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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 Product Quality Assessment III

Division of Product Quality Assessment XVIII

Effective Date: October 10, 2023

1. Division of Product Quality Assessment XVIII (DCDLAF).

A. Conducts science and risk-based assessment of product quality (including biopharmaceutics), which covers Drug Substance and/or Drug Product information in Investigational New Drugs (INDs); Controlled Correspondences (CCs); Drug Master Files (DMFs); New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs); Biologics License Applications (BLAs); supplemental NDAs, ANDAs, and BLAs; and other quality-related regulatory submissions throughout the product lifecycle.

B. Conveys risk-based recommendations on the approvability drug products, adequacy of drug substances, and product quality risks identified throughout the product lifecycle (including post-approval change management) to appropriate stakeholders within the Office of Pharmaceutical Quality (OPQ), the Center for Drug Evaluation and Research (CDER), the Food and Drug Administration (FDA), and industry.

C. Serves as a liaison and resource to OPQ offices, other FDA organizations, and external organizations on aspects related to drug quality, including product design, drug product and drug substance characterization and testing, and biopharmaceutics.

D. Participates in coordination with other offices in OPQ, CDER, and the FDA, as needed, in scientific investigations to evaluate and assess any quality problems.

E. Participates in inspections of manufacturing and testing facilities, as needed, using science and risk-based approaches to support product quality assessment of regulatory submissions.

F. Provides subject matter expertise in the development of policies, guidance, procedures, surveillance, and research supporting the evaluation of product quality for CDER regulated products.

2. Authority and Effective Date.

The functional statements for the Division of Product Quality Assessment XVIII 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 Product Quality Assessment III, Division of Product Quality Assessment XVIII organization structure depicting all the organizational structures reporting to the Director:

Division of Product Quality Assessment XVIII (DCDLAF)