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 Date: December 14, 2018

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

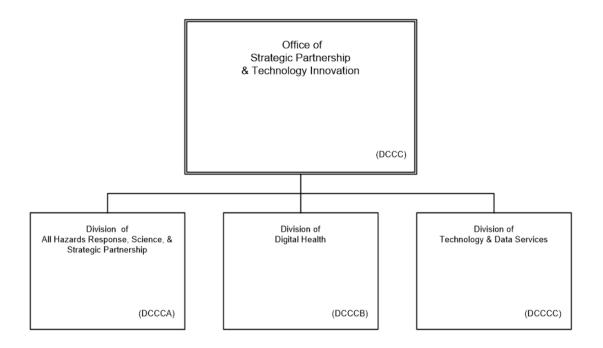
- A. Represents the Center and collaborates with a broad and diverse array of national and international entities including other government agencies, Congress, industry, academia, consumer and patient organizations, and healthcare professional organizations, with mutual interests in medical devices 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 Center for Devices and Radiological Health (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.

G. Directs and oversees all aspects of the Center's data, informatics, and information technology programs to ensure effective design, development, and utilization of information systems, electronic data and analytic tools to optimize regulatory business processes.

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 and effective on December 14, 2018.

Department of Health and Human Services Food and Drug Administration Center for Devices for 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.

These divisions report to the Office of Strategic Partnership & Technology Innovation (DCCC)

- Division of All Hazards Response, Science & Strategic Partnerships (DCCCA)
- Division of Digital Health (DCCCB)
- Division of Technology & Data Services (DCCCC)