LABORATORY QUALITY MANUAL

Fourth Edition

Implemented and Effective: November 2019

The CFSAN Laboratory Quality Manual contains basic quality requirements focusing on the quality and integrity of CFSAN scientific operations.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
COLLEGE PARK, MD 20740

Laboratory Quality Manual: Edition IV

Center for Food Safety and Applied Nutrition

Quality Statement

The mission of the Quality Management and Oversight Operations Staff (QMOOS) is to develop and sustain partnerships with program offices in the Center for Food Safety and Applied Nutrition (CFSAN) to establish achievable quality standards, conduct meaningful and productive assessments, and facilitate and promote improvements. As part of on-going quality improvement initiatives for CFSAN laboratories, the QMOOS strives to make quality a continuous part of daily laboratory activities through collaborative relationships with Center laboratory staff.

The Food and Drug Administration's (FDA) Staff Manual Guide (SMG) 2130.11 Guidance for Establishing a Laboratory Quality Management System defines a quality management system (QMS) as "a set of formal and informal business practices and processes that focus on customer needs, leadership vision, employee involvement, continual improvement, informed decision making based on real-time data, and mutually beneficial relationships with external business partners to achieve organizational outcomes." CFSAN's QMS communicates quality policies, quality objectives, quality principles, and continuous improvement in a quality framework that aligns with the Center's strategic direction and FDA's SMG 2130.11.

As part of CFSAN's QMS, the Laboratory Quality Manual (LQM) provides an operational framework in which the Center's laboratory quality assurance program can operate. The LQM defines quality standards, policies, and instructions to establish a credible laboratory quality assurance program. The LQM provides fundamental information to implement basic quality concepts, principles, and practices throughout CFSAN laboratories. The manual is a central resource for understanding the role of the QMOOS and quality assurance activities of CFSAN laboratories. This fourth edition updates and replaces the third edition from 2009.

Scope

The scope of the LQM includes all research/analytical testing, studies involving human subject protection*, and scientific integrity within CFSAN. The target audience includes Center Management Personnel, Scientific Personnel, and Quality Representatives. The manual focuses on the quality and integrity of CFSAN scientific operations.

The LQM describes laboratory quality system elements (QSEs) to provide the infrastructure for maintaining quality in CFSAN scientific operations. It establishes expectations for the development and implementation of quality procedures and requirements for scientific operations, designed to ensure high quality of research and services.

*This type of study is managed by a separate SOP.

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Objectives

1. Ensure the integrity of scientific data.
2. Ensure commitment to quality in all CFSAN scientific operations.
3. Prepare researchers for Center assessments and audits.
4. Ensure research practices follow the LQM and Office/Division/Branch Quality Control (QC) Plans.
5. Ensure sufficient documentation for the purpose of replicating research.
6. Ensure authenticity of records/documents and validity of conclusions.
7. Ensure quality management systems incorporate adequate review and audits of laboratory data.
8. Ensure adequate management review of scientific operations.
9. Provide Center Management Personnel, Scientific Personnel, and Quality Representatives with fundamental information about basic quality concepts, principles, and practices.

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The LQM contains a set of coordinated activities that function as building blocks for laboratory quality management, called quality system elements (QSEs). Each QSE defines quality assurance standards for CFSAN scientific operations.

Individual Office/Division Quality Control (QC) plans shall explain how each Office meets/addresses the standards outlined in each QSE. Documentation of policies, processes, and procedures related to each QSE forms an efficient laboratory quality management system.

Definitions

Audit: A methodical, formal, and systematic examination and review of a process or product conducted by qualified persons other than those responsible for the conduct or preparation of the process or product.

Best Practices: Techniques, methods, processes, and activities that are recognized within the scientific community as delivering appropriate quality, excellence, or results.

Continual Improvement: Ongoing activities to evaluate and positively change products, processes, and the quality system to increase effectiveness.

Corrective Action: Activity in response to a finding to prevent recurrence of a detected nonconformance. Action taken to eliminate or prevent a recurrence of root cause(s) and symptoms(s) of an existing deviation or nonconformance with respect to CFSAN laboratory policies or procedures and/or applicable regulations.

Customer: In this document customer is defined as: A person having an immediate, secondary, or other interest in a product or service that an organization provides.

Deviation: A nonconformance or departure of a characteristic from a specified product, process, or system requirement.

Element: A constituent part; a distinct section or portion within a larger group; one of the factors determining the outcome of a process.

Equipment: All instruments, measuring devices, and computer systems used in evaluating and/or performing research.

Finding: A conclusion of relative importance based on observation(s) and/or research.

Inspection: The process of measuring, examining, testing, and gauging one or more characteristics of a product or service and comparing the results with specified requirements to determine whether conformity is achieved for each characteristic.

Internal audit: An audit conducted within an organization by members of the organization to measure the strengths and weaknesses against its own procedures and/or external standards. It is also known as a first party audit.

Investigation: The process of observing or studying by close examination and systematic inquiry, making a systematic examination, or conducting an official inquiry. Investigations may be triggered by multiple factors, including but not limited to, systemic errors, official inquiry, and multiple nonconforming inspections.

Lifecycle: The activities that plan, produce, deliver, and service a work product.

Management Personnel: The managers and supervisors in an organization who lead, direct, and oversee the scientific operations.

Management Review: Formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives.

Metric: The measure used to evaluate the quality of a process or product/service.

Monitor: To watch over or check systematically for the purposes of collecting metrics.

Nonconformance: An unfulfilled requirement; “nonconformity” is an equivalent term.

Preventive Action: Action to eliminate the cause of a potential nonconformity or otherwise undesirable situation.

Project Lead: An individual who has primary responsibility for performing or overseeing research.

Procedure: Specified way to perform an activity. A procedure typically produces a specific result, either in the form of a measurement result or an end product.

Process: A set of interrelated activities (tasks, procedures, sub-processes) that transform inputs into desired outputs.

Protocol: In the natural sciences, a protocol is a predefined written procedural method in the design and implementation of experiments. This should establish standards that can be adequately assessed by peer review and provide for successful replication of results by others in the field. It should include safety, procedural, equipment, and reporting standards. A major part of this protocol is predefining and documenting excluded data to avoid bias.

Quality: A measure of a product's or service's ability to satisfy a stakeholder's stated or implied needs.

Quality Assurance (QA): Proactive and retrospective activities that provide confidence that requirements are fulfilled. All of the planned and systematic actions used in a Quality System to provide adequate confidence that a product, service, or process will satisfy given requirements for quality.

