Designation: D8398 – 22

Standard Practice for Management Responsibilities in Managing a Quality Management System (QMS)[1]

This standard is issued under the fixed designation D8398; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice provides the management responsibilities for the implementation and oversight of a quality management system (QMS). It can be applied to all cannabis operations, including cultivation, manufacturing, labeling, dispensing, and distribution. This practice does not address the quality management system details, but rather focuses on the main considerations for management's role in setting up a QMS. Guide D8222 provides an overview and some details about the components of a QMS. Other standards provide details on specific QMS components.

1.2 The term GxP as used in this practice is meant to include those good practices in the activities included in 1.1; namely cultivation, manufacturing, distribution, and all the relevant functions associated with these activities (for example, purchasing, testing, storing, and so forth).

1.3 Although this practice mentions the importance of health and safety, it is done so in the context of overall management responsibility. This practice does not address details of a health and safety system, but it identifies the importance of this as a management responsibility.

1.4 This practice encompasses a single component of the QMS (management responsibilities) that, when combined with the other elements, satisfies the requirements of a complete QMS.

1.5 The practices described in this standard are intended to apply to all products of a cannabis plant including those that can be classified as hemp and which contain cannabinoids and can be consumed/ingested via mouth, nose, skin (whether described as medicine, supplements, food, cosmetics, and so forth.).

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D8222 Guide for Establishing a Quality Management System (QMS) for Consumer Use of Cannabis/Hemp Products

D8270 Terminology Relating to Cannabis

D8346 Guide for Requirements for Quality Related Professions Within the Cannabis and Hemp Industries

2.2 *Other Standards:*

ISO 9001 Quality Management Systems – Requirements[3]

FDA Guidance for Industry – Quality Systems Approach to Pharmaceutical cGMP Regulations[4]

3. Terminology

3.1 *Definitions*—Refer to Terminology D8270.

4. Significance and Use

4.1 This practice is for any cannabis operation to use as a fundamental part of a robust quality management system (QMS).

4.2 Regulators can use this practice to develop regulations that require the implementation of QMS principles, specifically management's role and responsibilities. Further, regulators can

[1] This practice is under the jurisdiction of ASTM Committee D37 on Cannabis and is the direct responsibility of Subcommittee D37.02 on Quality Management Systems.

Current edition approved June 1, 2022. Published July 2022. DOI: 10.1520/D8398-22.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

[4] Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, http://www.fda.gov.

use this practice to help build a checklist to evaluate management's engagement and compliance with QMS based regulations.

4.3 Auditors would use this practice to assess the level of management engagement with an operations QMS.

4.4 Any cannabis operation that has implemented or seeks to implement a QMS would use this practice.

5. Management Capability and Responsibilities

5.1 Management shall assign and define a manager or management team responsible for performing the operations according to documented policies and procedures and all applicable laws and regulations.

5.2 Managers shall possess the qualifications (training, experience, and credentials) required to effectively execute the quality, safety, procedural, workforce, and compliance requirements assigned to them. These qualifications shall be listed in written job descriptions. See Guide D8346.

5.3 Management shall:

5.3.1 Provide all necessary resources to support the QMS.

5.3.2 Provide evidence that all managers have completed management training and instruction in the organization's standard operating procedures (SOPs) and record-keeping related to good practices (GxP) including worker/staff management, safety, sanitation, regulatory compliance and maintenance, and other defined topics critical to the organization's efficient and safe operation.

5.3.3 Ensure that roles and responsibilities are clearly documented and assigned.

5.3.4 Implement and maintain robust programs as defined in this practice to ensure operational viability, continuity, and environmental sustainability; appropriate guidance for a robust program can be found in reference documents including ISO 9001 and FDA Guidance on GMP.

5.3.5 Engage all stakeholders to contribute to safe, quality products and services.

5.3.6 Establish a work environment that places a priority on proactive quality planning and management of processes, rather than managing within a reactive environment.

5.3.7 Monitor and measure performance of the QMS.

5.3.8 Ensure operational strategies align with key policies including product quality, safety, customer relations, process management, workplace health and safety, information security, physical security, business continuity, environmental sustainability, and regulatory compliance.

6. Product Quality

6.1 Management shall ensure all products manufactured, processed, or sold by the operation meet all product quality specifications and requirements.

6.2 Management shall:

6.2.1 Design, develop, and implement a product quality program that ensures all facilities, equipment, processes, and people operate to produce products that meet defined specifications. These specifications shall be sufficient to define all characteristics in compliance with regulatory requirements that will ensure safe and effective use by the consumer.

6.2.2 Conduct and document an audit of the product quality program and record updates to the program and corrective action taken. This internal audit is an assessment that shall be conducted at least annually and more frequently as needed to ensure system effectiveness.

6.2.3 Designate managers responsible for product quality programs that have the skills, time allotment, and defined job descriptions to perform the requirements of the positions.

6.2.4 Create a process of routine review of the QMS for the purpose of continual improvement.

7. Health and Safety

7.1 Management shall develop and maintain a safe and healthy work environment for all workers, contractors, and visitors.

7.2 The health and safety program shall be documented and include annual training and periodic assessment for all workers.

7.3 For occupational health and safety standards, see Volume 11.03 of the *Annual Book of ASTM Standards*.[2]

8. Security

8.1 Management shall rigorously protect the people, products, information, systems, and assets associated with operational activity from risks and threats.

8.2 Management shall stay current with evolving security risks, conduct periodic risk assessments, and make appropriate improvements to the security program.

8.3 Management shall ensure all workers receive ongoing security training and follow security procedures.

9. Personnel

9.1 Management shall ensure that work processes are documented using SOPs. Detailed instructions shall be provided when necessary to ensure consistency in performance of important tasks.

9.2 Managers shall ensure workers receive appropriate training and refresher training to perform assigned responsibilities.

9.3 Workers shall have full access to current procedures, instructions, and training materials.

9.4 Managers shall ensure that worker performance is monitored and measured.

10. Regulatory Compliance

10.1 Management shall ensure the operation remains compliant with all applicable federal, state/provincial, county, and local regulations related to cannabis operations.

10.2 The organization shall provide appropriate training and retain training records for review.

10.3 The organization shall regularly monitor regulatory changes, make appropriate revisions to procedures, and update worker training.