SMG 2130.11

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

LABORATORY SCIENCE, LABORATORY SECURITY, ENVIRONMENTAL, AND OCCUPATIONAL SAFETY AND HEALTH PROGRAMS

LABORATORY QUALITY MANAGEMENT SYSTEM

Effective Date: April 19, 2019

1. PURPOSE

The purpose of this Staff Manual Guide (SMG) is to set forth the Food and Drug Administration's (FDA) scope, policy, definitions, and assignment of responsibility as they pertain to the establishment, implementation, and management of the Laboratory Quality Management System (LQMS) programs.

2. SCOPE

This SMG applies to all FDA laboratories, all laboratory activities (e.g., basic and applied research, test and evaluation, method development and validation), and to all organizational levels and laboratory management decisions impacting these activities.

3. POLICY

All FDA laboratories will be governed by an LQMS that is managed and coordinated within the Center/ORA.

The LQMS will conform to either:

1. The *FDA Guidelines for Establishing a Laboratory Quality Management System*, as appropriate,

   or

2. Good Laboratory Practices (GLP) or a consensus standard, such as, but not limited to ISO 9001, 13485, 17025, and 17043.

4. BACKGROUND AND DEFINITIONS

A. International Organization for Standardization (ISO) 9001

As described by ISO, "ISO 9001:2015 sets out the criteria for a quality management system and is the only standard in the family that can be certified to (although this is not a requirement)." This standard provides "guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved."[1]

B. International Organization for Standardization (ISO) 17025

As described by ISO, "ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods." It is "for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories."[2]

C. International Organization for Standardization (ISO) 17043

As described by ISO, "ISO/IEC 17043:2010 specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application."[3]

D. International Organization for Standardization (ISO) 13485

As described by ISO, "ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements."[4]

E. FDA Guidelines for Establishing a Laboratory Quality Management System

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[1] See https://www.iso.org/iso-9001-quality-management.html
[2] See https://www.iso.org/standard/39883.html
[3] See https://www.iso.org/standard/29366.html
[4] See https://www.iso.org/standard/59752.html

The *FDA Guidelines for Establishing a Laboratory Quality Management System* are developed collaboratively and communicates the essential elements of an LQMS. The *FDA Guidelines for Establishing a Laboratory Quality Management System* describes a structure and the high-level processes to be implemented in all laboratories that do not have a GLP or an ISO process.

F. Laboratory Quality Management System (LQMS)

For the purposes of this SMG, a laboratory quality management system is defined as the coordinated activities to direct and control an organization to achieve a systematic approach to improve accuracy, reliability, reproducibility, of laboratory data and timeliness of reporting.

G. Supervisor

For the purposes of this SMG, a supervisor is an individual employed by an agency having authority in the interest of the agency to hire, supervise, assign, promote, reward, transfer, furlough, layoff, recall, suspend, discipline, remove personnel, to address their grievances, or to effectively recommend such action. The supervisor is the individual who provides performance rating for personnel.

H. Laboratory Quality Management Manual

For the purposes of this SMG, a laboratory quality management manual is a document that outlines an organization's quality management system and conforms to the *FDA Guidelines for Establishing a Laboratory Quality Management System*.

I. Good Laboratory Practices (GLP)

For the purposes of this SMG, good laboratory practices (GLP) is a set of quality system of management principles intended to assure the quality and integrity of non-clinical laboratory studies.

5. RESPONSIBILITIES

A. Director of the Office of Laboratory Science and Safety

The Director of the Office of Laboratory Science and Safety (OLSS) is responsible for:

- Issuing Agency-wide directives related to LQMS;
- Leading and coordinating the effort to develop the *FDA Guidelines for Establishing a Laboratory Quality Management System*;

- Assisting Center and ORA efforts to implement and manage their LQMS programs;

- Assessing the effectiveness of LQMS implementation for program improvement, upon the request from Centers/ORA; and

- Facilitating the FDA OLSS LQMS Working Group to serve as the coordinating body to maintain the overall FDA LQMS program.

B. Center Directors and the Associate Commissioner for Regulatory Affairs (ACRA)

The Center Directors and ACRA, or designee, are responsible for:

- Implementing and sustaining Agency-wide and Center/ORA specific LQMS programs;

- Communicating laboratory quality policies to their employees;

- Reporting LQMS implementation progress, issues or concerns to the Director of the OLSS;

- Ensuring LQMS compliance;

- Approving the Center/ORA specific Laboratory Quality Management Manual for implementation and any subsequent revisions or amendments; and

- Ensuring corrective actions are effectively implemented to resolve and prevent non-compliance with Center/ORA specific Laboratory Quality Management Manuals.

C. Center/ORA Laboratory Quality Management (QM)/Quality Assurance (QA) Representatives/Staff

Center/ORA laboratory QM/QA representatives/staff are responsible for:

- Developing, implementing, and managing a Center/ORA specific Laboratory Quality Management program, including the Center/ORA specific Laboratory Quality Management Manual, in accordance with the *FDA Guidelines for Establishing a Laboratory Quality Management System*;

- Maintaining and reporting on the status of the program to the Center/ORA leadership;

- Proposing, collecting, and sharing quality metrics;

- Conducting internal assessment of LQMS activities and functions; for compliance with the approved Center/ORA specific Laboratory Quality Management Manual;

- Reporting of LQMS activities and functions to their respective Center Directors or ACRA, and the Director of the OLSS; and

- Representing their Center/ORA on the FDA OLSS LQMS Working Group.

D. Laboratory Principal Investigators (PIs)/Supervisors

Laboratory PIs/Supervisors are responsible for:

- Providing input in the development of an effective Center/ORA specific Laboratory Quality Management Manual;

- Supporting and maintaining the Center/ORA LQMS;

- Complying with the Agency-wide (OLSS) and Center/ORA LQMS policies and guidelines; and

- Taking corrective actions to resolve and prevent non-compliance with Center/ORA specific Laboratory Quality Management Manuals.

6. EFFECTIVE DATE

The effective date of this Staff Manual Guide is April 19, 2019. The Centers/ORA will fully implement their LQMS by April 19, 2022.

7. Document History – SMG 2130.11, "Laboratory Quality Management System"

STATUS	APPROVAL DATE	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/19/2019	N/a	OCS/OLS	RADM Denise Hinton, FDA Chief Scientist, OC/OCS

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