Quality Control (QC): The operations, techniques, and activities of a quality system that are used to fulfill requirements for quality of a project, product, service, process, or contract.

Quality Control Plan (QC plan): A document specifying which procedures and associated resources must be applied by whom and when to a specific project, product, service, process, or contract.

Quality System Element (QSE): A component of the quality system, used to implement and improve process effectiveness. Each QSE defines quality assurance standards for CFSAN scientific operations.

Quality Indicator: An element of a quality monitoring process that can be identified as needing improvement.

Quality Management System: An accountability procedure for all activities and functions that determine the quality policy, objectives, and responsibilities, and ensure that such activities are implemented.

Quality Planning: The procedure that specifies quality standards, practices, resources, specifications, and the sequences of activities relevant to particular projects, products, services, processes, or contracts.

Quality Policy: The intentions and directions of an organization regarding quality that are established by FDA and CFSAN management.

Quality Representative: A program manager who conducts quality assurance activities to ensure the integrity and quality of data. Such quality assurance activities include conducting audits. The Quality Representative ensures management and operation procedures are performed systematically to meet CFSAN quality laboratory management requirements and standards. The Quality Representative is designated by the Center Director and is independent of CFSAN Offices that conduct studies at CFSAN. For the purposes of this Manual, the Quality Representative for CFSAN is the QMOOS.

Quality System: A formalized business practice that defines management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill product/service requirements, customer satisfaction, and continual improvement. Quality planning, quality assurance, quality control, and quality improvement are components of a quality system.

Raw Data: Laboratory worksheets, records, memoranda, and notes, or exact copies thereof, that are the result of original observations and activities of a laboratory study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the copy of that transcript may be substituted for the original source as raw data.

Regulatory Samples: Compliance samples, official or investigational factory samples, official or investigational surveillance samples, official or investigational complaint samples, official or investigational documentary samples, and official post-seizure samples.

Scientific Personnel: The scientifically trained personnel responsible for the technical operations and process checks/verifications used to conduct laboratory studies. The Scientific Personnel incorporate the Quality Control procedures and tools created by the quality system (training, SOPs, checklists, etc.) to manage their day-to-day work and ensure scientific research and knowledge generated meet a high level of quality in terms of scientific validity and significance. Scientific Personnel in relation to this Manual include Project Leads, the Safety Office staff, and the Senior Science Advisory Staff (SSAS).

Specimen: Any material derived from a test system for examination or analysis.

Stakeholder: In this document, stakeholder means an individual or organization having ownership or interest in the delivery, results, and metrics of the quality system framework or business process improvements. Typical stakeholders are customers, employees, stockholders, board of directors, and executives.

Standard Operating Procedure (SOP): Written instruction designed to achieve uniformity of the performance of a specific function. SOPs set forth routine or standardized laboratory functions.

Test System: An animal, plant, or microorganism, or subparts thereof, to which a test or control article is administered or added for study. Test systems also include appropriate groups or components of the system not treated with a test or control article.

Work Activities: The activities that result in a project, product, service, process, or contract.

Work Products: The products CFSAN provides to internal and external stakeholders, e.g., analytical and worksheets, report drafts, and publications.

QSE A: Organization

CFSAN-sponsored scientific operations support the CFSAN mission and goals. Scientific operations must be conducted with the highest level of integrity and quality possible. A strong organizational commitment from CFSAN Management Personnel is essential. The CFSAN laboratory quality assurance program contains a set of QSEs that describe Management's quality expectations of research activities. At CFSAN, research quality and integrity are responsibilities of Management Personnel, Quality Representatives, and Scientific Personnel, which are discussed in QSE B.

CFSAN scientific studies and study personnel are not subject to Good Laboratory Practice (GLP) (21 CFR Part 58) as a regulatory requirement and are not subject to FDA Office of Regulatory Affairs (ORA) GLP inspections. At CFSAN Management's discretion, CFSAN internal scientific studies and studies sponsored by CFSAN but conducted by external collaborators may be conducted under GLP (21 CFR Part 58) as a quality system requirement to assure scientific integrity and study quality.

A.1 Organizational processes and procedures must:	
	A.1.a Define the Division/laboratory structure and maintain Division organizational charts.
	A.1.b Establish position/job descriptions outlining roles and responsibilities.
	A.1.c Promote communication regarding a laboratory quality management system within the Center/ORA to ensure effective working environments for all personnel.
	A.1.d Conduct management reviews of the laboratory quality management system.

QSE B: Roles and Responsibilities

This section entails the basic roles and responsibilities of CFSAN staff, categorized into Management Personnel, Scientific Personnel, and Quality Representatives. The duties described below are not all-inclusive. All staff must understand their responsibilities and authorities to allow for effective scientific operations.

B.1 Management Personnel

B.1.a CFSAN Senior Management

Senior Management is committed to laboratory quality through its support and leadership of the laboratory quality assurance program. This support is demonstrated through management's leadership and participation in the development, implementation and sustainment of Office/Division QC plans based on the QSEs outlined in the LQM, as well as regulatory and statutory requirements.

Senior Management is responsible for:

(1) Enforcing mandatory compliance with the Laboratory Quality Manual and supporting the establishment of a CFSAN laboratory quality system.
(2) Participating in QMS management reviews and follow-up actions.
(3) Ensuring the availability of resources to conduct work and laboratory quality management processes, including provision of a safe laboratory environment, appropriate scientific facilities and equipment, and an institutional system for the secure storage of scientific records.
(4) Providing resources to implement the LQM.
(5) Developing CFSAN scientific policies and laboratory programs to support policies.
(6) Planning, administering, coordinating, evaluating, and promulgating overall Center scientific, regulatory, compliance, enforcement and management programs, policies and plans.

B.1.b Office/Division Management with responsibilities for overseeing scientific laboratories and studies

Office/Division Management is responsible for:

(1) Ensuring the Project Lead designs the project and submits the proposal to FDA's Component Automated Research Tracking System (CARTS).
(2) Replacing the Project Lead promptly when necessary.
(3) Ensuring projects/protocols are properly amended to reflect changes in responsible personnel in CARTS.
(4) Ensuring personnel clearly understand their functions.
(5) Ensuring QC plans are developed according to the CFSAN LQM.
(6) Providing separate laboratory space, as needed, for the performance of routine and specialized procedures required by scientific operations.
(7) Reviewing reports of CFSAN Quality Assurance activities
    I.e. internal audit reports, corrective/preventive actions, management reviews, and continual improvement efforts.
(8) Maintaining overall responsibility to ensure that deviations and complaints are addressed.
    I.e. Division QC plans or standard operating procedures (SOPs) should address how deviations and complaints are documented and handled.

