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Standard Guide for Establishing a Quality Management System (QMS) for Consumer Use of Cannabis/Hemp Products[1]

This standard is issued under the fixed designation D8222; 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 guide focuses on the core elements of an effective quality management system (QMS) necessary to optimize consumer and product safety, product quality, and conformance with requirements from industry, governmental agencies, and other authorities having jurisdiction. This guide incorporates basic quality principles, guidelines, and industry best practices necessary to establish a QMS adaptable to all organizations.

1.2 Laws and regulations from authorities having jurisdiction supersede recommendations within this guide.

1.3 *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.*

1.4 *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]

D8220 Guide for Conducting Recall/Removal Procedures for Products in the Cannabis Industry

D8229 Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry

D8244 Guide for Analytical Laboratory Operations Supporting the Cannabis/Hemp Industry

D8250 Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products

D8282 Practice for Laboratory Test Method Validation and Method Development

D8286 Guide for Processing Cannabis Product Complaints

2.2 *ASQ Document:*[3]

Failure Mode and Effects Analysis (FMEA) Brief Summary

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *controlled document, n*—a document with an alphanumeric assignment that is integrated into a QMS and subject to revision and revision tracking.

3.1.2 *equipment, n*—non-expendable, tangible moveable property needed for the performance of a task or useful in effecting an obligation.

3.1.3 *instrumentation, n*—equipment capable of performing measurements used to generate analytical data (for example, GC-MS, IR, NMR, balances, etc.).

3.1.4 *qualified individual, n*—an individual who meets applicable skill, experience, education, or other requirements of an employment position that they hold or seek, and who can perform the essential functions of the job with or without reasonable accommodation.

3.1.5 *planned deviation, n*—pre-approved deviations from the current operational document or system, covering a specified period or number of batches.

3.1.5.1 *Discussion*—Planned deviations must be approved before execution. Planned deviations should be handled through approved change control procedures.

3.1.6 *recall, n*—a product recall is the process of retrieving defective or potentially unsafe goods from consumers and providing those consumers with compensation.

3.1.7 *removal, n*—a product is removed from the supply chain, but not for health and safety reasons.

3.1.8 *unplanned deviation, n*—a state of nonconformance from the designed systems or procedures at any stage of manufacturing, packaging, testing, holding, or storage of the product.

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[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 American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

3.2 *Abbreviated Terms:*

3.2.1 *BMR, n*—batch manufacturing record

3.2.2 *CAPA, n*—corrective actions/preventive actions

3.2.3 *CPP, n*—critical process parameters

3.2.4 *CQA, n*—critical quality attributes

3.2.5 *FMEA, n*—Failure Mode and Effects Analysis; a process for characterizing and mitigating risks by assigning risk priority numbers

3.2.6 *IQ/OQ/PQ, n*—installation, operational, and performance qualifications

3.2.7 *IPC, n*—in-process controls

3.2.8 *MBR, n*—master batch records

3.2.9 *QA, n*—quality assurance

3.2.10 *QC, n*—quality control

3.2.11 *QMS, n*—quality management system

3.2.12 *SOPs, n*—standard operating procedures

4. Summary of Guide

4.1 This guide encompasses both adult-use and medicinal cannabis/hemp activities associated with processing, packaging, labeling, quality control, and distribution.

4.2 This guide does not cover QMS elements as they relate to laboratory operations (Practice D8282 and Guide D8244).

4.3 The QMS framework includes the core QMS elements as exhibited in Table 1.

5. Significance and Use

5.1 Effective decision-making in a quality systems-controlled environment comes from an informed understanding of quality issues and associated risks. As such, management should monitor and review the performance of the QMS at pre-planned and regular intervals to ensure the system's effectiveness and identify opportunities for improvement of the QMS itself. Management should also provide oversight of the QMS by an independent quality practitioner(s) to assure its effectiveness.

5.2 Moreover, risk-based decision-making encompasses all elements of the QMS and should be at the forefront of each decision. Consumer safety is the top priority, regardless of other considerations.

5.3 Aspects of risk should be considered relative to intended (or unintended) uses of a product to ensure consumer safety. Management should assign priorities and adequate resources to activities or actions based on assessing the risk, including the probability of harm and the potential severity of that harm. It is essential to engage appropriate parties in evaluating the risk. Such parties may include:

5.3.1 Consumers;

5.3.2 Manufacturing personnel;

5.3.3 Marketing personnel; and

5.3.4 Other stakeholders, as needed.

5.4 Implementation of risk management includes assessing the risks, implementing risk management controls commensurate with the level of risk, and evaluating the risk management efforts' results. Risk management assessment is an iterative process and continues when additional information emerges that changes the potential risk's nature.

5.5 Risk management works in conjunction with process understanding to manage and control change and helps drive continuous improvement.

6. Quality Manual

6.1 The quality manual is a document that summarizes the implemented components of the QMS. It provides a general summary of the key elements comprising the content of the QMS.

6.2 The quality manual presents an overview of the functional QMS elements defining the QMS practices within the organization. The quality manual should give short descriptions of all content for the categories found in Table 1.

