SMG 1280.20a

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

Effective Date: October 10, 2023

1. Office of Product Quality Assessment III (DCDLA).

A. Oversees, coordinates, and prioritizes the work of the different Product Quality Assessment divisions. Communicates and shares relevant information between Product Quality Assessment divisions and within the Office of Pharmaceutical Quality (OPQ).

B. Plans, develops, and directs the office strategy, within OPQ's mission, to continuously improve or enhance the effectiveness and efficiency of quality assessment activities.

C. Executes and communicates high-level decisions, manages resources, monitors performance, and directs operations of the Product Quality Assessment divisions.

D. Directs and coordinates strategic communication of recommendations on the approvability of drug products, adequacy of drug substances, and product quality risks identified throughout their lifecycle (including post-approval change management) to appropriate stakeholders within other offices in OPQ, the Center for Drug Evaluation and Research (CDER), the Food and Drug Administration (FDA), and industry.

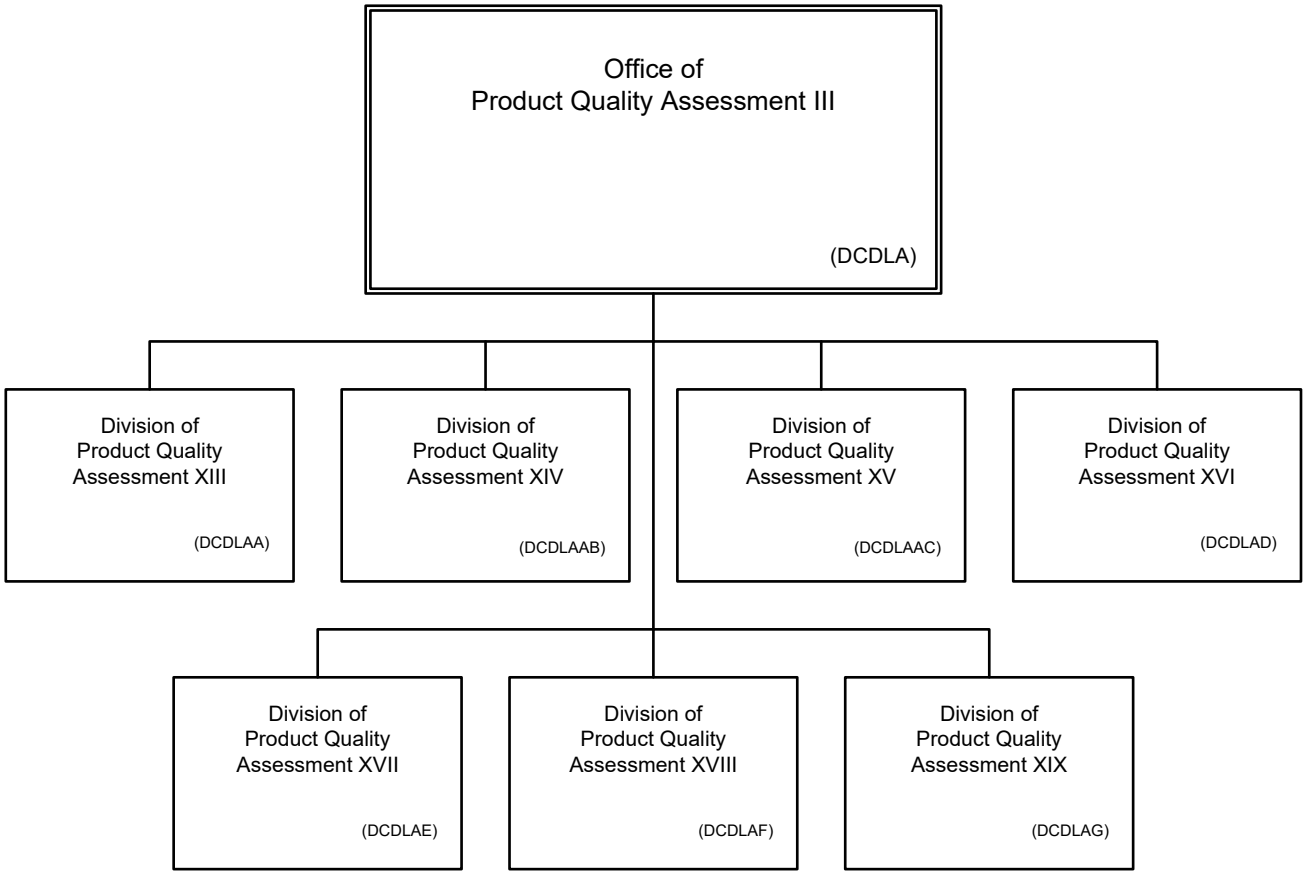
E. Serves as a liaison and resource to offices within OPQ, other offices within the FDA, and outside organizations on aspects related to drug quality including product design, drug product and drug substance characterization and testing, biopharmaceutics, as well as provides subject matter expertise in the development of policies, procedures, surveillance, and research that supports the evaluation of drug product or drug substance quality for CDER regulated products.

F. Coordinates with other OPQ, CDER, and/or FDA organizations, as needed, in scientific investigations and inspections to evaluate and assess any drug product or drug substance quality problems.

2. Authority and Effective Date.

The functional statements for the Office of Product Quality Assessment III were approved by the Secretary of Health and Human Services on August 10, 2023, and effective on October 10, 2023.

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



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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 organization structure depicting all the organizational structures reporting to the Director:

Office of Product Quality Assessment III (DCDLA)
Division of Product Quality Assessment XIII (DCDLAA)
Division of Product Quality Assessment XIV (DCDLAB)
Division of Product Quality Assessment XV (DCDLAC)
Division of Product Quality Assessment XVI (DCDLAD)
Division of Product Quality Assessment XVII (DCDLAE)
Division of Product Quality Assessment XVIII (DCDLAF)
Division of Product Quality Assessment XIX (DCDLAG)