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Management Personnel	(9) Reviewing and acting on quality management recommendations. (10) Establishing quality objectives derived from strategic priorities. (11) Prioritizing, selecting, and approving written research plans that utilize FDA resources. (12) Communicating the importance of customer satisfaction when fulfilling quality requirements. (13) Participating in reviews/audits of scientific operations, including addressing deviations cited/reported and corrective action implementation and documentation. (14) Assuring communication, understanding, and implementation of the laboratory quality management system CFSAN-wide, by providing appropriate training for staff and monitoring compliance with the LQM. (15) Ensuring laboratory quality procedures are established and used to monitor adherence to work and quality system directives. (16) Delegating authority and responsibility, while retaining accountability. (17) Ensuring planned work is accomplished, the quality system is adhered to, and staff are performing their work within established laboratory quality procedures. Supervisors are accountable for ensuring that staff are knowledgeable of work and quality system procedures and tools, as well as ensuring/performing required QC functions. (18) Reviewing progress of scientific operations at scheduled intervals. QC plans must describe the frequency of such reviews. (19) Developing and implementing QC measures to address QSEs outlined in the LQM. (20) Ensuring current and new staff receive appropriate fundamentals and safety training. (21) Promoting the professional development of scientists by encouraging publication in/editorial service to peer-reviewed journals, presentations at professional meetings, full participation in appropriate professional or scholarly societies, and other activities that may benefit the public's health.
B.2 Scientific Personnel	
	B.2.a Project Lead The Project Lead must ensure procedures indicated in the approved project/protocol are followed by laboratory personnel and appropriate documentation is maintained to support the results of scientific operations. For each laboratory study, a scientist or other professional of appropriate education, training and experience, or combination thereof, must be identified as the Project Lead. The Project Lead has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results. The QC plan must define the role of the Project Lead. The Project Lead must be responsible for creating a new project proposal in CARTS. The Project Lead must initiate the drafting of a new intramural research project proposal and complete required information such as administrative data, assignment of personnel, project description, milestones, approvers, and project profile. The Project Lead must provide a final report and close the project in CARTS at the conclusion of the study. For more information on CARTS, visit the CARTS SharePoint. Project Leads are responsible for:

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Scientific Personnel	(1) Conducting scientific experiments. (2) Documenting and reporting research results. (3) Ensuring amendments to the project/protocol are documented in CARTS. (4) Maintaining pertinent documentation regarding all project activities. (5) Communicating on a regular basis with contractors who provide project support. (6) Maintaining relevant analyses as part of raw data for the project/protocol. (7) Documenting and addressing circumstances that may affect the quality and/or integrity of scientific operations. (8) Ensuring equipment is adequately inspected, cleaned and maintained. (9) Preparing a final report (e.g., CARTS write-up, validated method, peer-reviewed publication, oral presentation, etc.) in accordance with CFSAN policies. (10) Ensuring raw data, documentation, protocols, specimens, and final reports (if necessary) are archived at the completion of a study. (11) Ensuring the study is conducted safely and in accordance with the laboratory safety plan, safety procedures, and safety requirements. (12) Ensuring personnel properly maintain neat and clean working areas as required by the experimental protocol. (13) Ensuring all involved in scientific operations practice general housekeeping procedures and maintenance. (14) Ensuring all laboratory personnel have proper and documented training of procedures, instruments, etc. (15) Discussing any deficiencies with supervisors.
	B.2.b Laboratory Personnel Laboratory Personnel are responsible for: (1) Conducting scientific experiments. (2) Documenting and reporting research results. (3) Obtaining appropriate education and training, and acquiring experience as identified by the Project Lead. Such records must be presented to the Project Lead. (4) Taking necessary personal sanitation and health precautions to avoid compromising the research environment. (5) Wearing clothing appropriate for duties performed. Such clothing must be changed as often as necessary to prevent microbiological, radiological, or chemical contamination. (6) Reporting to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on the study or the health of those conducting studies. (7) Maintaining a neat and clean work area. This must include taking steps to ensure that benches, cabinets, ceilings, walls, and floors are kept clean and free of clutter. Any unused or nonfunctional equipment must be promptly and properly stored, and/or permanently removed.
B.3 Quality Representatives	
	B.3.a Quality Management and Oversight Operations Staff (QMOOS)

Quality Representatives	The CFSAN QMOOS is responsible for managing the laboratory Quality Assurance (QA) Program. The QMOOS assures Management that facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the CFSAN LQM, best practices, and applicable requirements. Quality Representatives must be entirely separate from and independent of the laboratory personnel engaged in the direction and conduct of scientific operations and activities related to regulatory samples and research. The QMOOS is responsible for: (1) Auditing quality-related research activities. (2) Maintaining all audit reports and related documents to ensure quality standards are met. (3) Periodically submitting written status reports to Management. Such reports note any issues and corrective actions taken. (4) Maintaining and updating the CFSAN LQM. (5) Utilizing CARTS to identify approved studies for research audits. (6) Monitoring and facilitating Corrective and Preventive Actions (CAPA) and continual improvement efforts.
	B.3.b Laboratory Quality Assurance Council The purpose of the CFSAN Laboratory Quality Assurance Council is to establish a collaborative relationship between the CFSAN QMOOS and Center liaisons from CFSAN research laboratory offices. Council members must assist with developing and communicating quality management policies and guidance related to laboratory quality assurance principles, training, SOPs, process improvements, and other documents and information needed for an effective laboratory quality assurance and audit program.

QSE C: Scientific Integrity

To best serve customers, stakeholders, and employees, the organization Management Personnel, Scientific Personnel, and Quality Representatives must be free of undue internal and external pressures that may adversely affect the quality of their work. Ethics standards promote and strengthen confidence in the integrity of the Office/Division. Federal, departmental, and FDA ethical standards must be understood and followed by employees.

According to the SMG 9001.1 FDA Staff Manual Guides, Volume IV - Agency Program Directives: Scientific Integrity at FDA: Access to reliable scientific and technological information is central to FDA's mission and regulation of human and veterinary drugs, biological products, medical devices, cosmetics, tobacco, and food. FDA must rely on the best available science to make difficult decisions with respect to those products. In making those decisions, an unbiased presentation and full evaluation/analysis of the data (including underlying assumptions and uncertainties) is critical.

