

SMG 1251A.20

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

Effective: August 8, 2023

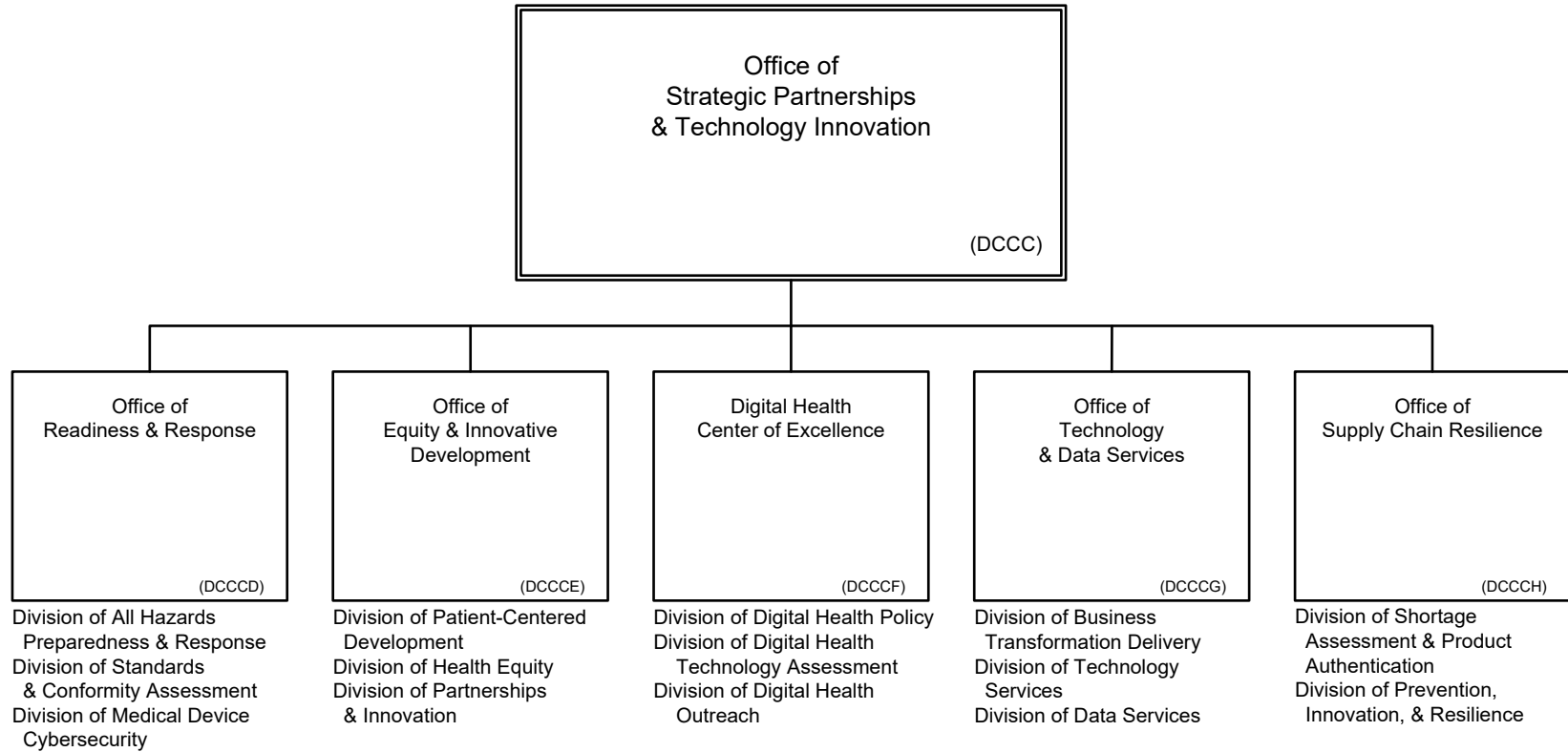
1. Office of Strategic Partnerships and Technology Innovation (DCCC).

- A. Represents the Center for Devices and Radiological Health (CDRH) and collaborates with a broad and diverse array of national and international entities including other government entities, Congress, industry, academia, consumer and patient organizations, and healthcare professional organizations, with mutual interests in medical devices and radiation-emitting products.
- B. Provides leadership in advancing partnerships with patient organizations, healthcare professional organizations, industry, scientific and other external organizations to support broad national and international patient-focused and regulatory science programs and activities related to the safety, effectiveness, and quality of medical devices and the safety of radiation-emitting products.
- C. Provides leadership and facilitates collaboration in fostering the development of medical devices to respond to unmet public health needs and to address challenges of bringing innovative medical devices to market that are safe, effective and high quality.
- D. Provides leadership and strategic direction on software and digital health topics for the Center.
- E. Provides leadership, oversight, and coordination for the Center in matters relating to emergency preparedness and response activities involving CDRH-regulated products or facilities.
- F. Provides world-wide leadership in standards implementation and utilization for medical device innovation and manufacturing, and radiation-emitting product safety.

2. Authority and Effective Date.

The functional statements for the Office of Strategic Partnerships and Technology Innovation were approved by the Secretary of Health and Human Services on June 27, 2023, and effective on August 8, 2023.

**Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Strategic Partnerships and Technology Innovation**



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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 Strategic Partnerships and Technology Innovation organization structure depicting all the organizational structures reporting to the Director:

Office of Strategic Partnerships and Technology Innovation (DCCC)
Office of Readiness and Response (DCCCD)
Office of Equity and Innovative Development (DCCCE)
Digital Health Center of Excellence (DCCCF)
Office of Technology and Data Services (DCCCG)
Office of Supply Chain Resilience (DCCCH)

These organizations report to the Office of Readiness and Response (DCCCD):

Division of All Hazards Preparedness and Response
Division of Standards and Conformity Assessment
Division of Medical Device Cybersecurity

These organizations report to the Office of Equity and Innovative Development (DCCCE):

Division of Patient-Centered Development
Division of Health Equity
Division of Partnerships and Innovation

These organizations report to the Digital Health Center of Excellence (DCCCF):

Division of Digital Health Policy
Division of Digital Health Technology Assessment
Division of Digital Health Outreach

These organizations report to the Office of Technology and Data Services (DCCCG):

Division of Business Transformation Delivery
Division of Technology Services
Division of Data Services

These organizations report to the Office of Supply Chain Resilience (DCCCH):

Division of Shortage Assessment and Product Authentication
Division of Prevention, Innovation, and Resilience