

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 Program Regulatory Operations

Effective Date: October 10, 2023

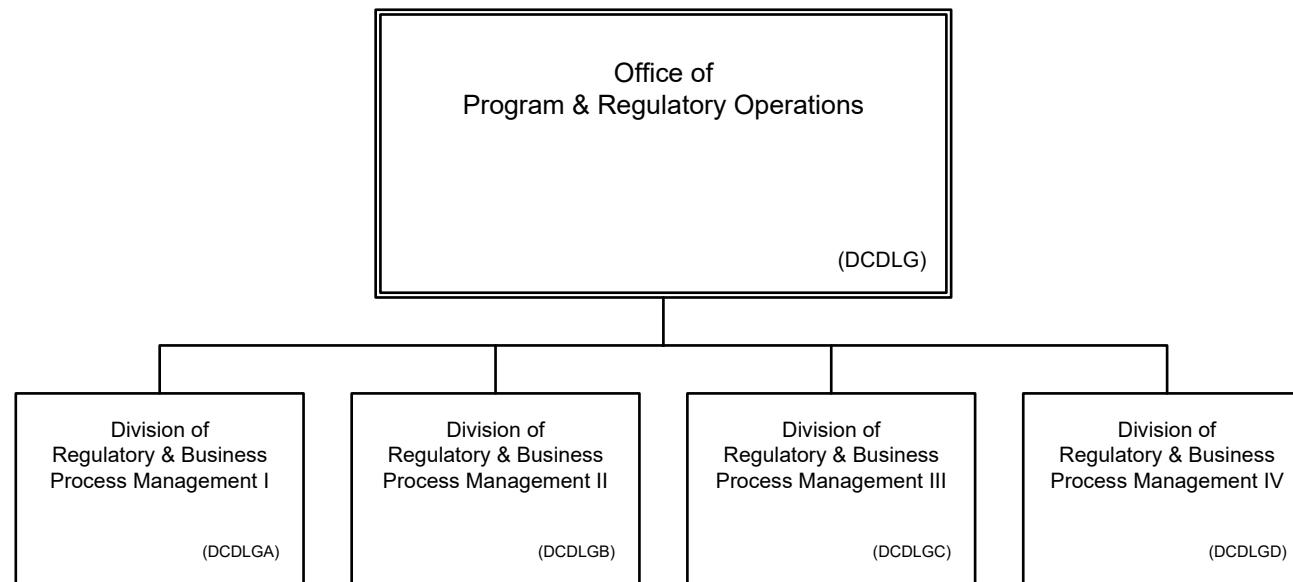
1. Office of Program Regulatory Operations (DCDLG).

- A. Oversees the operations and regulatory processes associated with quality assessments (including inspection) in collaboration with other offices in The Office of Pharmaceutical Quality (OPQ), The Center for Drug Evaluation and Research (CDER), and The Food and Drug Administration (FDA).
- B. Provides leadership in program and project management to support cross-functional committees and workgroups that provide governance to the regulatory assessment initiatives and processes.
- C. Coordinates triaging for quality-related regulatory submissions to identify and mitigate risks and optimize assignments to disciplinary assessors.
- D. Tracks and monitors workload and key performance indicators related to quality assessment activities to identify trends and areas for improvement. Develops plans and implements improvements to enhance the efficiency of regulatory processes for quality assessment activities.
- E. Provides subject matter expertise to support the development of policies and procedures, the implementation of Information Technology platforms, and other initiatives related to operations and regulatory processes for quality assessment activities.

2. Authority and Effective Date.

The functional statements for the Office of Program Regulatory Operations 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 Program and Regulatory Operations**



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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 Program and Regulatory Operations organization structure depicting all the organizational structures reporting to the Director:

Office of Program and Regulatory Operations (DCDLG)
Division of Regulatory and Business Process Management I (DCDLGA)
Division of Regulatory and Business Process Management II (DCDLGB)
Division of Regulatory and Business Process Management III (DCDLGC)
Division of Regulatory and Business Process Management IV (DCDLGD)