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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 Program Regulatory Operations

Division of Regulatory and Business Process Management II

Effective Date: October 10, 2023

1. Division of Regulatory and Business Process Management II (DCDLGB).

A. Manages the operations and regulatory processes of The Office of Pharmaceutical Quality (OPQ) cross-disciplinary quality assessment teams to efficiently conduct science and risk-based assessments of New Drug Applications (NDAs), Biologics Licensing Applications (BLAs), Abbreviated New Drug Applications (ANDAs), their supplements, and other regulatory submissions throughout the drug product lifecycle.

B. Tracks the overall progress of quality-related submissions by creating plans, timelines, and other supporting materials to expedite the communication and completion of assessment activities by all relevant disciplines.

C. Manages the quality assessment workload by triaging quality-related regulatory submissions, optimizing assignments to disciplinary assessors, and monitoring the status of assignments.

D. Serves as the primary point of contact for submissions to internal and external stakeholders through providing progress updates to The Food and Drug Administration (FDA) leadership and responding to inquiries from industry.

E. Serves as subject matter experts that support cross-functional workgroups for the development of policies and procedures and implementation of Information Technology platforms that support regulatory processes for quality assessment activities.

F. Plans, schedules, and manages meetings with industry representatives and assessment teams to address quality-related topics.

2. Authority and Effective Date.

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

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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 Program and Regulatory Operations, Division of Regulatory and Business Process Management II organization structure depicting all the organizational structures reporting to the Director:

Division of Regulatory and Business Process Management II (DCDLGB)