

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Regulatory Affairs**

**Office of Partnerships and Operational Policy**

**Office of Quality Management Systems**

Effective Date: December 14, 2018

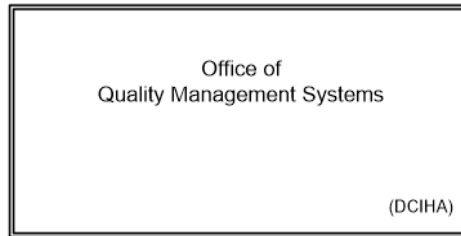
**1. Office of Quality Management Systems (DCIHA).**

- A. Provides direction and counsel to the Associate Commissioner for Regulatory Affairs (ACRA), the Deputy ACRA and the Office of Regulatory Affairs (ORA) managers in the development of strategies for applying quality management to core program areas and business processes.
- B. Plans, develops, and implements policies and programs to identify, prevent and correct process deficiencies.
- C. Communicates and trains ORA managers and staff on Quality Management System (QMS) principles and requirements.
- D. Manages the review and evaluation of ORA's quality system to determine adequacy and compliance with established QMS guidelines.
- E. Reviews ORA QMS programs according to documented procedures to ensure continuing suitability, adequacy and effectiveness.
- F. Represents ORA during external audits of ORA's programs.
- G. Manages enterprise-wide process improvement and quality projects.

**2. Authority and Effective Date.**

The functional statements for the Office of Quality Management Systems were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Office of Partnerships and Operational Policy  
Office of Quality Management Systems**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Partnerships and Operational Policy, Office of Quality Management Systems organization structure depicting all the organizational structures reporting to the Director:

Office of Quality Management Systems (DCIHA)