SMG 1280.40

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administrations

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Policy for Pharmaceutical Quality

Effective Date: September 25, 2019

1. Office of Policy for Pharmaceutical Quality (DCDLC).

A. Develops, implements, and updates science-and risk-based policies, standards, guidance documents, and internal policies, such as Manual of Policies and Procedures (MAPPs), related to the assessment of drug components and drug product (including drug-containing combination products) for human use. Pharmaceutical quality policies include those governing the standards and assessments in the Chemistry, Manufacturing and Controls section of applications for marketing approval and related submissions, and Current Good Manufacturing Practices. Evaluates the Food and Drug Administrations (FDA) findings such as deficiencies and inspectional citations for conformance to established regulations, policies, and standards.

B. Leads and coordinates development of regulations, guidance documents, standards, Compliance Programs, and MAPPs with various business partners (e.g., Office of Pharmaceutical Quality (OPQ) staff, Office of Compliance, other Center for Drug Evaluation and Research (CDER) offices and the Office of Regulatory Affairs) that address drug quality assessment from application review through market availability for all human drugs (human drugs include brand name drugs, generic drugs, biotechnology drugs, prescription drugs, and over-the-counter). Ensures that assessments are based on a thorough understanding of the product, process, dosage form, and clinically-relevant risk factors, and that regulatory policies and standards incorporate benefit-risk considerations.

C. Provides executive leadership of the CDER Council of Pharmaceutical Quality. Develops strategic product quality plans and initiates policy projects, with input from Council members, to address specific unmet needs. Collaborates with the FDA Council of Pharmaceutical Quality to address emerging drug product quality trends and establish strategic policy objectives in cooperation with OPQ.

D. Coordinates product quality outreach to and external communications to and from all stakeholders (Government Accountability Office, Congress, public, industry, and other domestic and foreign government agencies) to ensure consistent interpretation and application of CDER's pharmaceutical quality policies and programs.

E. Collaborates with OPQ laboratories and helps prioritize research to support policy development and regulatory decision-making. Ensures that the research and scientific knowledge is identified, developed, if necessary, and appropriately used in policy development.

F. Coordinates OPQ engagement with national (e.g., Consumer Product Safety Commission, Department of Defense, National Institute of Standards and Technology) and internal regulatory authorities (e.g., International Council for Harmonization, Pharmaceutical Inspection Cooperation Scheme, World Health Organization) to ensure harmonization or convergence of policies and procedures for the efficient and effective regulation of pharmaceutical quality. Leads OPQ efforts to identify and develop strategic partnerships and information-sharing arrangements with other government agencies, foreign and domestic, related to pharmaceutical quality.

2. Editorial & Project Management Staff (DCDLC1).

A. Provides advice to the Office Director and to other Office of Policy for Pharmaceutical Quality (OPPQ) senior leadership regarding the planning, development, and evaluation of regulatory programs and policies related to pharmaceutical quality.

B. Provides project management, writing, and editorial support to policy-related working groups led by OPPQ staff.

C. Manages incoming requests for OPPQ policy input, policy document clearance, or other requests for a coordinated OPQ response to policy issues.

D. Develops and maintains systems to analyze OPPQ processes, including policy document and evaluation, and the FDA clearance and publication of policy documents.

E. Oversees the development of decision-making processes and documents and participates fully in discussions and decisions concerning OPPQ policy-related projects.

3. Compendial Operations & Standards Staff (DCDLC2).

A. Coordinates OPQ participation in external standards organizations with Subject Matter Experts from other OPQ offices, as appropriate.

B. Evaluates proposals from the United States of Pharmacopoeia (USP) and other "official compendia" (under the Food, Drug, & Cosmetic Act, section 501(b)) for changes to existing standards or development of new standards regarding drug components and drug products, including over-the counter products, and determines if issues require FDA review.

C. Conducts reviews of proposed monographs, chapters, and standards and coordinates the gathering and compilation of inter-Office/inter-Center input, as necessary.

D. Develops and conveys the Center's (and Agencies, as needed) consensus responses regarding USP and other compendial proposals and proposed standards to originating organizations.

E. Manages the FDA/USP liaison program to the various USP Expert Committees, Panels, Subcommittees, and Council of the Convention.

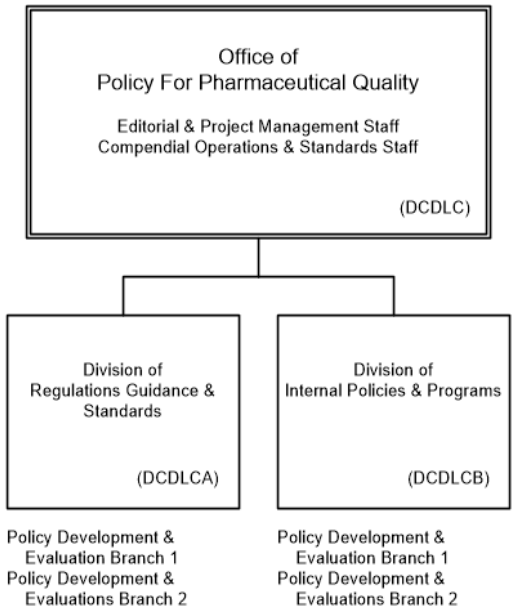
F. Serves as a liaison for outside collaborations (e.g., Pharmaceutical Quality Research Institute and American Society for Testing and Materials), as well as national and international harmonization activities (e.g., International Conference on Harmonization efforts) related to pharmaceutical quality.

G. Serves as a Center resource for issues related to compendial and standards operations, including issues such as labeling and nomenclature, and coordinates collaboration with USP, Homeopathic Pharmacopeia, and foreign pharmacopeias.

4. Authority and Effective Date.

The functional statements for the Office of Policy for 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 Policy For 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, Office of Policy for Pharmaceutical Quality organizational structures depicting all the organizational structures reporting to the Director.

Office of Policy for Pharmaceutical Quality (DCDLC).

These organizations report to the Office of Policy for Pharmaceutical Quality:

Editorial & Project Management Staff

Compendial Operations & Standards Staff

Division of Regulations Guidance & Standards (DCDLCA)

Division of Internal Policies & Programs (DCDLCB)

These organizations report to the Division of Regulations Guidance & Standards:

Policy Development & Evaluation Branch 1

Policy Development & Evaluation Branch 2

These organizations report to the Division of Internal Policies & Programs:

Policy Development & Evaluation Branch 1

Policy Development & Evaluation Branch 2

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