SMG 1280.40

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

Office of Policy for Pharmaceutical Quality

Effective Date: October 10, 2023

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

A. Develops, implements, evaluates, and updates science-and risk-based policies and standards related to pharmaceutical quality for the Center for Drug Evaluation and Research (CDER)-regulated drugs (including drug-containing combination products), including for assessment and inspection. Evaluates the Food and Drug Administration's (FDA's) 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 Manuals of Policies and Procedures (MAPPs) with various business partners (e.g., Office of Pharmaceutical Quality (OPQ), Office of Compliance, other CDER offices, and the FDA inspections and investigations organizational entity) that address drug quality for all human drugs (human drugs include brand name drugs, generic drugs, biotechnology drugs, prescription drugs, and over-the-counter drugs). Leverages these documents to ensure that pharmaceutical quality assessments are based on a thorough understanding of the product, manufacturing 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 on 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 on 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 entities) 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 international organizations (e.g., International Council for Harmonization, Pharmaceutical Inspection Cooperation Scheme, and 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. Compendial Operations and Standards Staff (DCDLC2).

A. Leads CDER's strategic engagement with the United States Pharmacopeia (USP) and serves as the organizational liaison to standards development organizations (e.g., ASTM International) as well as national and international harmonization activities (e.g., Pharmacopeial Discussion Group) related to pharmaceutical quality.

B. Coordinates CDER's participation in external pharmaceutical quality-related standards development activities through the FDA liaison program to the various USP Expert Committees, Panels, Subcommittees, and Council of the Convention, and other standards developing organizations. Liaisons are Subject Matter Experts from other OPQ and CDER offices.

C. Evaluates proposals from the USP and other "official compendia" (under the Federal Food, Drug, and 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.

D. Conducts reviews of proposed monographs, chapters, and standards and coordinates the gathering and compilation of inter-Office/inter-Center input, as necessary. Develops and conveys the Center's (and FDA's, as needed) consensus responses to USP, other compendia, and standards-setting organizations regarding proposed standards. Collaborates with other FDA organizations to provide CDER input on standards activities led by them (e.g., the International Organization for Standardization).

E. 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 of the United States, and foreign pharmacopeias.

F. Coordinates and provides leadership to the Pharmaceutical Quality Standards Working Group (PQSWG) and represents CDER at the FDA Standards Committee.

3. 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 August 10, 2023, and effective on October 10, 2023.

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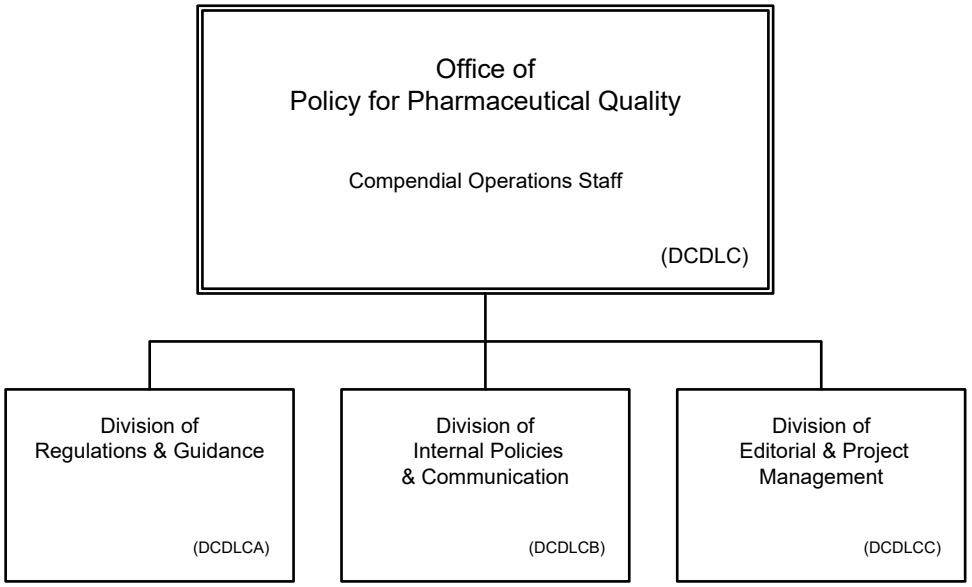

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Policy for Pharmaceutical Quality organization structure depicting all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

Office of Policy for Pharmaceutical Quality (DCDLC)
Compendial Operations Staff
Division of Regulations and Guidance (DCDLCA)
Division of Internal Policies and Communication (DCDLCB)
Division of Editorial and Project Management (DCDLCC)