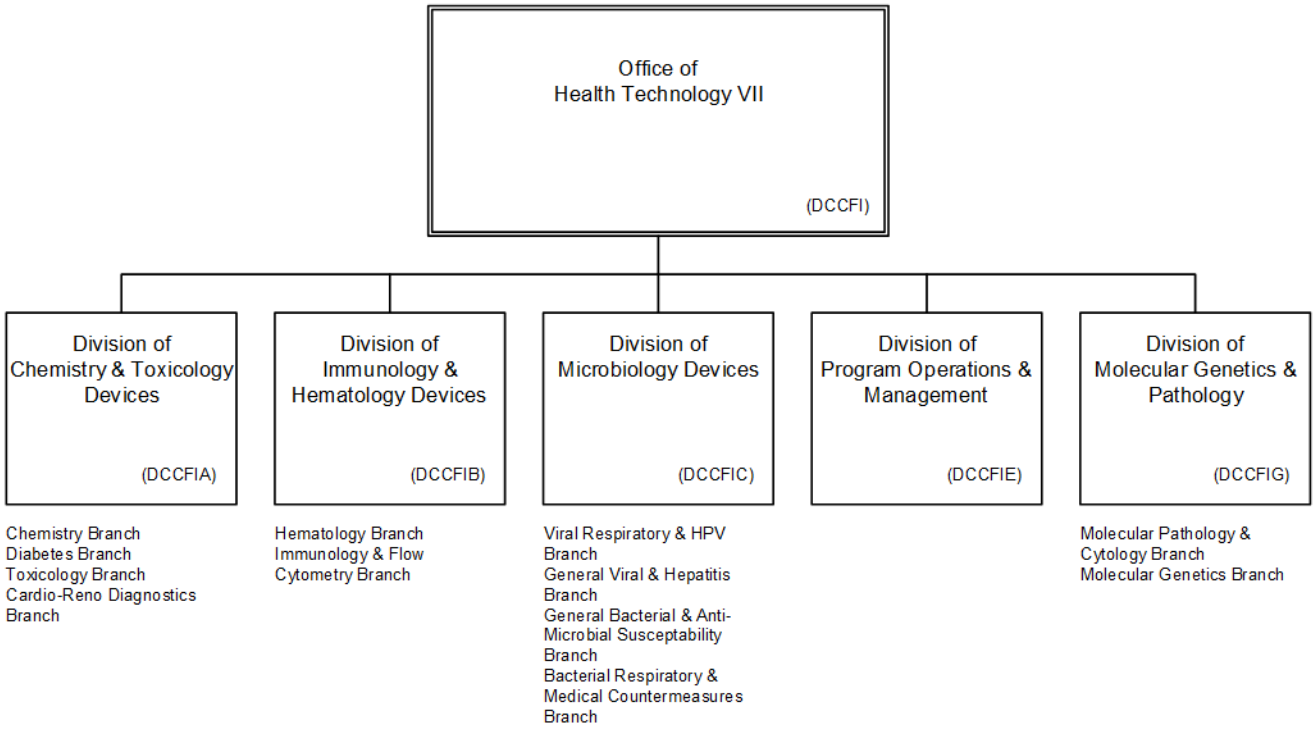
E. Maintains and analyzes device-related compliance data and uses this data to support Office and Center-level activities.

F. Participates in the development of national and international consensus standards, and voluntary guidelines through interaction with appropriate national and international standards committees.

2. Authority and Effective Date.

The functional statements for the Office of Health Technology VII were approved by the Deputy Secretary of Health and Human Services on October 22, 2021, and effective on January 6, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Health Technology VII



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Product Evaluation & Quality, Office of Health Technology VII organization structure depicting all the organizational structures reporting to the Director.

Office of Health Technology VII (DCCFI)

- Division of Chemistry & Toxicology Devices (DCCFIA)
  - Chemistry Branch
  - Diabetes Branch
  - Toxicology Branch
  - Cardio-Renal Diagnostics Branch
- Division of Immunology & Hematology Devices (DCCFIB)
  - Hematology Branch
  - Immunology & Flow Cytometry Branch
- Division of Microbiology Devices (DCCFIC)
  - Viral Respiratory & HPV Branch
  - General Viral & Hepatitis Branch
  - General Bacterial & Antimicrobial Susceptibility Branch
  - Bacterial Respiratory & Medical Countermeasures Branch
- Division of Radiological Health (DCCFID)
  - Magnetic Resonance & Electronic Products Branch
  - Diagnostic X-Ray Systems Branch
  - Nuclear Medicine & Radiation Therapy Branch
  - Mammography, Ultrasound & Imaging Software Branch
- Division of Program Operations & Management (DCCFIE)
- Division of Molecular Genetics & Pathology (DCCFIG)
  - Molecular Pathology & Cytology Branch
  - Molecular Genetics Branch