

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 Regulatory Programs

Division of Regulatory Programs IV

Effective Date: January 6, 2022

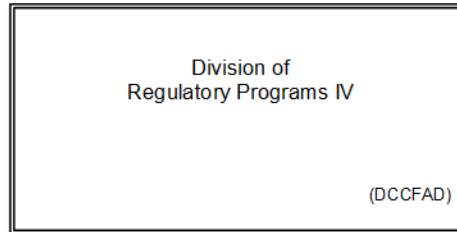
1. Division of Regulatory Programs IV (DCCFAD).

- A. Responsible for identifying customer needs based on knowledge of CDRH business processes and regulations as well as through interactions with staff, translating these needs into business requirements, and coordinating development activities for regulatory systems and tools.
- B. Develops advanced analytical tools and performs analyses of internal and external data for the purposes of supporting business processes and external data calls, assessing review performance, informing regulatory decision-making, and determining strategy in areas that may impact the marketing growth, availability, or quality of medical devices.
- C. Incorporates review policies and procedures into both internal and external tools and templates that simplify, ensure the consistency of, and streamline the review process, primarily through automation, consolidation of data resources, integration with existing regulatory systems, and use of review guides (templates) based on established regulation, policy and guidance.

2. Authority and Effective Date.

The functional statements for the Division of Regulatory Programs IV 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
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Division of Regulatory Programs IV**



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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 Regulatory Programs, Division of Regulatory Programs IV organization structure depicting all the organizational structures reporting to the Director.

Division of Regulatory Programs IV (DCCFAD)