SMG 1280.1a

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 Pharmaceutical Quality

Effective Date: October 10, 2023

1. Office of Pharmaceutical Quality (DCDL).

A. Oversees and coordinates the overall regulation of human pharmaceutical quality within Center for Drug Evaluation and Research (CDER), including submission review, manufacturing facility assessment, and surveillance of the quality of marketed pharmaceutical products.

B. Plans, develops, and directs the office strategy within the framework of CDER policies related to pharmaceutical quality. Executes high-level decisions, monitors performance, and directs operations of subordinate offices.

C. Designs and strategizes appropriate research, research support, new technology, policy, and regulatory support for the various functions of subsidiary offices, while creating a work environment that encourages creative thinking, collaboration, and transparency.

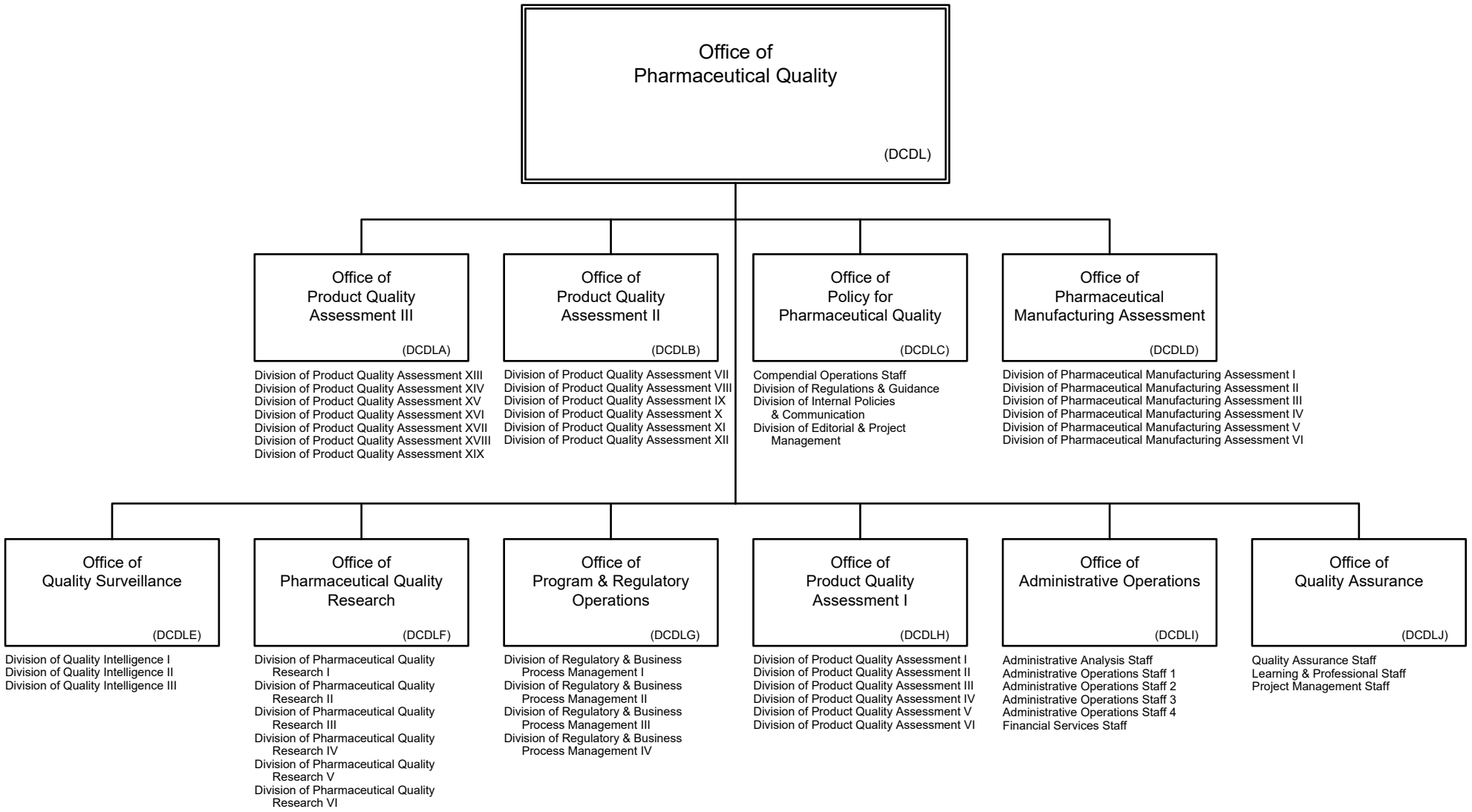
D. Analyzes, approves, and executes the management of resources, budget, and grants with transparency that imparts public trust and achieves the organization's mission, while using technology and expertise to enhance processes and decision making.

