

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

Division of Editorial and Project Management

Effective Date: October 10, 2023

1. Division of Editorial and Project Management (DCDLCC).

- A. Provides project management, writing, and editorial support to develop, implement, and update science and risk-based policies, such as regulations, guidance documents, internal policies, and Manuals of Policies and Procedures (MAPPs), related to pharmaceutical quality for the Center for Drug Evaluation and Research (CDER) regulated drugs. Coordinates clearance of the Office of Pharmaceutical Quality (OPQ) led documents.
- B. Provides advice to the Office Director and to other Office of Policy for Pharmaceutical Quality (OPQ) senior leadership regarding the planning, development, and evaluation of regulatory programs and policies related to pharmaceutical quality. This includes identifying ways to streamline and refine processes.
- C. Manages incoming requests for OPQ policy input, policy document clearance, or other requests for a coordinated and aligned OPQ response to policy issues.
- D. Develops and maintains systems by which to facilitate development of OPQ deliverables, including policy documents, and the Food and Drug Administration (FDA) clearance and publication of OPQ policy documents. This also includes development of plans to ensure compliance to records management requirements and the ready availability of information in order to quickly and accurately respond to data calls at the Center, FDA, and Department of Health and Human Services levels.

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

2. Authority and Effective Date.

The functional statements for the Division of Editorial and Project Management were approved by the Secretary of Health and Human Services on August 10, 2023, and effective on October 10, 2023.

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(DCDLCC)

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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, Division of Editorial and Project Management organization structure depicting all the organizational structures reporting to the Director:

Division of Editorial and Project Management (DCDLCC)