Establishing and maintaining integrity of scientific processes and scientific data are crucial to the agency's ability to make sound decisions and maintain public trust. While there may be differing conclusions based on research data and multiple considerations in a policy approach or regulatory decision made based on research findings, the underlying research data and findings should be obtained and reported with integrity and never be altered for any reason. FDA has a long and continuing history of ensuring integrity of its scientific and regulatory processes and, as a result, has put in place related policies, procedures, and initiatives such as process management.

C.1 FDA's Key Principles of Scientific Integrity

FDA's Key Principles of Scientific Integrity	C.1.a Maintain a firm commitment to science-based, data-driven decision making.
	C.1.b Shield the agency's scientific work and staff from political influence.
	C.1.c Facilitate the free flow of scientific and technical information.
	C.1.d Protect the integrity of scientific data and ensure its accurate presentation, including the underlying assumptions and uncertainties.
	C.1.e Require a fair and transparent approach to resolving internal scientific disputes while carefully considering differing views.
	C.1.f Support whistleblower protection.
	C.1.g Select and promote scientists based on their knowledge, expertise, and integrity.
	C.1.h Use peer-reviewed data and research in making decisions (where feasible) that are appropriate and consistent with the law.
	C.1.i Maintain openness and select qualified advisory committee members based on expertise, with transparency about conflicts of interest.
C.2 Foundations of Scientific Integrity	
	C.2.a A Culture of Scientific Integrity Maintain a culture of scientific integrity that ensures scientific decisions are the product of honest investigation, open discussion, refined understanding, and a firm commitment to evidence. Such a culture must be shielded from inappropriate political influence.
	C.2.b FDA's Office of Scientific Integrity (OSI) seeks to promote a culture of scientific integrity across the agency. Created in 2009, OSI reports to the Chief Scientist and works with the Office of the Commissioner and the agency's Centers to: (1) Ensure that the agency's policies and procedures with respect to scientific integrity are up to date and applied across the agency. (2) Strengthen the actual and perceived credibility of scientific reviews and decision making.

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Foundations of Scientific Integrity	C.2.c FDA policies and programs seek to strengthen the scientific quality, integrity and credibility of scientific reviews and decision making at the agency as follows: (1) FDA Scientist Review Committees – a system of committees designed to review the scientific credentials and qualifications of prospective and current scientific employees and to ensure that selection of scientists is based on their scientific and technical knowledge, credentials and integrity. (2) Scientific Peer Review – consistent with the "Final Information Quality Bulletin for Peer Review" issued by the Office of Management and Budget in 2005, FDA publishes on its website an agenda of peer review plans and completed peer review reports for scientific information that is likely to have a clear and substantial impact on important policies or private sector decisions.
	C.2.d Good Scientific Practice All research conducted at CFSAN must adhere to the fundamental rule of good scientific practice (SMG 9001.1, and 42 CFR Parts 50 and 93). Research must be conducted with integrity and in a responsible manner, to withstand close scrutiny and comply with high ethical standards. Each QC plan must describe Office/Division expectations for scientific integrity. Scientific validation of experimental protocols and analytical results against scientific literature and expected results contributes to the integrity of data and quality of the research being conducted. Any inconsistency and non-repeatability in expected results should generate further analysis to identify the root causes and implement corrective actions. All information must be documented.

QSE D: Facilities

Each research facility must be of suitable size and construction to facilitate the proper conduct of laboratory studies. It must be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

D.1 Animal Care Facilities

Animal Care Facilities: Guidelines of the Institutional Animal Care and Use Committee (IACUC) must be followed when studies involve animals to ensure that the study is conducted in compliance with animal care and animal facilities guidelines.

D.2 Animal Supply Facilities

There must be storage areas, as needed, for feed, bedding, supplies and equipment. Storage areas for feed and bedding must be separated from areas housing the test systems and must be protected against infestation or contamination. Perishable supplies must be preserved using appropriate means. Facility Operations and Engineering Management provides assistance and recommendations on space utilization, provides assistance with relocations and maintains air quality and air flow, temperature, and humidity for the laboratory.

D.3 Laboratory operation areas:

Separate laboratory space should be provided, as needed, for the performance of routine and specialized procedures required by laboratory studies.

D.4 Archiving specimens Space must be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of specimens from completed studies, as necessary.	
D.5 Laboratory Housekeeping CFSAN laboratories must be maintained in a clean and orderly fashion to help ensure the quality and integrity of the data generated.	
	D.5.a The Project Lead, in conjunction with line management, must ensure all personnel involved in laboratory studies have proper housekeeping procedures to help ensure the quality and integrity of study data. The Project Lead must discuss any deficiencies with laboratory supervisors.
D.6 Office/Division quality control plans must describe and document laboratory facilities and safety.	
	D.6.a Allocate appropriate space for laboratory activities. The laboratory's allocated space must be organized so work can be performed without compromising the quality of work and the safety of personnel.
	D.6.b Secure access to laboratory areas, as appropriate.
	D.6.c Maintain clean work benches/areas in the laboratory.
	D.6.d Document and control the laboratory environmental conditions as required or where they may influence the quality of research.
	D.6.e Maintain efficient communication channels with staff.
QSE E: Purchasing and Inventory	
Availability of dependable and reliable supplies is essential. This QSE describes how the quality and quantity of reagents and supplies are ensured for scientific operations. Efficient and cost-effective laboratory operations require uninterrupted availability of reagents, supplies, and services. Inventory management of laboratory chemicals, reagents, and equipment ensures research operations are uninterrupted, supplies are available, chemicals/reagents are within expiration dates, laboratory waste is minimized, and equipment is operational and available for use.	
E.1 Supply and Reagent Availability QC plans must describe how supplies and reagents are available when needed	

Supply and Reagent Availability	E.1.a Reagents and supplies must not be lost due to improper storage or kept and used beyond expiration dates, unless efficacy-tested.
	E.1.b The laboratory system for managing the reagents and supplies must take into account availability, lifespan, and difficulty in obtaining specialty reagents and supplies. Ensure the supplies and reagents are in stock and within their expiration dates. QC plans must emphasize the importance of continuously monitoring the expiration dates.
	E.1.c QC plans must describe if and when expired reagents can be used, and how expired reagents are tracked and labeled.
E.2 Supply Procurement Staff must ensure study/laboratory supply requirements are met.	
	E.2.a QC plans must ensure staff know who to contact to order supplies or ensure staff are aware of how to order supplies.
	E.2.b Credit card agreements and contracts should clearly address payment mechanisms and provisions to assure reliable availability and delivery of reagents and supplies.
E.3 Inventory Control Each Office/Division must describe current inventory control in an SOP or QC plan and should develop forms and/or logs required to manage inventory. Please note: Activities may vary among CFSAN facilities, so not all tasks may be applicable. Activities specific to a facility must be described in the facility's QC plan.	
	E.3.a Designate personnel to manage inventory control.
	E.3.b Analyze the needs of the laboratory.
	E.3.c Establish the minimum stock needed for an appropriate time period.
	E.3.d Establish a system for receipt, inspection, identification (i.e. labeling), usage (i.e., "First in First Out"), storage, and disposal.
	E.3.e Ensure hazardous chemicals, hazardous biological agents and toxins (HBATS), radioactive materials, controlled substances and equipment are inventoried.

