SMG 1280.42

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

Division of Internal Policies & Programs

Effective Date: September 25, 2019

1. Division of Internal Policies & Programs (DCDLCB).

A. Leads and coordinates development of new internal policy documents related to assessment of pharmaceutical quality information in submissions or applications and through inspection of manufacturing establishment, including Manual of Policies and Procedures (MAPPs) and Compliance Programs, with input from subject matter experts across Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation and Research (CDER), and, as appropriate, the Office of Regulatory Affairs (ORA) and other Centers/Offices throughout the Food and Drug Administration (FDA).

B. Evaluates, routinely and collaboratively, existing internal policies, standards, and programs to determine whether they meet their intended objectives and are followed by OPQ staff and business partners including ORA. Revises the existing documents and/or training/outreach for such documents, as applicable.

C. Analyzes and provides recommendations on policy relating to novel, controversial, or precedent-setting issues in assessment of pharmaceutical quality through submission or application assessment or manufacturing establishment inspections and related information.

D. Leads the development of OPQ responses to controlled correspondence and coordinates product quality outreach to and communications from OPQ staff and business partners.

E. Coordinates the review and clearance of non-OPQ-led internal policy documents, including MAPPs, on behalf of OPQ.

2. Policy Development & Evaluation Branch 1 (DCDLCB1).

A. Leads and coordinates development of new internal policy documents such as MAPPs governing the pharmaceutical quality assessment of Investigational New Drugs, New Drug applications, Biologic License Applications, Abbreviated New Drug applications, and combination product applications, including policies for cross-cutting chemistry, manufacturing and controls issues.

B. Assesses, routinely, existing internal policy documents to determine whether revisions are needed to improve effectiveness or implementation, reflect the most recently available scientific information, or incorporate information from application assessment.

C. Leads and coordinates efforts to revise existing internal policy documents as applicable, with input from subject matter experts across OPQ, CDER, and, as appropriate, ORA and other Centers/Offices throughout the FDA.

D. Assesses, actively, CDER communications related to quality issues, including integrated quality assessments and letters to sponsors/applicants, for conformance to OPQ policy.

E. Leads the development of OPQ responses to controlled correspondence and coordinates product quality outreach to and communications from OPQ staff and business partners.

E. Coordinates (with OPQ/Office of Program & Regulatory Operations and ORA) internal outreach and training on new and revised internal policy documents to ensure consistent interpretation and application of policies.

3. Policy Development & Evaluation Branch 2 (DCDLCB2).

A. Leads and coordinates development of new internal policy documents such as Compliance Programs governing the assessment of pharmaceutical quality through manufacturing establishment inspections.

B. Routinely assesses existing internal policy documents to determine whether revisions are needed to improve effectiveness or implementation, reflect the most recently available scientific information, or incorporate information from application review.

C. Leads and coordinates efforts to revise existing internal policy documents as applicable, with input from subject matter experts across OPQ, CDER, and, as appropriate, ORA and other Centers/Offices throughout the FDA.

D. Assesses, actively, CDER communications related to quality issues, including Form FDA 483s and establishment inspection reports, for conformance to OPQ policy.

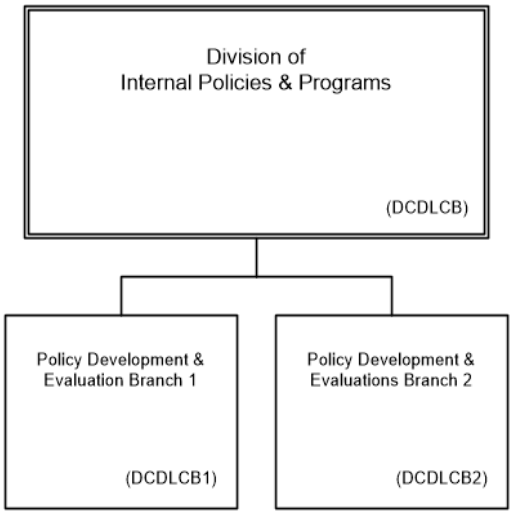
E. Leads the development of OPQ responses to controlled correspondence and coordinates product quality outreach to and communications from OPQ staff and business partners.

E. Coordinates (with OPQ/Office of Program & Regulatory Operations and ORA) internal outreach and training on new and revised internal policy documents to ensure consistent interpretation and application of policies.

4. Authority and Effective Date.

The functional statements for the Division of Internal Policies and Programs 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
Division of Internal Policies & Programs



Staff Manual Guide 1280.42
Organizations and Functions
Effective Date: December 14, 2018

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 Internal Policies & Programs organizational structures depicting all the organizational structures reporting to the Director.

Division of Internal Policies & Programs (DCDLCB).

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

Policy Development & Evaluation Branch 1 (DCDLCB1)

Policy Development & Evaluation Branch 2 (DCDLCB2)

Back to Organizations and Functions, Volume I (1000-1300)