

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 Strategic Partnerships and Technology Innovation

Digital Health Center of Excellence

Division of Digital Health Policy

Effective: August 8, 2023


1. Division of Digital Health Policy (DCCCFA).

- A. Provides oversight and leadership in the development, review, and implementation of legislation, regulations, policies, procedures, and guidances related to software and digital health technologies across the life cycle.
- B. Serves as an expert resource for software and digital health policy matters by providing advice and consultation to the Center for Devices and Radiological Health, the Food and Drug Administration, and other U.S. Government entities.

2. Authority and Effective Date.

The functional statements for the Division of Digital Health Policy were approved by the Secretary of Health and Human Services on June 27, 2023, and effective on August 8, 2023.

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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 Scientific Programs and Technology Innovation, Digital Health Center of Excellence, Division of Digital Health Policy organization structure depicting all the organizational structures reporting to the Director:

Division of Digital Health Policy (DCCCFA)