

SOP Title	SOP No.	Version No.	Effective date
Managing Deviations and CAPAs	QA.SOP-004	00	YYYY/MM/DD

## MANAGING DEVIATIONS AND CAPAs

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### 1. Purpose

- 1.1. This procedure describes the process of identifying, evaluating, resolving, and documenting incidents that could negatively impact the quality or safety of a cannabis product, or cause a regulatory non-conformance.

### 2. Scope

- 2.1. This procedure applies to planned and unplanned deviations from established procedures (SOPs) or regulatory standards.

### 3. Responsibilities

- 3.1. **All Personnel:** To report a deviation or non-conformance to the Quality Assurance Person or Production Manager as soon as it is detected.
- 3.2. **Quality Assurance Person(QAP)/Production Manager:** To assess the impact of an incident on the quality and safety of a cannabis product and ensure that suitable action is taken to mitigate actual and potential risks.

### 4. Acronyms and Definitions

- 4.1. **Accessibility (of a product):** The availability of the product to the consumer.
- 4.2. **Corrective measures:** Action aimed at directly correcting a problematic situation.
- 4.3. **Corrective and Preventive Action (CAPA):** Set of measures aimed at analyzing and correcting a quality problem to prevent it from recurring.
- 4.4. **Detectability (of a risk):** The ability to identify or detect a risk when it occurs.
- 4.5. **Incident:** An event that may have a significant impact on a process or product.
- 4.6. **Likelihood (of a risk):** The possibility of a potential risk occurring.
- 4.7. **Planned deviation:** A temporary change to an existing procedure that is made intentionally to re-evaluate a process.
- 4.8. **Root cause:** A fundamental reason for the occurrence of a deviation or problem.
- 4.9. **Severity (of a risk):** The extent of damage to people, a product or a process as a result of an event.

**SOP TO BE CONTINUED...**