

SMG 1232A.5

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Human Foods Program

Office of Quality Assessment and Management

Effective Date: May 13, 2024

1. Office of Quality Assessment and Management (DCRN).

- A. Leads quality initiatives for the Human Foods Program (HFP) and advises the HFP leadership.
- B. Evaluates and makes fitness-for-use determinations of food safety systems. Makes recommendations to the leadership on maximizing domestic and international regulatory partners' food safety work to increase public health protection.
- C. Assesses and monitors efficacy and efficiency of the HFP and recommends improvement options.
- D. Leads innovative approaches on leveraging external food safety systems to inform risk prioritization in collaboration with other offices in the HFP.

2. Quality Assessment Staff (DCRN1).

- A. Conducts audits of domestic and international regulatory partners to measure their performance against program standards. Audits include reviews of regulatory systems and more specifically the inspection, investigation, sample collection and analysis, enforcement, response, recovery, and/or outreach components of these regulatory systems.
- B. Supports the development of program standards and associated audit programs that may apply to international and/or State regulatory partners and the HFP.
- C. Maintains expertise in the program standards (e.g., Systems Recognition, Equivalence Program, compliance with Food and Drug Administration (FDA) standards, international standards such as Codex, and others).

- D. Develops assessment tools, audit reports, and other records for the official administrative file and/or for external stakeholders.
- E. Works in collaboration with FDA's inspections and investigations program to evaluate field operations using quality management systems.
- F. Develops processes for analyzing, sorting, leveraging, acceptance for use determinations on external third-party global audits and assessments.
- G. Supports quality oversight of state food and feed contract inspection activities (inspection report review, conducting field audits under the Field Management Directive (FMD) 76, data analysis for inspection audits (FMD76)) in coordination with Office of Integrated Food Safety System Partnerships and FDA's inspections and investigations program.
- H. Performs quality control and auditing as needed, including Internal System Audits, Laboratory Flexible Funding Model (LFFM)/Lab Auditing & Foreign Lab Audits, Lab Accreditation for the Analyses of Foods (LAAF) Accreditation Body Audits, and state lab audits.

3. Quality Management Staff (DCRN2).

- A. Establishes, implements, and maintains a robust HFP-wide quality management system (QMS) that encompasses the HFP's processes, procedures, and documentation; including defining quality standards, guidelines, and templates to ensure consistent practices.
- B. Conducts regular internal audits and assessments to evaluate the effectiveness of quality management systems, including planning and executing audits, identifying non-conformities, and making recommendations for corrective actions and improvements.
- C. Fosters a culture of continuous quality improvement throughout the organization, including collecting and analyzing quality data, identifying improvement opportunities, facilitating process enhancements, and promoting innovation and learning.
- D. Monitors and reports key quality performance indicators (KPIs) to track the effectiveness of the quality management program, including collecting data, analyzing trends, preparing reports, and communicating the results to HFP leadership.
- E. Establishes, implements, and maintains a laboratory quality management system (LQMS) to assure data integrity and quality of the operations and human subject protection in the HFP laboratories and applied science areas.

- F. Serves as the HFP quality lead to the laboratory International Organization for Standards (ISO) accreditation bodies; leads quality efforts and coordinates laboratory ISO accreditation activities with Office of Chief Scientist.
- G. Serves as the Application Integrity and Research Integrity Policy coordinators: manages and investigates reported concerns related to the Application Integrity and Research Integrity Policy and reports the findings to the HFP and the FDA leadership.

4. Authority and Effective Date.

The functional statements for the Office of Quality Assessment and Management were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Human Foods Program
Office of Quality Assessment and Management**

Office of
Quality Assessment & Management

Quality Assessment Staff
Quality Management Staff

(DCRN)

Staff Manual Guide 1232A.5
Organizations and Functions
Effective Date: May 13, 2024

The following is the Department of Health and Human Services, Food and Drug Administration, Human Foods Program, Office of Quality Assessment and Management organization structure depicting all the organizational structures reporting to the Director:

Quality Assessment Staff (DCRN1)

Quality Management Staff (DCRN2)