SMG 1263.16a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of New Drugs

Office of Program Operations

Effective Date: September 25, 2019

1. Office of Program Operations (DCDGM).

A. Serves as liaison between Offices within the Office of New Drugs (OND), other centers, the Food and Drug Administration (FDA), and external stakeholders on the dissemination of information related to office activities.

B. Plans and executes internal and external events/meetings on behalf of the new drugs regulatory program as appropriate.

C. Designs and implements new regulatory programs and business processes; monitors their performance and identifies opportunities for improvement.

D. Leads capacity planning and workload analysis for purposes of office-wide resource allocation.

E. Designs and implements organization-wide strategies to support overall talent development and learning needs of all OND staff.

2. Executive Operations Staff (DCDGM1).

A, Acts as the liaison with Center and Office leaders across the FDA, and with external stakeholders on the dissemination of information and updates on scientific and regulatory activities within the OND.

B. Serves as the regulatory interface between FDA, industry, and the American and international public, as appropriate, for all OND related non-product specific issues.

C. Leads the planning of all internal and external events that communicate Office-wide trends across the new drugs program to Office staff members and relevant external parties.

D. Supports the routine and one-off disclosure of regulatory program information and data to both FDA colleagues and external parties, as needed.

E. Coordinates the operations of the OND Director and Deputy Directors, insuring that the goals and priorities of the Office are carried out.

3. Business Process & Analysis Staff (DCDGM2).

A. Oversees the operation life-cycle of OND business processes (e.g. Administrative, Informatics, Regulatory, Scientific).

B. Assesses operations, identifying opportunities for collaboration with process owners to enhance consistency and efficiency, reduce burden on staff, or meet a new need.

C. Coordinates development and refinement of business processes and best practices through continuous review and analysis.

D. Documents, maintains, and disseminates the resulting operational processes to stakeholders through available avenues (e.g. Center for Drug Evaluation and Research (CDER) Standard Templates, Standard Operating Procedures, Web).

E. Develops and maintains intra and inter-Center agreements that define agreed-upon levels of support by OND staff to support the overall work performed by FDA.

F. Leads routine capacity planning work to predict future workload and guide the allocation of OND resources.

4. Learning & Talent Development Staff (DCDGM3).

A. Partners with OND senior leaders, CDER and other FDA learning organizations to design and implement innovative learning, performance and talent development solutions that support OND employees.

B. Supports the professional development of all OND staff members by developing, evaluating and assessing training, skill-building and other mentorship programs to assist in career development.

C. Manages discipline-specific, technical learning and other development programs designed to ensure OND staff members continue to hone their professional skills.

D. Develops designs, and implements organization development programs to strengthen engagement, enhance culture and increase satisfaction of all OND staff members.

5. Program Development, Implementation & Management Staff (DCDGM4).

A. Oversees and provides centralized development, implementation, and management (e.g. coordination and evaluation) of OND programs in a manner that 1) meets statutory, regulatory and user-fee requirements, 2) supports review staff members' questions, and 3) standardizes program related review work across the OND to the extent possible.

B. Reviews and evaluates the routine performance of all new and existing regulatory programs to identify opportunities for improvement and to fulfill the immediate and long-term needs and goals of review teams.

C. Works across review teams, Divisions, and Offices within the OND to standardize the methodologies, processes, policies and documentation in the application of a new laws, provisions, regulations, user fee commitments, and regulatory programs to the review process.

D. Maintains dashboards, tools, databases and other resources that support reporting requirements and data call requests for regulatory programs.

E. Develops and implements new programs as needed in response to changes in laws, provisions, regulations, or user-fee commitments, that impact OND.

F. Manages and provides oversight of new and existing OND programs.

6. Authority and Effective Date.

The functional statements for the Office of Program Operations were approved by the Secretary of the Health and Human Services on September 25, 2019.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of New Drugs
Office of Program Operations

Office of Operations
Executive Operations Staff
Business Process & Analysis Staff
Learning & Talent Development Staff
Program Development, Implementation & Management Staff

(DCDGM)

Staff Manual Guide 1263.16a
Organizations and Functions
Effective Date: September 25, 2019

The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Office of Program Operations organization structure depicting all the organizational structures reporting to the Director.

Office of Program Operations (DCDGM).

These organizations report to the Office of Program Operations:

Executive Operations Staff

Business Process & Analysis Staff

Learning & Talent Development Staff

Program Development, Implementation & Management Staff

Back to Organizations and Functions, Volume I (1000-1300)