SMG 1121.50

FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF COMMUNICATIONS AND QUALITY PROGRAM MANAGEMENT

Effective Date: 1/10/2014

1. OFFICE OF COMMUNICATIONS AND QUALITY PROGRAM MANGAGEMENT (DLLRF).

A. Provides leadership, coordination and management of the Associate Commissioner for Regulatory Affairs (ACRA) priority policies and issues impacting the Office of Regulatory Affairs (ORA) and Agency operations.

B. Identifies, triages, supervises, and tracks related actions from start to finish in conjunction with senior leadership across ORA.

C. Provides leadership and direction for all ORA communications. Prepares, coordinates, and develops relevant material in collaboration with other FDA technical, regulatory, and policy units as necessary.

D. Oversees project management activities of major ORA-wide or other ACRA-level initiatives following project management best practices. Develops policies and procedures on all aspects of project planning.

E. Manages and maintains ORA's Quality Management System (QMS).

F. Provides leadership and direction for the planning, development and monitoring of the educational information programs and public participation activities implemented for consumers, the media, academia, and health care professionals by public affairs and health communications staff.

2. QUALITY MANAGEMENT SYSTEMS STAFF (DLLRF2).

A. Develops programs to ensure that quality provisions are planned, developed and implemented to identify, prevent and correct unsatisfactory conditions and elements, which influence the regulatory correctness and responsiveness of transactions and services.

B. Provides policy guidance and advisory assistance to ORA managers in the development of strategies for applying quality management to core program areas.

C. Communicates and trains ORA managers and staff on QMS principles and requirements.

D. Conducts a Quality Management System Assessment (QMSA), which is a comprehensive review and evaluation of materials, tools, processes, and strategy of ORA's quality system to determine adequacy and compliance with established Quality Management System guidelines.

E. Reviews ORA QMS programs according to documented procedures to ensure continuing suitability, adequacy and effectiveness of the QMS.

3. PROJECT COORDINATION STAFF (DLLRF3).

A. Provides for ORA's project management support on ORA-wide assignments involving complex problems and issues related to Agency programs, strategies, and implementation of new legislation.

B. Manages, conducts, and analyzes studies designed to improve ORA's business processes and procedures. Coordinates with leadership and staff throughout ORA to gather input, develop recommendations for efficiencies in current work processes, and implement changes.

4. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Deputy Commissioner for Operations and Chief Operating Officer, effective January 10, 2014.

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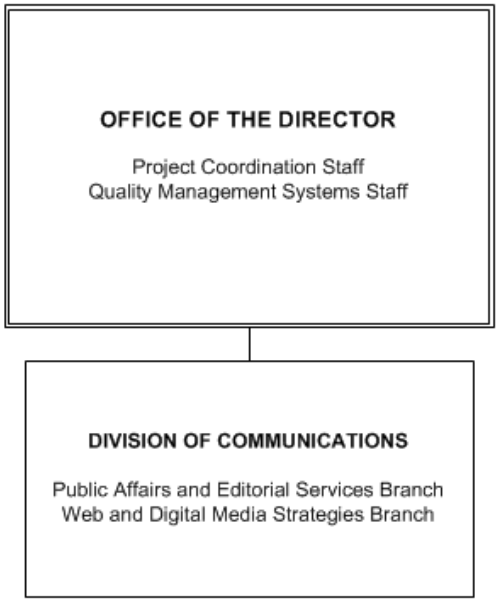

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EFFECTIVE DATE: January 10, 2014

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs, Office of Communications and Quality Program Management organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Project Coordination Staff
- Quality Management Systems Staff
- Division of Communications
    - Public Affairs and Editorial Services Branch
    - Web and Digital Media Strategies Branch