

**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 VIII**

Effective Date: January 6, 2022

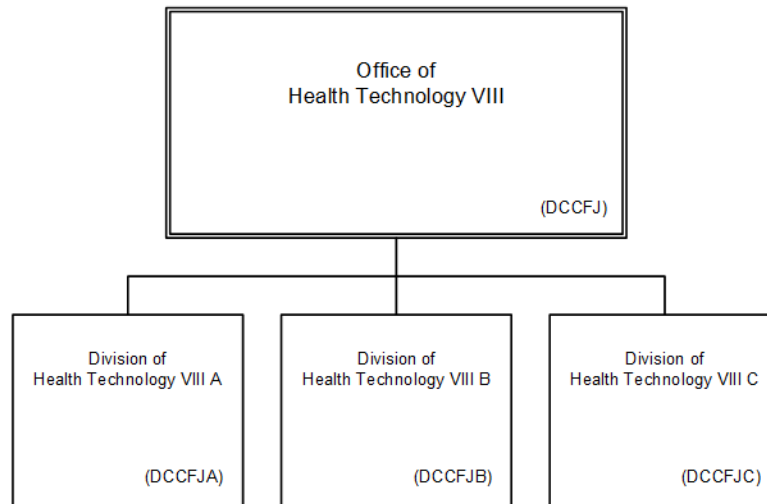
**1. Office of Health Technology VIII (DCCFJ).**

- 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, postmarket 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 VIII 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 Product Evaluation and Quality  
Office of Health Technology VIII**



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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 VIII organization structure depicting all the organizational structures reporting to the Director.

Office of Health Technology VIII (DCCFJ)

- Division of Health Technology VIII A (DCCFJA)
- Division of Health Technology VIII B (DCCFJB)
- Division of Health Technology VIII C (DCCFJC)