7. QMS Elements

7.1 *Document Control:*

7.1.1 Controlled documents should be written and reviewed by qualified and authorized personnel whose training and expertise have been documented within the organization's training program.

7.1.2 There should be a standard operating procedure (SOP) defining all document control policies and procedures.

7.1.3 Controlled documents include dynamic documents such as policies, procedures, specifications, work instructions, and other updated and approved documents when corrections or improvements are implemented and static documents that

TABLE 1 QMS Sections and Elements

Section	Element	Section	Element	Section	Element
6	Quality Manual	7.6	Complaints	7.12	Master Batch Records
7.1	Document Control	7.7	Recall/Removal	7.13	Internal Auditing
7.2	Change Management	7.8	Supplier Qualification	7.14	Qualification and Validation
7.3	Deviations	7.9	Facilities/Equipment	7.15	Continuous Improvement
7.4	Corrective and Preventive Actions (CAPA)	7.10	Personnel Qualifications and Training		
7.5	Risk Management	7.11	Records		

are permanent records of what has occurred in the past. Prior versions of dynamic documents become permanent records when new versions are approved.

7.1.4 Controlled documents include all documents and records that support the manufacturing operation and the QMS operation. These documents and records include but are not limited to the following:

7.1.4.1 Policies;

7.1.4.2 SOPs and work instructions;

7.1.4.3 Qualified individual criteria;

7.1.4.4 Internal training curriculum;

7.1.4.5 Master batch and batch manufacturing records;

7.1.4.6 Training records;

7.1.4.7 Maintenance records;

7.1.4.8 Process, equipment, supplies, product, and other verification and validation data;

7.1.4.9 Facility, process equipment, material, product, and other specifications;

7.1.4.10 Operation, owners, and user manuals;

7.1.4.11 Schematics;

7.1.4.12 Calibration records and test data;

7.1.4.13 Corrective and preventive action records;

7.1.4.14 Deviation records;

7.1.4.15 Complaint and recall records;

7.1.4.16 Change management records;

7.1.4.17 Internal and external audit records; and

7.1.4.18 Supplier qualification records.

7.1.5 Documents may exist as hard copies, electronic, or both.

7.1.6 All changes made to procedures should be justified, recorded, and only implemented after validation and approval.

7.1.7 Current and authorized procedures and work instructions should be readily available to the staff responsible for executing their protocol at all times.

7.1.8 All obsolete procedures, work instructions, specifications, and other such documents should be identified, located, and secured in a manner that prevents accidental usage for the current operations.

7.1.9 Quality assurance staff or other authorized personnel should periodically review all documents and, when necessary, revise them to ensure continuing suitability and compliance with applicable requirements.

7.1.10 Documents should be uniquely identified and include the following:

7.1.10.1 Document identification (unique alpha-numeric designation);

7.1.10.2 Document title;

7.1.10.3 Date of effectiveness;

7.1.10.4 Current revision date and chronological revision history;

7.1.10.5 Page numbering, and

7.1.10.6 Identification of issuing/approval authorities.

7.1.11 All documents should be reviewed and approved for use by authorized personnel before implementation.

7.1.12 Current revision status and distribution of documents should be established and readily available to preclude the use of invalid or obsolete documents.

7.2 *Change Management:*

7.2.1 Change management should include a process for tracking changes and their outcomes.

7.2.2 There should be an SOP that defines all change control procedures.

7.2.3 Change management applies to any change within the QMS relative to procedures, instrumentation, equipment, raw material, process, or product specifications.

7.2.4 Changes that occur within the following should be subjected to change management protocol:

7.2.4.1 Facilities,

7.2.4.2 Equipment,

7.2.4.3 Instrumentation,

7.2.4.4 Software systems,

7.2.4.5 Key management/corporate structure/ownership,

7.2.4.6 Corporate policy,

7.2.4.7 Customer requirements,

7.2.4.8 Product specifications,

7.2.4.9 The material used in the production or testing of the product,

7.2.4.10 Processes that may affect product, and

7.2.4.11 Modifications to SOPs from revision or corrective action/preventive action initiatives.

7.2.5 The change management program should affect all changes related to procedures and be fully documented and verified such that all appropriate elements have been registered and all procedures and policies involved are updated to reflect the changes. These changes should include:

7.2.5.1 Updating all relevant SOPs for procedural changes and listing the progressive chronology of these changes,

7.2.5.2 Modifying all documents supporting existing specifications affected by the change event, and

7.2.5.3 Supporting modified documentation resulting from corrective and preventive actions (CAPA) efforts resulting in protocol change.

7.3 *Deviations:*

7.3.1 The purpose of the deviation protocol is to ensure that deviations are documented and thoroughly investigated to determine their impact on quality. This investigation includes root cause analysis to avoid recurrence.

7.3.2 There should be an SOP for handling all deviations.

7.3.3 Deviation management and record-keeping may be included in SOPs and work instructions.

7.3.4 Circumstances may require deviation from approved instructions to occur, resulting in a planned deviation. These are known in advance, allowing for appropriate planning and consideration before their occurrence.