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Inventory Control	E.3.f The QC plan must describe how a Project Lead determines the quantity of materials required and how much should be readily available. The Project Leads must identify all the supplies and reagents that are needed for each study and must use all available information to estimate the usage of supplies and reagents for the period of time between ordering new materials. All kits, reagents and solutions must be dated and initialed when received or made. If expired materials must be used in a study, they must be efficacy-tested and documented.

QSE F: Personnel

This section provides direction to effectively manage human resources. Refer to pertinent sections of SMG 2130.11 for more information on personnel.

CFSAN laboratory management must provide adequate resources to support the scientific mission and define training practices. Laboratory managers/supervisors must, when appropriate, define appropriate qualifications for each role in the laboratory, and ensure staff are trained per job descriptions and approved SOPs.

F.1 New Staff Procedures

Ensure new staff understand their roles and responsibilities.

	F.1.a Maintain records of the relevant educational and professional qualifications, training and experience and assessments of competence of all personnel.
	F.1.b Maintain job tasks that describe responsibilities, authorities and tasks for all personnel.
	F.1.c Introduce new staff to the organization, or area in which a person will work according to the terms and conditions of employment.
	F.1.d Develop an orientation to introduce new staff to the work environment and their specific tasks, duties and responsibilities.
	F.1.d (1) Orient new staff to the roles of the FDA, CFSAN, and assigned Office/Division. Provide an overview to discuss the roles of the Center and Office/Division to explain how the Office/Division fits into the Center's mission.
	F.1.d (2) Introduce key personnel and lines of authority.
	F.1.d (3) Coordinate with internal and external scientific experts to discuss regulatory and safety issues related to food additives, food, and cosmetic products when applicable.

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New Staff Procedures	F.1.d (4) Discuss policies and procedures regarding facilities and safety.
	F.1.d (5) Review personnel policies including ethics, data integrity and confidentiality of information. Include the Center's mission, goals, and conflicts of interest.
	F.1.d (6) Review the Division quality control plan that outlines the policies of the organization and information about the laboratory quality system.
	F.1.d (7) Ensure new staff understand their job tasks.
	F.1.d (8) Provide an overview of standard operating procedures (SOPs).
F.2 New Laboratory Personnel Training Maintain documentation of training, certifications, and/or authorizations for new laboratory personnel. All training documentation for new laboratory personnel must be signed and dated at the time of training. The effectiveness of the training/laboratory notebook must be periodically reviewed by Management. QC plans must describe the frequency of documented reviews.	
	F.2.a All new laboratory personnel must be trained on policies, processes, procedures, SOPs, and written instructions related to research activities.
	F.2.b All new laboratory personnel should be trained on documentation of verbal changes in experimental protocols.
	F.2.c All new laboratory personnel must be trained on how and when to use the Component Automated Research Tracking System (CARTS) and other applicable systems.
	F.2.d All new laboratory personnel must receive ethics training, which should include topics related to scientific and research integrity such as presented in Responsible Conduct of Research Training (RCR Training).
	F.2.e Supervise laboratory personnel undergoing training at all times.
	F.2.f Ensure skills gained from training are incorporated into day-to-day work activities. This may require specific authorizations to perform research activities.

New Laboratory Personnel Training	F.2.g Act upon suggestions to improve common practices and day-to-day research activities.
	F.2.h Foster and increase interactions between science leadership and researchers across the groups housed in different Offices to develop a unified science strategy.
	F.2.i Create greater in-house awareness of the research portfolios by publicizing abstracts, summaries or peer-reviewed publications (outside of CARTS) across the Foods and Veterinary Medicine (FVM) program.
	F.2.j. Establish SOPs for research collaborations between Offices and train researchers on SOP expectations, which would increase coordination.
F.3 Current Laboratory Personnel Training and Continuing Education Maintain documentation of training, certifications, and/or authorizations for current staff. All training documentation for current staff must be signed and dated at the time of training. The effectiveness of the training/laboratory notebook must be periodically reviewed by Management. QC plans must describe the frequency of documented reviews.	
	F.3.a Training should be linked to the job tasks and competencies to address gaps in specific tasks to be performed by the staff.
	F.3.b Competency should be reassessed after any position-specific training, such as after the introduction of new analyzers or methodology.
	F.3.c Cross training on multiple methodologies may be done to allow staff to acquire additional skills.
	F.3.d The QC plan must describe and ensure each individual engaged in the conduct of or responsible for supervising a laboratory study must have education, training, and experience, or a combination thereof, to enable these individuals to properly perform the assigned duties.
	F.3.e Quality control training must be consistent with duties and responsibilities as outlined in quality control plans.
	F.3.f Training must include policies contained in this manual and Office/Division quality control plans.
	F.3.g Training must include laboratory practices and procedures needed to do relevant research.

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Current Laboratory Personnel Training	F.3.h Safety training must be consistent with duties and responsibilities.
	F.3.i Quality control plans must describe how training and experience for each individual engaged in or supervising the conduct of a laboratory study is documented and maintained.
	F.3.j Training and experience should be documented by curriculum vitae, resumes, training certificates, etc.

QSE G: Equipment and Reagents

CFSAN must maintain equipment inventories, as well as controls for equipment used for testing or measuring. CFSAN scientific operations must ensure equipment is maintained in a validated state throughout their lifecycle to conform to appropriate scientific standards and applicable regulatory requirements and laws.

