

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 Quality Assurance

Effective Date: October 10, 2023

1. Office of Quality Assurance (DCDLJ).

- A. Leads the development, implementation, and maintenance of the quality management system for the Office of Pharmaceutical Quality (OPQ).
- B. Leads and manages the internal management review process and business processes for OPQ including developing key performance indicators for OPQ work products, processes, and services.
- C. Oversees, tracks, and coordinates the design, development, and implementation of OPQ-specific training and developmental programs to ensure the skill sets and competencies of staff are maintained and continually improved.
- D. Develops, implements, and maintains the Enterprise Risk Management System for OPQ.
- E. Provides enterprise level program and project management support for OPQ for OPQ-wide initiatives, cross-cutting issues, strategic planning, and workload or staffing issues in a OPQ sub-office including supporting new initiatives and processes through operationalization.
- F. Coordinates information technology needs for OPQ and advocates for OPQ with the Center for Drug Evaluation and Research (CDER) and Food and Drug Administration (FDA) levels Information Technology (IT) organizations and maintains the CDER information technology strategic plan.

2. Quality Assurance Staff (DCDLJ1).

- A. Develops, implements, maintains, and updates the Quality Management System (QMS) for OPQ including management of the internal change management system in OPQ.
- B. Works closely with the other functional units throughout OPQ by assessing the quality of the work products, processes, or services to ensure they are fit-for-purpose and timely.
- C. Manages the internal OPQ documentation that is part of the QMS system to ensure procedures are defined, developed, and appropriately implemented.
- D. Coordinates internal audits that will assess OPQ's process and system performance, reports audit outcomes, and works with OPQ staff in the identification, tracking, and management of internal continual improvement opportunities.
- E. Facilitates the internal non-conformance reporting system for identifying and tracking any non-compliant work products, processes and services and ensures the identification and implementation of any corrective and preventive actions associated with the non-conformances.
- F. Implements, maintains, monitors, and reports all complaints and other feedback related to OPQ's internal products, processes, and services.

3. Learning and Professional Development Staff (DCDLJ2).

- A. Coordinates with all OPQ Offices to identify relevant training, cross-training, development, and professional certification needs and requirements for all job functions in OPQ.
- B. In coordination with the Quality Assurance Staff, develops and facilitates internal training and development programs for OPQ.
- C. Coordinates with OPQ sub-offices to develop a professional development program that will enhance individual career growth.
- D. Determines, develops, and implements all relevant professional certification requirements within OPQ.
- E. Works closely with other Offices in OPQ in designing, developing, implementing, and monitoring the individual development plan (IDP) program.
- F. Works closely with the CDER learning and organizational development functions organizations to implement CDER-wide training efforts.

4. Project Management Staff (DCDLJ3).

- A. Works with OPQ Leadership to develop, monitor, and maintain the office strategic plan.
- B. Manages intra/inter-office projects or OPQ-level committees when needed in support of OPQ strategic goals and priorities
- C. Collaborates with OPQ sub-offices to facilitate the development, maintenance, and improvement of OPQ core processes
- D. Provides technology support for the enhancement of office communication and collaboration
- E. Provides technical liaison services to support the prioritization, development and implementation of IT projects in collaboration with the Informatics Program Management function and the FDA primary IT organization.

5. Authority and Effective Date.

The functional statements for the Office of Quality Assurance 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 Quality Assurance**



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

Office of Quality Assurance (DCDLJ)
Quality Assurance Staff
Learning and Professional Staff
Project Management Staff