

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 Regulations and Guidance

Effective Date: October 10, 2023

1. Division of Regulations and Guidance (DCDLCA).

- A. Leads and coordinates the development and lifecycle management of external pharmaceutical quality policies for the Center for Drug Evaluation and Research (CDER) regulated drugs. This includes regulations and guidance documents which promote the consistent production of high-quality drug components and drug products in conformance with pharmaceutical quality policies, such as the Current Good Manufacturing Practice regulations, by regulated industry.
- B. Evaluates, routinely and collaboratively, existing regulations and guidance to determine whether they meet their intended objectives. Revises the existing documents and/or training/outreach for documents, as applicable.
- C. Leads the development of responses to quality related issues in Citizen Petitions through collaboration with other Office of Pharmaceutical Quality (OPQ) sub-offices and CDER's Office of Regulatory Policy.
- D. Leads the development of, and revisions to, business rules for data systems related to information on inactive ingredients in approved products, validates new information to be added to the data system, responds to the needs of internal business partners to implement improvements, and informs stakeholders of system updates.
- E. Coordinates the review and clearance of non-OPQ-led regulations and guidance on behalf of OPQ.

- F. Coordinates product quality outreach participates in responding to communications from external stakeholders, and actively solicits feedback from internal stakeholders to ensure consistent interpretation and application of external-facing pharmaceutical quality policies and programs.

2. Authority and Effective Date.

The functional statements for the Division of Regulations and Guidance 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
Office of Policy for Pharmaceutical Quality
Division of Regulations and Guidance**

Division of
Regulations & Guidance

(DCDLCA)

Staff Manual Guide 1280.41
Organizations and Functions
Effective Date: October 10, 2023

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 Regulations and Guidance organization structure depicting all the organizational structures reporting to the Director:

Division of Regulations and Guidance (DCDLCA)