7.3.5 When a deviation occurs unexpectedly, it is considered as an unplanned deviation (nonconforming work) requiring a work stoppage and initiation of corrective action procedures.

7.3.6 Deviations from established instructions are subject to investigation and quality assurance (QA) approval.

7.3.7 Deviation approval/closure is based on the adequacy of impact/risk analysis and any proposed corrective or preventive actions.

7.3.8 The information and data from the investigations resulting from the deviation should be included in the batch

manufacturing record (BMR) of any affected product batch regardless of the final disposition.

7.3.9 Each deviation should be assigned a unique number and archived as part of document control protocol.

7.4 *Corrective and Preventive Actions (CAPA):*

7.4.1 The purpose of the CAPA procedures are to ensure that existing non-conformities are corrected, and their recurrence is prevented. For information on this topic, see Guide D8229.

7.4.2 CAPA protocols capture and track the completion of improvements identified in deviation and complaint investigations, audits, and annual product reviews.

7.4.3 In response to CAPA, changes in procedures, processes, or specifications are implemented and documented through the change management program.

7.4.4 The CAPA protocol information is monitored, reviewed, approved, and tracked by qualified personnel.

7.5 *Risk Management:*

7.5.1 The purpose of the risk management system is to provide a means to identify, evaluate, measure, and document risks, including their likelihood to occur, probability, and potential impact on systems, processes, or materials within production and storage facilities, or the products produced.

7.5.2 There should be an SOP for risk management assessment procedures.

7.5.3 The evaluation and mitigation of risks apply to all quality systems and operations throughout manufacturing operations.

7.5.4 The level of effort, formality, and documentation of the quality risk management process is commensurate with the level of risk.

7.5.5 Risk analysis can be measured using Hazard Analysis Critical Control Point (HACCP, see Practice D8250, Failure Mode and Effects Analysis (FMEA), or other risk assessment tools where process risks are considered, measured, and recommended actions implemented as part of a CAPA protocol.

7.6 *Complaints:*

7.6.1 All complaints and reasons for returned goods should be evaluated. For information on this topic, see Guide D8286.

7.6.2 There should be an SOP for handling consumer complaints. The SOP should include a protocol for receiving, logging, verifying, tracking, and documenting.

7.6.3 The complaint should be reviewed and investigated by QA personnel to determine whether to research a product complaint. The findings and follow-up action of any investigation must extend to all relevant batches and records.

7.6.4 The record of the product complaint must include the following (if applicable should include):

7.6.4.1 The name and description of the product;

7.6.4.2 The batch number of the product, if available;

7.6.4.3 The date and contact information of the complainant;

7.6.4.4 The nature of the complaint;

7.6.4.5 The reply to the complainant, if any; and

7.6.4.6 The results of the complaint investigation and any follow-up actions implemented as a result.

7.6.5 Any associated deviation and CAPA numbers should be logged with the specific complaint report and archived.

7.7 *Product Recall/Removal:*

7.7.1 Each manufacturer should establish and maintain procedures for identifying product during all material receipt, production, inventory, and distribution stages.

7.7.2 There should be an SOP for the organization's protocols for handling recalls and product removals. For more information on this subject, see Guide D8220.

7.7.3 Throughout the life cycle of a cannabis/hemp product, a label containing a unique identifier for the material should be applied and maintained to ensure the cannabis/hemp product's traceability.

7.7.4 A recall/removal system should be established to document, investigate properly, and follow-up on any potential problems related to products that have been affected by a mandate for market recall or removal of the product within the organization's distribution network.

7.7.5 Recalls/removals are customer-facing functions that should be administered by the QA group in conjunction with the sales department, inventory control, and organizational management.

7.7.6 Product recalls/removal procedures should be in place to allow their efficient execution when required.

7.7.7 A recall/removal team should be formed, and a recall coordinator, generally a representative from QA, be appointed as the recall/removal team leader.

7.7.8 Mock recalls should be practiced at a specified frequency, including traceability to customers and balancing recall/withdrawn quantities with existing inventory.

7.7.9 The mock recall's effectiveness should be evaluated by authorized personnel, and a CAPA issued for non-conformances.

7.7.10 Recall/removals require a swift and efficient removal of a product from the marketplace, particularly if the recall is due to product safety concerns. Traceability to all consumers and isolating the lots to be recalled is required. The sales department will notify customers affected and determine the number of units recalled or withdrawn by reconciling existing inventory.

7.7.11 Authorized personnel will notify customers affected and determine the number of units recalled or withdrawn by reconciling existing inventory.

7.7.12 Product recalls for reasons involving the compromising of consumer (human or animal) health and safety should involve jurisdictional regulatory entities and their requirements.

7.8 *Supplier Qualification/Approval:*

7.8.1 Supplier quality assessments and subsequent approvals are attained by auditing the supplier and determining the efficacy of their QMS's ability to consistently meet required specifications for raw materials, components, active pharmaceutical ingredients, equipment and instrumentation, contract services, and process equipment.

7.8.2 There should be an SOP defining minimum required steps to conduct and maintain records relative to supplier qualification and approval activities.