G.1 Equipment Inventories and Controls

	G.1.a Remove equipment from service when not functioning properly or when calibration or maintenance has not been performed.
	G.1.b Contact appropriate group for assessment and/or repair when equipment is not functioning properly.
	G.1.c Develop and maintain schedule and records for the maintenance and calibration of equipment.
	G.1.d Perform tasks to monitor equipment validation, calibrations and maintenance.
	G.1.e Maintain control of equipment user manuals.
	G.1.f Review data and records related to equipment.
	G.1.g Develop and maintain quality control plans to provide additional information regarding equipment design, maintenance and calibration.
	G.1.g (1) Maintain equipment in a safe working condition and in working order. This must include examination of electrical safety, emergency stop devices (where they exist) and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. At a minimum, manufacturers' schedules and/or instructions must be used.

Equipment Inventories and Controls	G.1.g (2) Ensure equipment is operated at all times by trained and authorized personnel.
	G.1.g (3) Ensure the laboratory has a preventive maintenance document for each piece of equipment, which may be the manufacturer's instructions.
	G.1.g(4) Ensure the laboratory has a documented procedure for the selection, purchasing and management of equipment.
	G.1.g (5) When applicable, ensure the laboratory has a documented procedure for the calibration of equipment that directly or indirectly affects study results.
	G.1.g (6) Whenever equipment is found to be defective, ensure that it is taken out of service and clearly labeled as out of service. Ensure that defective equipment is not used by laboratory personnel until repaired.

G.2 Project Lead Oversight of Equipment Maintenance

The Project Lead must ensure equipment is adequately inspected, cleaned and maintained. Equipment used for the generation, measurement or assessment of data must be adequately tested, calibrated and/or standardized.

The QC plans must describe the methods, materials and schedules to be used in the routine equipment inspection, cleaning, maintenance, testing, calibration and/or standardization of equipment. The plans must specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The Project Lead is responsible for the performance of each operation needed for equipment maintenance.

The Project Lead must ensure written records of all inspections, maintenance, testing, calibrating and/or standardizing operations are maintained. These records, containing the date of the operation, must describe whether the maintenance operations were routine and followed the written standard operating procedures. QC plans must determine the written records to keep for non-routine repairs performed on equipment as a result of failure and malfunction. Such records must document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

The Divisions or Project Leads must set a calibration, cleaning, maintenance and replacement frequency or schedule for all specific or relevant laboratory equipment.

Please note: Activities may vary among CFSAN facilities, so not all tasks may be applicable. Activities specific to a facility must be described in the facility's QC plan.

	G.2.a Calibrated thermometers must be used to make sure laboratory thermometers are operating within the appropriate range. Thermometers must be calibrated annually to make sure laboratory thermometers are operating within the appropriate range.

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Project Lead Oversight of Equipment Maintenance	G.2.b Operational checks on balances should be performed by the research scientists or designee for all critical measurements. Operational checks should be documented. Balances should be serviced and calibrated annually by an outside professional calibration service or designee.
	G.2.c Automatic pipettes should be calibrated annually (or period defined by the Office/Division) by designated personnel.
	G.2.d The QC plan must describe documentation of the serial number and the date calibrated, and where information is kept for all equipment.
	G.2.e Identity of the equipment, manufacturer's name, model and serial numbers or other unique identification, contact information for the supplier or the manufacturer must be documented.
	G.2.f Date of receiving equipment and date of entering into service, location and condition when received (i.e. new, used or reconditioned) must be documented.
	G.2.g Manufacturer's instructions, equipment records confirming acceptability for intended use, maintenance records and preventive maintenance schedules must be retained.
	G.2.h Equipment performance records that confirm the equipment's ongoing acceptability for use of purpose; damage to, or malfunction, modification, or repair of the equipment must be documented.
	G.2.i pH meters should be checked with standard buffers before each use and standardization documented.
	G.2.j Operational checks before each use should be documented in the appropriate location (i.e. instrument logbook or laboratory notebook).
G.3 Quality control checks and validation for equipment	
	G.3.a Ensure that all persons who will be using the equipment are appropriately trained and understand how to properly operate the equipment and perform all necessary routine maintenance procedures. Training must be documented.
	G.3.b Document operational checks before use of an instrument in an instrument logbook located near the equipment.
	G.3.c Monitor the equipment management activities, including reviewing all equipment records, routinely updating maintenance procedures as necessary and ensuring that all procedures are followed.

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G.4 Management of reagents and solutions should be described in the Office/Division QC plan.	
	G.4.a All reagents and solutions in the laboratory areas should be labeled to indicate identity, titer or concentration, storage requirements, and expiration date.
	G.4.b Office/Division QC plans must describe how purchased chemicals, solutions, media, and reagents are received and tracked.
	G.4.c Solutions and other reagents prepared in the laboratory must, in addition to F,4,a, also be labeled to indicate date of preparation and the preparer's initials. QC plans must define other information that may be pertinent to labels. An example of a statement that may be included in the QC plan is stated below. *Solutions and other reagents prepared in the laboratory should be labeled to indicate identity, date of preparation and preparer's initials. Other information that may be pertinent (e.g., concentration, storage conditions, expiration date, etc.) should also be indicated on the label. The Project Lead should evaluate the need for expiration dating of a prepared solution. In cases where the expiration date is uncertain, a best estimate may be made and indicated on the label. Use of these solutions after the estimated expiration date may be done after efficacy testing and approval by the project lead.*
	G.4.d Deteriorated or outdated reagents and solutions Deteriorated or outdated reagents and solutions should not be used and must be properly disposed of in accordance with Center safety standards. If used for training purposes, they must be labeled with "expired" and "for training purposes only". Quality control plans must describe the use of deteriorated or outdated reagents and solutions. An example of a statement that may be included in the QC plan is stated below. *Materials that have exceeded the manufacturer's expiration date should be labeled or marked clearly. Such materials may be retained and used in non-critical applications, such as training of personnel. If desired for use in experimentation, the materials should be efficacy tested and documented as appropriate. Documentation must be readily accessible.*
	G.4.e Hazardous components and special protective measures Reagents and solutions that contain hazardous components and require special protective measures while handling and storing (e.g., need for protective equipment, use in a hood, peroxide-forming compounds that pose acute safety hazards, etc.) must have an appropriate warning sticker affixed to each container.

QSE H: Documentation

Documents and records must be controlled and managed from creation to destruction. Document control includes identifying authors/dates associated with creating, reviewing, revising, tracking versions, and approving documents such as policies, processes, protocols, procedures, and forms. Documents must be traceable, secure, protected from adulteration, and dispositioned accordingly.

CFSAN laboratory managers must review document control procedures to ensure applicable documents are uniquely-identified, dated, version-controlled, reviewed and approved. Reviews must occur periodically at defined intervals (stated in QC plans) and be managed accordingly to prevent the use of obsolete documents. Documents must be readily accessible for use by research personnel and archived or destroyed as applicable records management guidelines state. Audit trails must be incorporated to ensure personnel are accountable for their edits.

