SMG 1258.1

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

Effective Date: December 14, 2018

1. Office of Product Evaluation and Quality (DCCF).

A. Collaboratively supports Center in assuring the enforcement of the Medical Device Amendments of 1976 including the Safe Medical Devices Act of 1990 and 1992, the Food and Drug Administration Modernization Act and the Radiation Control for Health and Safety Act of 1972 relating to the safety and effectiveness of medical devices and radiation-emitting electronic products.

B. Responsible for setting strategy and overseeing device specific clinical evidence and analysis, and regulatory functions and programs activities to ensure quality end-to-end device evaluation, and the consistent interpretation and application of regulatory policy and guidance.

C. Ensures that these functions and program activities are aligned to the overall strategy and priorities of the Center for Devices and Radiological Health (CDRH) and the Food and Drug Administration (FDA).

2. Quality and Analytics Staff (DCCF1).

A. Responsible for serving as a strategic partner to the Quality Management group and assessing the overall performance of the organization.

B. Coordinates with the central quality management group, setting quality standards and executing quality programs in the Super Office. Gathers and analyzes data related to division and office performance and to support management of the overall organization. This includes cross cutting analysis and reports required by internal and external stakeholders, and supporting Medical Devices User Fee Act (MDUFA) negotiations.

C. Responsible for developing tools to enhance quality assurance within the office. The interface between the office and the Business Information Solutions.

3. Clinical and Scientific Policy Staff (DCCF2).

D. Responsible for clinical oversight and coordination, management of communities of practice, and coordination of the Safety Signal Management Program.

E. Provides clinical oversight and coordination which includes training of medical officers, development and guidance on the use of benefit-risk principles and patient perspectives, assessment of clinical versus statistical significance in complex reviews and the applications of other new policies to clinical review.

F. Provides clinical expertise as needed in complex evaluations of medical devices.

G. Responsible for the management of the communities of practice initiative involves identifying appropriate topics that would benefit from the creation of communities of practice, launching the supporting infrastructure for these communities of practice, and coordinating/facilitating communications and meetings of communities of practice within and beyond CDRH.

H. Provides direction and oversight of the Safety Signal Management Program, coordinating activities of signal managers across the device specific programs, setting standards and policies for signals management, and making final determinations on signals as required.

4. Strategic Initiatives Staff (DCCF3).

A. Responsible for developing and driving strategic initiatives that cut across offices.

B. Coordinates and provides leadership of strategic priorities, leveraging office staff as necessary in project based working groups.

5. Regulations Policy and Guidance Staff (DCCF4)

A. Provides authoritative advice and guidance to the Office Director on management policies, guidelines, issues and concerns that impact Office/Center program and initiatives.

6. Operations Staff (DCCF5)

A. Directs, coordinates and controls the resource management activities of the Office. Coordinates and provides analysis, execution and evaluation of business operations; coordinates and carries out transactions needed to ensure the effective operation of business needs including human capital, performance management, budget formulation, procurement, facilities and information technology management.

