

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

Division of Program Operations and Management

Effective Date: January 6, 2022

1. Division of Program Operations and Management (DCCFIE).

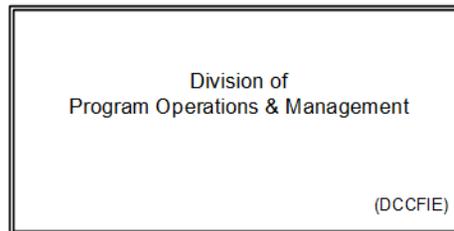
- A. Develops and interprets policy guidance in response to specific requests from the medical device and electronic products industries, trade associations, other Federal agencies, other countries, congress, State agencies, and the general public.
- B. Conducts management and program analysis studies and participates in the program planning process to identify operational goals and evaluation methods. Designs and recommends systems and procedures and develops policy recommendation to implement study conclusions.
- C. Develops policies and coordinates cross-cutting pre and postmarket activities to improve efficiencies within and between the Office and other offices.
- D. Coordinates activities on programs and policies concerning premarket review activities, postmarked market surveillance, and quality with Center and Food and Drug Administration (FDA) components or other organizations.
- E. Provides authoritative advice and guidance to the Office Director on management policies, guidelines, issues and concerns that impact Office/Center program and initiatives.
- F. Advises the Office Director regarding all administrative management matters.

G. Provides leadership, guidance and directs the development of long-range strategic management and operational plans, and systems for Office activities and directs technical support.

2. Authority and Effective Date.

The functional statements for the Division of Program Operations and Management 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 VII
Division of Program Operations and Management**



Staff Manual Guide 1258.95
Organizations and Functions
Effective Date: January 6, 2022

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, Division of Program Operations & Management organization structure depicting all the organizational structures reporting to the Director.

Division of Program Operations & Management (DCCFIE)