H.1 All laboratory research should be carefully documented in a form that will allow access for analysis and review.

It is important for investigators to recognize research data records as legal documents for establishing research priority and patent rights, allowing independent re-analysis of the data, supporting the veracity of published results against challenges, supporting regulatory decision-making and satisfying data requests of congressional committees and courts of law.

Research conducted at CFSAN is chronologically documented in an official laboratory notebook and may be used as legal evidence. Research data generated at or for CFSAN are FDA property.

H.2 Records

Records include primary data, such as data in notebooks, printouts, computer-based storage devices, photographs, slides, negatives, films, scans, images, auto-radiograms, electrophysiological recordings, gels, blots, printed records, observations and notes, electronic data, video and audio records, spectra, samples, specimens and other materials containing raw unprocessed information collected during the research process.

Secondary data include various representations and summaries of the primary data, such as statistical analyses, graphic charts, data tables and conclusions.

All records should be legible, identifiable, and readily retrievable when in secure storage.

H.3 Archiving records/data

Records are defined as significant or non-significant and consist of raw data, documents, projects, protocols, final reports and specimens. To ensure study information is properly archived, the Project Lead must include on FDA form 3255a an index of all study material before submitting data to the Federal Records Center.

Significant data are projects by FDA scientists who received recognition outside their noted area of expertise, projects altering political, economic, scientific or social priorities, projects changing research or administrative policies within the Department of Health and Human Services (DHHS) or FDA and research resulting in extensive federal scrutiny or investigation or in widespread media attention. Non-significant data do not meet the above definition.

Significant data must be kept permanently, and paper records transferred to the Federal Records Center three years after research completion. Non-significant records must be kept for three years.

H.4 Recording Laboratory Data

The official laboratory notebook is the primary medium for recording laboratory data. However, other forms of documentation such as forms, diagrams and electronic media may replace or be used in conjunction with laboratory notebooks with appropriate cross-referencing.

QC plans must identify electronic data outputs and systems for documentation, cross-referencing, backup and storage of the work (i.e., copying files to a shared drive, a second hard drive, or other optical or magnetic media) used by the Office/Division.

H.5 Official Laboratory Notebook

	H.5.a Data generated, except those that are generated by automated data collection systems, must be recorded directly and promptly in black or blue ink in the official laboratory notebook. If data are stored in a laboratory notebook and an electronic file, the data must match.
	H.5.b Changes in entries (manual and automatic data entries) must not obscure the original entry and must be dated and initialed.
	H.5.c In automated data collection systems, the individual responsible for direct data input/collection must be identified at the time of data input/collection.
	H.5.d Data collected as output from an instrument (i.e., images, instrument printouts, etc.) should be saved permanently as a hardcopy (fastened with a permanent attachment to a consecutive page in the laboratory notebook) or recorded in an approved non-modifiable electronic file (such as a read-only CD or a signed and certified pdf file) with location and identification documented in the laboratory notebook.
	H.5.e Specimens, cells or samples collected should be individually identified. An entry in a permanent record (i.e., laboratory notebook) should describe the relevant sample information, storage conditions and location.
	H.5.f Data received from collaborators or sources outside an investigator's laboratory should be labeled with date of receipt and source, then catalogued in a laboratory notebook noting where data are stored.
	H.5.g The Project Lead must periodically review official laboratory notebooks used in studies.

H.6 Standard Operating Procedures (SOPs)

SOPs describe how specific operations and methods must be performed. These may include sampling operations, sample preparation, calibrations, measurement procedures and any operation done frequently. Peer review of all methodology is a minimum requirement to ensure understandability, enhance continuity of a measurement process and receive the benefit of technical feedback.

Laboratories must contain SOPs for routine operations/testing. SOPs ensure the quality and integrity of data. A historical file of SOPs and all revisions/versions must be maintained.

SOPs	H.6.a SOPs must be maintained, filed and distributed in a manner in which all necessary personnel have access.
	H.6.b SOPs must be prepared and approved by authorized personnel.
	H.6.c SOPs must be developed for routine or repetitive laboratory tasks, as necessary.

H.7 Electronic Laboratory Notebook (ELN)

The ELN is an initiative to allow scientists to replace paper notebooks with digital records, including audit trails that comply with 21 CFR Part 11 (electronic records and electronic signatures), required quality controls and cross database interfaces. An ELN is a computer program which can be used to document research, experiments and procedures performed in a laboratory. ELNs also allow for direct incorporation of data from laboratory instruments to streamline processes. With this technology, scientists will be able to save, organize, compile, share and protect Intellectual Property (IP).

QSE I: Sample Management

The integrity of sample workflows directly affects the accuracy and reliability of scientific operations. Careful handling throughout the pre-analytical, analytical, and post-analytical phases is essential to preserve data integrity. Sample management procedures must be documented in QC plans, encompassing how the quality of samples is maintained throughout all phases of scientific operations.

Samples addressed in this section refer to general research samples. Regulatory samples must have separate procedures established as necessary. For information on official and regulatory samples, please refer to the Chain of Custody policy.

Sample management procedures* in a QC plan must outline how personnel ensure:

- Receipt of samples are confirmed (i.e., with date and time)
- Proper identification of samples is maintained.
- Chain of custody is monitored by documenting names, dates, and times during sample handling.
- Rejection criteria (i.e., leaking containers or unlabeled samples) and response procedures for rejected samples are established.
- Samples are properly labelled, adequate in quantity, in good condition, and appropriate for testing to prevent samples from experiencing loss, deleterious change, or cross-contamination. The appropriate personnel must be delegated custodial responsibilities to maintain such criteria.
- Samples that require special handling have separate procedures in place (as needed).
- Samples are stored in appropriate conditions given the nature of the samples.
    - (Storage instructions may include retention time, conditions for storage, etc.)
- Samples are disposed of in accordance with the Sample Retention Requirement section of the Retention of Bioavailability and Bioequivalence Testing Policy.
- Samples are archived for a period of at least two years after the study is completed, terminated, or discontinued.

* Only relevant sample management procedures appropriate to a laboratory's scientific operations must be included in the QC plan.

QSE J: Process Management

This section is derived from section 3.5 of the *Guidelines for Establishing a Laboratory Quality Management System*.

