SMG 1280.50

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 Manufacturing Assessment

Effective Date: October 10, 2023

1. Office of Pharmaceutical Manufacturing Assessment (DCDLD).

A. Oversees, coordinates, and prioritizes the work of the different Pharmaceutical Manufacturing Assessment divisions. Communicates and shares relevant information between Pharmaceutical Manufacturing 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 and enhance the effectiveness and efficiency of manufacturing assessment, including process, facilities, microbial controls, and sterility assurance assessment.

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

D. Directs and coordinates strategic communication of manufacturing-specific risk identified throughout the product lifecycle (including post-approval change management) to appropriate stakeholders in OPQ, the Center for Drug Evaluation and Research (CDER), the Food and Drug Administration (FDA), and industry.

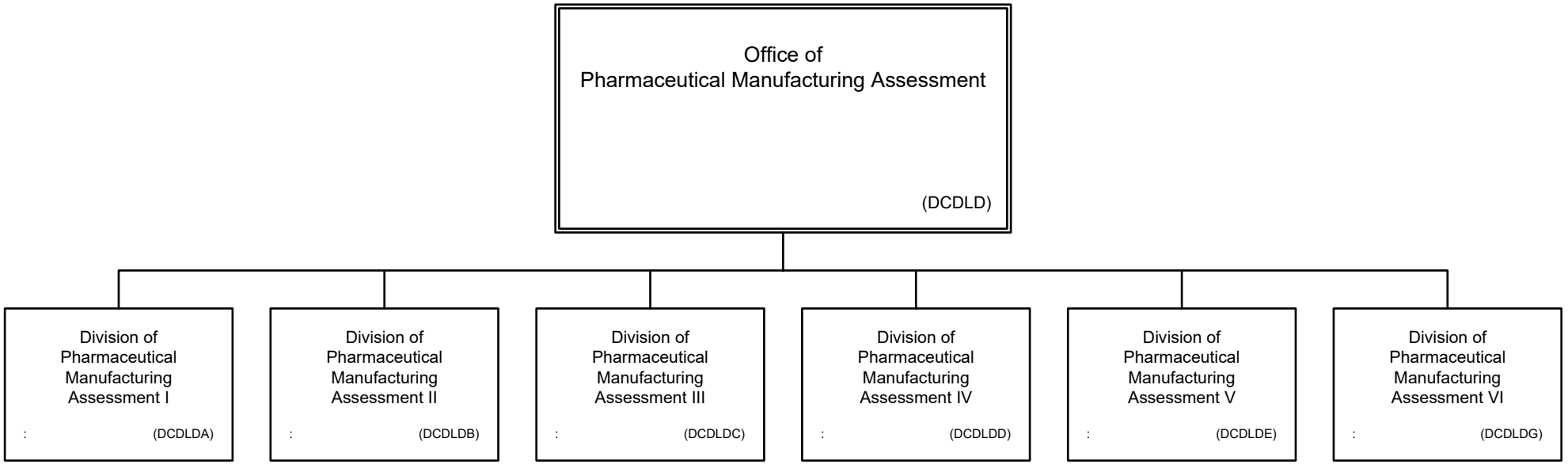
E. Manages and coordinates the pre-approval inspections (PAIs), pre-license inspections (PLIs), and product specific post-approval programs. Serves as OPQ's primary point of contact to stakeholders within the FDA regarding regulatory and scientific matters related to PAIs and PLIs. Coordinates with other organizational entities in OPQ, CDER, and FDA as needed in scientific investigations to evaluate and assess any drug product quality problems.

F. Serves as a liaison and resource to offices within OPQ, other offices in the FDA, and outside organizations on aspects related to manufacturing, facilities, and product quality. Provides subject matter expertise in the development of policies and procedures, surveillance, and research that supports the evaluation of manufacturing and facilities for CDER regulated products.

2. Authority and Effective Date.

The functional statements for the Office of Pharmaceutical Manufacturing Assessment 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 Pharmaceutical Manufacturing Assessment



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

Office of Pharmaceutical Manufacturing Assessment (DCDLD)
Division of Pharmaceutical Manufacturing Assessment I (DCDLDA)
Division of Pharmaceutical Manufacturing Assessment II (DCDLDB)
Division of Pharmaceutical Manufacturing Assessment III (DCDLDC)
Division of Pharmaceutical Manufacturing Assessment IV (DCDLDD)
Division of Pharmaceutical Manufacturing Assessment V (DCDLDE)
Division of Pharmaceutical Manufacturing Assessment VI (DCDLDG)