

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 Pharmaceutical Quality Research

Division of Pharmaceutical Quality Research II

Effective Date: October 10, 2023

1. Division of Pharmaceutical Quality Research II (DCDLFB).

- A. Provides state of the art analytical support for characterizing complex drug substances, excipients, products, and dosage forms (including both small molecule and biologic drugs).
- B. Conducts laboratory research and/or testing that supports quality assessment, inspection, quality standards and policy development, education, surveillance, and rapid response to public emergency activities.
- C. Conducts research to evaluate the product and process design and assess their impact on product quality, pharmaceutical equivalence, and bioequivalence.
- D. Develops *in vitro* test systems and quantitative analysis procedures for product quality assessment and prediction, as well as comparability, biosimilarity, interchangeability, and bioavailability/bioequivalence determinations.
- E. Evaluates emerging manufacturing technologies to inform a regulatory risk-based framework for quality assessment, as well as quality standards and policy development. Manufacturing technologies may include new process designs, process analytical technology, process modeling, process controls, statistical product quality monitoring, and data analytics.

- F. Provides subject matter experts and hands-on laboratory training relevant to the Food and Drug Administration in support of assessment, inspection, surveillance, and policy functions.

2. Authority and Effective Date.

The functional statements for the Division of Pharmaceutical Quality Research 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 Pharmaceutical Quality Research, Division of Pharmaceutical Quality Research II organization structure depicting all the organizational structures reporting to the Director:

Division of Pharmaceutical Quality Research II (DCDLFB)