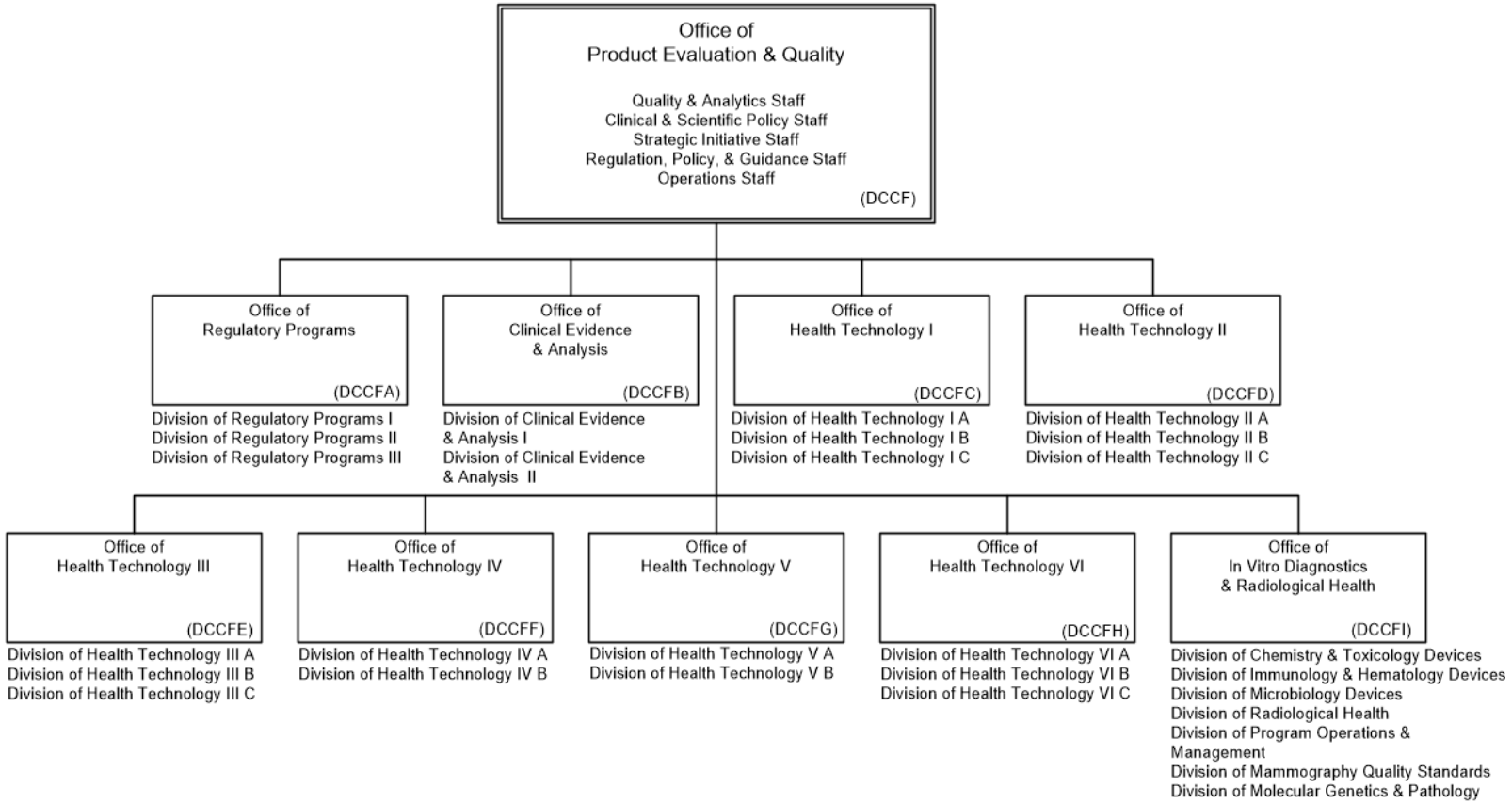
B. Directs and conducts management and program analyses to provide guidance to the Office Director on administrative and technical policies, guidelines, and issues that impact Office initiatives and program areas.

C. Tasked with the management and administration of Office of Product Evaluation and Quality (OPEQ) resources designed to support ongoing programs. Ensures proper distribution of payroll funds, facility plans, human resource allocations, property, and laboratory support needs.

7. Authority and Effective Date.

The functional statements for the Office of Product Evaluation and Quality 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 and Radiological Health
Office of Product Evaluation and Quality



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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 and Quality organization structure depicting all the organizational structures reporting to the Director.

These staffs and offices report to the Office of Product Evaluation & Quality (DCCF)

- Quality & Analysis Staff
- Clinical & Scientific Policy Staff
- Strategic Initiatives Staff
- Regulation, Policy & Guidance Staff
- Operations Staff

These divisions report to the Office of Regulatory Programs (DCCFA)

- Division of Regulatory Programs I
- Division of Regulatory Programs II
- Division of Regulatory Programs III

These divisions report to the Office of Clinical Evidence & Analysis (DCCFB)

- Division of Clinical Evidence & Analysis I
- Division of Clinical Evidence & Analysis II

These divisions report to the Office of Health Technology I (DCCFC)

- Division of Health Technology I A
- Division of Health Technology I B
- Division of Health Technology I C

These divisions report to the Office of Health Technology II (DCCFD)

- Division of Health Technology II A
- Division of Health Technology II B
- Division of Health Technology II C

These divisions report to the Office of Health Technology III (DCCFE)

- Division of Health Technology III A
- Division of Health Technology III B
- Division of Health Technology III C

These divisions report to the Office of Health Technology IV (DCCFF)

- Division of Health Technology IV A
- Division of Health Technology IV B

These divisions report to the Office of Health Technology V (DCCFG)

- Division of Health Technology V A
- Division of Health Technology V B

These divisions report to the Office of Health Technology VI (DCCFH)

- Division of Health Technology VI A
- Division of Health Technology VI B
- Division of Health Technology VI C

These divisions report to the Office of In Vitro Diagnostics & Radiological Health (DCCFI)

- Division of Chemistry & Toxicology Devices
- Division of Immunology & Hematology Devices
- Division of Microbiology Devices
- Division of Radiological Health
- Division of Program Operations & Management
- Division of Mammography Quality Standards
- Division of Molecular Genetics & Pathology