"Process management describes systematic control and organization of laboratory processes and procedures to ensure the quality of laboratory-based data and results. Implementation of quality processes and procedures in the laboratory environment reduces systematic errors, decreases testing/results variability, increases efficiency through standardization, and facilitates reproducibility and consistency of data and results. Laboratory processes and procedures performed on a routine basis (e.g., common lab procedures, preventive maintenance, calibration, laboratory operations (cleanliness, spill clean-up, etc.)) should follow a standardized format or SOP, as appropriate.

Laboratory process management is categorized into 1) management processes, 2) support processes, and 3) operational processes. Operational processes relevant to the laboratory environment include strategic planning and program review (e.g., review of research quality, mission relevance), protocol development, and publication clearance. Implementation of these processes may occur at different levels in the organization (for example, strategic planning and program review may occur at the Center level while protocol development might occur at the level of an individual scientist or operational laboratory unit).

Laboratories must have established work processes and procedures appropriate to meet laboratory quality requirements.

Scientific operations must be optimized by ensuring the following are applied as deemed applicable to the functions of the laboratory:

Laboratory Management Processes:

a. Laboratory activities should be planned and documented (e.g., laboratory activities are identified in an approved protocol, research plan, including any amendments) supported by adequate SOPs, defined good documentation practices (electronic/manual documentation where original entries are not obscured, and changes are justified and identified by date and the person making the change)

b. Procedures should be established for internal and external assessments as well as defining quality indicators for assessments (see Assessments)

c. Procedures should be established to evaluate customer satisfaction (e.g., customer surveys, customer feedback, interviews) (see Customer Satisfaction)

Laboratory Support Processes:

a. Inventory management (see Equipment, Purchasing and Inventory)

b. Laboratory information and data management (see Information Management)

Laboratory Operational Processes:

a. Strategic planning and program review

b. Protocol development

c. Publication clearance

d. SOPs"

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QSE K: Occurrence Management

Occurrence management establishes procedures to identify and investigate unintended consequences and errors from laboratory processes or procedures, to determine root cause, and to initiate corrective measures and improvement plans to eliminate recurrence, as appropriate.

As occurrences or quality issues are identified and reported by personnel with corrective actions taken, the output of the occurrence management process must have a continually-improving organization.

CFSAN laboratory management must oversee non-conformance management procedures. These procedures describe steps to investigate non-conformances. Once a non-conformance is identified, the laboratory management, along with the QMOOS, must provide guidance on conducting risk assessments to correct the non-conformances and identify and implement Corrective Action/Preventive Action (CAPA) procedures.

K.1 Corrective Actions

Corrective actions are steps to address the root causes of an existing nonconformance or undesirable situation to prevent recurrence. Existing nonconformities or undesirable situations should be identified during an internal laboratory quality audit. This process must be outlined in a QC plan, and each instance must be documented.

	K.1.a Identify the root cause(s) of the nonconformance or undesired situation.
	K.1.b Develop a plan to eliminate or reduce the cause(s) to prevent recurrence.
	K.1.c Implement the plan.
	K.1.d Monitor the process to assess the effectiveness of the action(s) taken and revise the plan if necessary.
	K.1.e Re-check the solution.

K.2 Preventive Actions

Preventive actions are steps taken to remove conditions that could potentially lead to the occurrence of a nonconformance or undesirable situations. The preventive action process is designed to keep risk as low as possible by avoiding nonconformance that impedes quality.

Action must be taken to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions must be appropriate for the effects of the potential non-conformance or undesirable situation.

	K.2.a Review laboratory data and information and adherence to established laboratory SOPs to determine where potential nonconformities exist.
	K.2.b Determine the root cause(s) of potential nonconformities.
	K.2.c Evaluate the need for preventive action to inhibit the event of nonconformities and implement recommended preventive action.

Preventive Actions	K.2.d Record the results of preventive action taken.
	K.2.e Review the effectiveness of the preventive action taken.

QSE L: Assessment and Continual Improvement

A high quality of work must be maintained within CFSAN laboratories through assessments and continual improvement practices. Assessments help identify areas of improvement, allowing personnel to develop solutions for deficiencies that may affect the data integrity of their work. Continual improvement practices are often more frequent than assessments. Personnel employ continual improvement practices to maintain the quality of scientific operations on a routine basis.

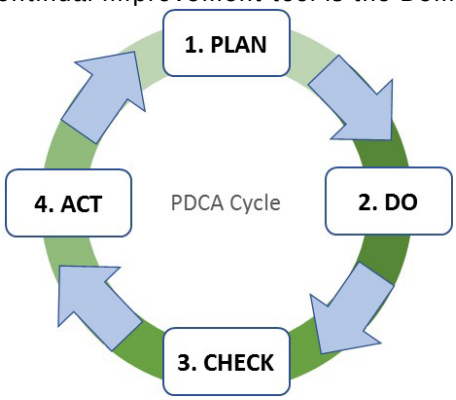
L.1 Assessment

The CFSAN internal laboratory quality audit program assesses efficiency of laboratory operations and data integrity of scientific results to ensure that work products are credible, accurate, reliable, and reproducible. The audit process documents the audit findings in a report. Audit reports do not indicate pass or fail, but whether there is a high degree of consistency/conformance or need for improvement. A high degree of conformance can be accomplished by taking appropriate corrective actions to address nonconformances. The Project Lead is responsible for documenting any non-conformity, outlier, or malfunction. Corrective actions must be implemented and verified as complete.

Non-conformances must be tracked via the CAPA process. Findings must be discussed with the Chief/Supervisor of the organizational unit being audited, prior to the drafting of the official report. A written report must be provided to the Associate Director or Division Director and Branch Chief responsible for the audited areas. The report findings must also be presented to Senior Management during the management review process. Follow up by reviewing CAPAs during the next on-site or directed audit to assess for effectiveness.

L.2 Continual Improvement

Employing continual improvement practices in the laboratory such as training or recertifications for current staff strengthens the quality of scientific operations. Continual improvement helps constantly maintain updated practices and knowledge in evolving research settings. An example of a continual improvement tool is the Deming Plan, Do, Check, Act (PDCA) Cycle.



Based on the WHO Content Sheet 15-1 Continual Improvement Concept, The PDCA Cycle components include:

Plan: Identify areas of improvement and the potential sources. Establish processes to make these identifications. Develop an improvement plan.

Do: Implement the improvement plan.

Check: Monitor the effectiveness of the improvement practices through review and audit processes. Revise improvement plan if necessary.

Act: Take any corrective actions needed and check to ensure the solution was effective. Continue the improvement cycle by beginning the next planning process.

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