

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administrations

Center for Drug Evaluation and Research

Office of Pharmaceutical Quality

Office of Program & Regulatory Operations

Effective Date: September 25, 2019

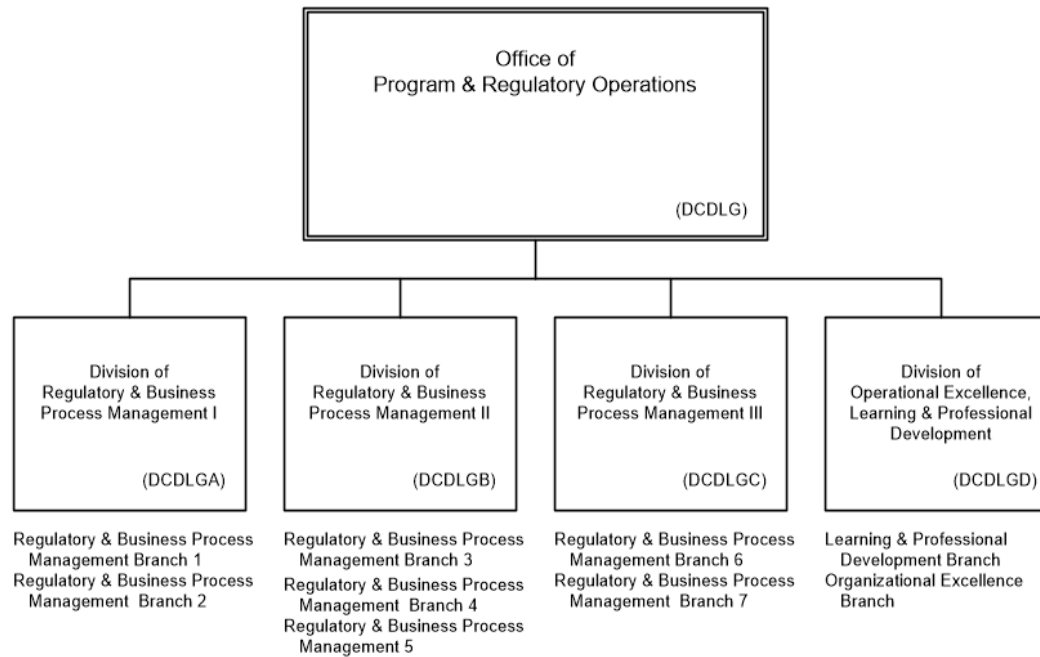
1. Office of Program & Regulatory Operations (DCDLG).

- A. Leads and manages the business processes, quality management system, and training and development system within the Office of Pharmaceutical Quality (OPQ).
- B. Leads and manages all processes associated with drug quality reviews and facility inspections, in collaboration with OPQ functional office leadership.
- C. Designs, develops, and implements internal processes to support the drug quality reviews and inspections.
- D. Monitors, reports and leads corrective and preventive actions relating to the performance of internal processes, as defined by standard procedures.
- E. Designs, develops, and implements OPQ-specific training and developmental programs to ensure the skill sets and competencies of staff are maintained and continually improved.

2. Authority and Effective Date.

The functional statements for the Office of Program & Regulatory Operations was approved by the Secretary of Health and Human Services on September 25, 2019.

**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**



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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 organizational structures depicting all the organizational structures reporting to the Director.

Office of Program and Regulatory Operations (DCDLG).

These organizations report to the Office of Program and Regulatory Operations:

Division of Regulatory & Business Process Management I (DCDLGA)

Division of Regulatory & Business Process Management II (DCDLGB)

Division of Regulatory & Business Process Management III (DCDLGC)

Division of Operational Excellence, Learning & Professional Development (DCDLGD)

These organizations report to the Division of Regulatory & Business Process Management I:

Regulatory & Business Process Management Branch 1

Regulatory & Business Process Management Branch 2

These organizations report to the Division of Regulatory & Business Process Management II:

Regulatory & Business Process Management Branch 3

Regulatory & Business Process Management Branch 4

Regulatory & Business Process Management Branch 5

These organizations report to the Division of Regulatory & Business Process Management III:

Regulatory & Business Process Management Branch 6

Regulatory & Business Process Management Branch 7

These organizations report to the Division of Operational Excellence, Learning & Professional Development:

Learning & Professional Development Branch

Organizational Excellence Branch

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