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: September 25, 2019

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. Scientific Staff (DCDL1).

A. Determines needs and priority for scientific research to support CDER quality initiatives, policies, programs and goals.

B. Provides leadership, advocacy, direction, scientific skill, coordination and

tracking for research and science activities across Office of Pharmaceutical Quality (OPQ) in partnership with individual OPQ offices.

C. Collaborates and coordinates with the Office of Generic Drugs to implement the Generic Drug User Fee Act regulatory science research program.

D. Integrates research science into CDER quality policies and regulatory review through collaboration with other disciplines in OPQ and other CDER offices.

E. Coordinates and collaborates with appropriate OPQ office(s) to provide a review and consult of complex scientific issues identified in citizen petition and quality assessment of applications under the one quality voice concept.

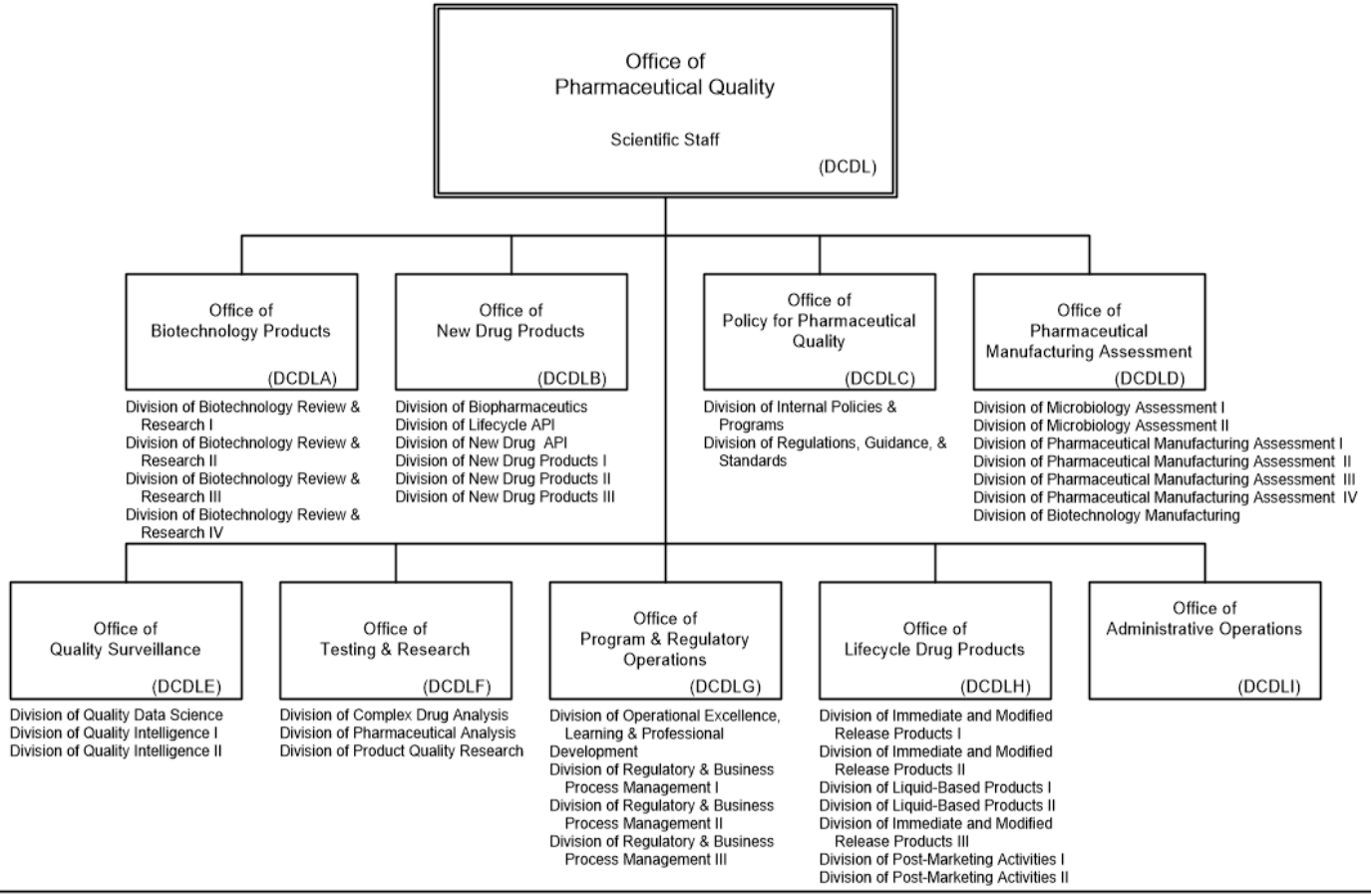
F. Develops and implements computational tools to support the risk-based assessment of drug product quality and manufacturing processes.

G. Protects and advances the public health through review, regulation, and research of botanical products.

3. Authority and Effective Date.

The functional statements for the Office of Pharmaceutical Quality were approved by the Secretary of 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 Pharmaceutical Quality



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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 organizational structures depicting all the organizational structures reporting to the Director.

Office of Pharmaceutical Quality (DCDL).

These organizations report to the Office of Pharmaceutical Quality:

Scientific Staff

Office of Biotechnology Products (DCDLA)

Office of New Drug Products (DCDLB)

Office of Policy for Pharmaceutical Quality (DCDLC)

Office of Pharmaceutical Manufacturing Assessment (DCDLD)

Office of Quality Surveillance (DCDLE)

Office of Testing & Research (DCDLF)

Office of Program & Regulatory Operations (DCDLG)

Office of Lifecycle Drug Products (DCDLH)

Office of Administrative Operations (DCDLI)

These organizations report to the Office of Biotechnology Products:

Division of Biotechnology Review & Research I

Division of Biotechnology Review & Research II

Division of Biotechnology Review & Research III

Division of Biotechnology Review & Research IV

These organizations report to the Office of New Drug Products:

Division of Life Cycle API

Division of New Drug API

Division of New Drug Products I

Division of New Drug Products II

Division of New Drug Product III

Division of Biopharmaceutics

These organizations report to the Office of Policy for Pharmaceutical Quality:
Editorial & Project Management Staff
Compendial Operations & Standards Staff
Division of Regulations, Guidance & Standards
Division of Internal Policies & Programs

These organizations report to the Office of Pharmaceutical Manufacturing Assessment:
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 Microbiology Assessment I
Division of Microbiology Assessment II
Division of Biotechnology Manufacturing

These organizations report to the Office of Quality Surveillance:
Division of Quality Data Science
Division of Quality Intelligence I
Division of Quality Intelligence II

These organizations report to the Office of Testing & Research:
Division of Product Quality Research
Division of Pharmaceutical Analysis
Division of Complex Drug Analysis

These organizations report to the Office of Program & Regulatory Operations:
Division of Regulatory & Business Process Management I
Division of Regulatory & Business Process Management II
Division of Regulatory & Business Process Management III
Division of Operational Excellence, Learning & Professional Development

These organizations report to the Office of Lifecycle Drug Products:
Division of Immediate & Modified Release Products I

Division of Immediate & Modified Release Products II
Division of Immediate & Modified Release Products III
Division of Liquid-Based Products I
Division of Liquid-Based Products II
Division of Post-Marketing Activities I
Division of Post-Marketing Activities II

These organizations report to the Office of Administrative Operations:
Administrative Analysis Staff
Administrative Operations Staff 1
Administrative Operations Staff 2
Administrative Operations Staff 3
Administrative Operations Staff 4
Administrative Operations Staff 5
Financial Services Staff

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