

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

Effective Date: October 10, 2023

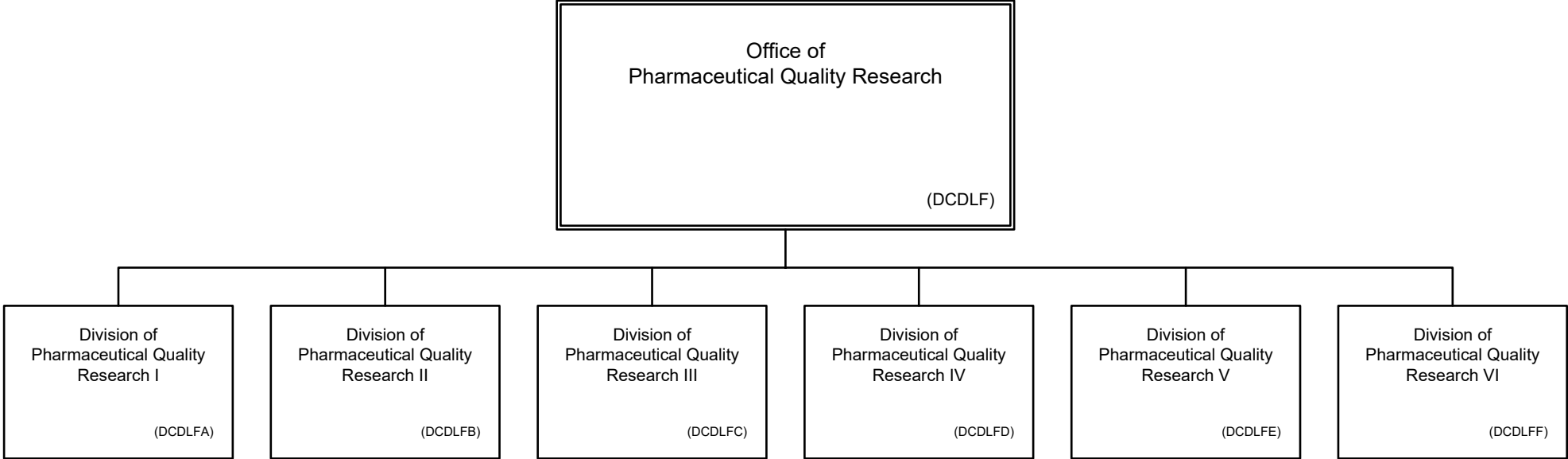
1. Office of Pharmaceutical Quality Research (DCDLF).

- A. Conducts laboratory research that supports quality assessment, inspection, quality standard, policy development, education, surveillance, and rapid response activities.
- B. Performs drug quality surveillance testing and laboratory-based investigational activities to support the Office of Pharmaceutical Quality (OPQ) and the Center for Drug Evaluation and Research as needed for public health emergencies and to generate data to inform decision making.
- C. Provides advice, collaborative research opportunities, and scientific training for the Food and Drug Administration's (FDA) on pharmaceutical quality, comparability/biosimilarity/interchangeability, pharmaceutical equivalence, and bioavailability/bioequivalence issues includes manufacturing, formulation, analytical testing, and modeling.
- D. Participates in relevant quality assessment and policy development activities.
- E. Supports OPQ laboratory science needs including coordination of extramural research through contracts or grants and administers extramural research activities for OPQ.

2. Authority and Effective Date.

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

Office of Pharmaceutical Quality Research (DCDLF)
Division of Pharmaceutical Quality Research I (DCDLFA)
Division of Pharmaceutical Quality Research II (DCDLFB)
Division of Pharmaceutical Quality Research III (DCDLFC)
Division of Pharmaceutical Quality Research IV (DCDLFD)
Division of Pharmaceutical Quality Research V (DCDLFE)
Division of Pharmaceutical Quality Research VI (DCDLFF)