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Standard Guide for Corrective Action and Preventive Action (CAPA) for the Cannabis Industry¹

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1. Scope

1.1 This guide applies to all entities that cultivate, process, manufacture, test, and distribute cannabis products.

1.2 This guide defines corrective action and preventive action (CAPA) and the significance of an effective CAPA process and CAPA subsystem.

1.3 This guide defines instruction on the establishment of adequate processes and procedures for the identification, analysis, measurement, and correction of quality issues.

1.4 *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.*

1.5 *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. Terminology

2.1 Definitions:

2.1.1 *aberrant results, n*—aberrant results

2.1.2 *active failure, n*—errors made by frontline workers such as manufacturing technicians, machine operators, drivers, and so forth.

2.1.3 *adverse trend, n*—trend of deficiencies (issues) that may negatively impact quality if not corrected.

2.1.4 *change management system, n*—formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner.

2.1.5 *closed-loop system, n*—system that an operation, process, or mechanism is regulated by feedback.

2.1.6 *consumer, n*—person or organization that receives a product or service anywhere within a product's life cycle.

2.1.7 *consumer product, n*—any tangible product for sale that is used for personal, family, household, or non-business purposes.

2.1.8 *correction, n*—immediate action to eliminate a detected nonconformity.

2.1.8.1 *Discussion*—Corrections are typically one-time fixes. Corrections are also known as remedial or containment actions.

2.1.9 *corrective action, n*—action to eliminate the causes of a detected nonconformity or other undesirable situation.

2.1.9.1 *Discussion*—Corrective action is taken to prevent recurrence of the issue.

2.1.10 *corrective action and preventive action, CAPA, n*—systematic approach that includes actions needed to correct, avoid occurrence, and eliminate the cause of potential nonconforming product and other quality problems.

2.1.11 *corrective action and preventive action (CAPA) plan, n*—encompasses the identification of corrective or preventive actions or both, the verification and validation of corrective or preventive actions or both, and the evaluation of the plan's effectiveness.

2.1.12 *data analysis, n*—analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems.

2.1.12.1 *Discussion*—Appropriate statistical methodology should be used when necessary to detect recurring quality problems.

2.1.13 *data sources, n*—processes within a quality management system (QMS) that provide quality information that could be used to identify nonconformities or potential nonconformities.

2.1.14 *deviation, n*—departure from an approved instruction, procedure, specification, or standard.

2.1.15 *harm, n*—physical injury or damage to the health of people or damage to property or the environment.

2.1.16 *hazard, n*—potential source of harm.

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