E. Leads and coordinates partnerships between Offices, Centers, and Agencies to secure internal and external collaborative support. This includes international harmonization and collaboration.

2. Authority and Effective Date.

The functional statements for the Office of Pharmaceutical Quality were approved by the Secretary of Health and Human Services on August 10, 2023, and effective on October 10, 2023.

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality



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Organizations and Functions
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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality organization structure depicting all the organizational structures reporting to the Director:

Office of Product Quality Assessment III (DCDLA)
Office of Product Quality Assessment II (DCDLB)
Office of Policy for Pharmaceutical Quality (DCDLC)
Office of Pharmaceutical Manufacturing Assessment (DCDLD)
Office of Quality Surveillance (DCDLE)
Office of Pharmaceutical Quality Research (DCDLF)
Office of Program and Regulatory Operations (DCDLG)
Office of Product Quality Assessment I (DCDLH)
Office of Administrative Operations (DCDLI)
Office of Quality Assurance (DCDLJ)

These organizations report to the Office of Product Quality Assessment III (DCDLA):
Division of Product Quality Assessment XIII
Division of Product Quality Assessment XIV
Division of Product Quality Assessment XV
Division of Product Quality Assessment XVI
Division of Product Quality Assessment XVII
Division of Product Quality Assessment XVIII
Division of Product Quality Assessment XIX

These organizations report to the Office of Product Quality Assessment II (DCDLB):
Division of Product Quality Assessment VII
Division of Product Quality Assessment VIII
Division of Product Quality Assessment IX
Division of Product Quality Assessment X
Division of Product Quality Assessment XI
Division of Product Quality Assessment XII

These organizations report to the Office of Policy for Pharmaceutical Quality (DCDLC):
Compendial Operations Staff
Division of Regulations and Guidance

Division of Internal Policies and Communication
Division of Editorial and Project Management

These organizations report to the Office of Pharmaceutical Manufacturing Assessment (DCDLD):
Division of Pharmaceutical Manufacturing Assessment I
Division of Pharmaceutical Manufacturing Assessment II
Division of Pharmaceutical Manufacturing Assessment III
Division of Pharmaceutical Manufacturing Assessment IV
Division of Pharmaceutical Manufacturing Assessment V
Division of Pharmaceutical Manufacturing Assessment VI

These organizations report to the Office of Quality Surveillance (DCDLE):
Division of Quality Intelligence I
Division of Quality Intelligence II
Division of Quality Intelligence III

These organizations report to the Office of Pharmaceutical Quality Research (DCDLF):
Division of Pharmaceutical Quality Research I
Division of Pharmaceutical Quality Research II
Division of Pharmaceutical Quality Research III
Division of Pharmaceutical Quality Research IV
Division of Pharmaceutical Quality Research V
Division of Pharmaceutical Quality Research VI

These organizations report to the Office of Program and Regulatory Operations (DCDLG):
Division of Regulatory and Business Process Management I
Division of Regulatory and Business Process Management II
Division of Regulatory and Business Process Management III
Division of Regulatory and Business Process Management IV

These organizations report to the Office of Office of Product Quality Assessment I (DCDLH):
Division of Product Quality Assessment I
Division of Product Quality Assessment II
Division of Product Quality Assessment III
Division of Product Quality Assessment IV
Division of Product Quality Assessment V
Division of Product Quality Assessment VI

These organizations report to the Office of Administrative Operations (DCDLI):
Administrative Analysis Staff
Administrative Operations Staff 1
Administrative Operations Staff 2
Administrative Operations Staff 3
Administrative Operations Staff 4
Financial Services Staff

These organizations report to the Office of Quality Assurance (DCDLJ):
Quality Assurance Staff
Learning and Professional Staff
Project Management Staff