

	Standard Operating Procedure	SOP Number QS-108	Revision 4
	Corrective and Preventative Action (CAPA)	Effective Date 11/29/21	Page Page 1 of 7
Written by/ Date <i>SS 11/29/21</i>	Reviewed by/ Date <i>H. Bunn 11/04/21</i>	Approved by/ Date <i>J. A. Miller 11/24/21</i>	
Title: QC Laboratory Director	Title: Quality Systems Manager	Title: QA Manager	

## 1.0 Purpose

This procedure provides a method for implementing and tracking corrective and/or preventive action to take to eliminate causes of non-conformities or other undesirable situations.

## 2.0 Scope

This procedure applies to CAPA in response to exception data (see Section 6.1.1) and non-exception data (see Section 6.1.2). This procedure applies to all Ion Labs' products, processes or systems associated with cGMP requirements or ISO 17025 laboratory requirements.

## 3.0 Responsibilities

3.1 It is the responsibility of individuals assigned to complete a CAPA to:

- 3.1.1 Review and understand the source of the CAPA (i.e. the event or situation that created the need for the CAPA)
- 3.1.2 Review and understand the root cause analysis leading to the CAPA
- 3.1.3 Execute the CAPA plan
- 3.1.4 Initiate Effectiveness Checks as applicable
- 3.1.5 Initiate closure of the CAPA when the CAPA plan is completed

3.2 It is the responsibility of Quality Management to:

- 3.2.1 Approve and Reject CAPA plans and CAPA forms
- 3.2.2 Implement, execute, and maintain this procedure.

3.3 It is the responsibility of Document Control (DC) to:

- 3.3.1 Process CAPA forms.
- 3.3.2 Monitor open CAPA and report open and late CAPAs.

## 4.0 References

- 4.1 QS-108-F1, Form, Corrective Action Preventative Action (CAPA) Assignment
- 4.2 QS-108-F2, Form, Corrective Action Preventative Action (CAPA) Closure
- 4.3 QS-112, SOP, Core Quality Systems and Quality Events
- 4.4 QS-112-F1, Form, Quality Event Extension Request
- 4.5 QS-112-F2, Form, Quality Event Cancellation Request
- 4.6 QS-112-F3, Form, Quality Event Amendment Request
- 4.7 C-201, SOP, Deviation and Investigation Procedure
- 4.8 D-105, SOP, Out of Specification / Out of Trend Investigation
- 4.9 C-403, SOP, Change Control Procedure
- 4.10 H-101, SOP, Internal Audits
- 4.11 QS-101, SOP, Complaints
- 4.12 QS-107, SOP, Recall Procedure
- 4.13 QS-111, SOP, Root Cause Analysis
- 4.14 QS-114, SOP, Quality Risk Management
- 4.15 QS-113, SOP, Effectiveness Checks

## 5.0 Definitions

- 5.1 **CAPA** – Corrective and Preventive Action (also known as Corrective Action / Preventative Action) consists of improvements to processes take to eliminate causes of non-conformities or other undesirable situations.
- 5.2 **Corrective Action (CA)** - Action taken to permanently correct and prevent recurrence of nonconforming product and other quality system problems.
- 5.3 **Preventative Action (PA)** - Action taken to eliminate the cause of potential nonconformities to prevent occurrence before they happen. These types of actions anticipate potential problems and eliminate the most likely causes of the problem so they are less likely to occur in all areas of operation.

- 5.4 **DC** – Document Control
- 5.5 **CQS** – Core Quality System(s) is a system (i.e. Standard Operating Procedure (SOP) or combination of SOPs) that handle and manage a quality event and that are within the scope of SOP QS=112 Core Quality Systems and Events. NOTE: There are Quality Systems outside the scope of QS-112 that handle Quality Events; however, they do not meet this definition of CQS.
- 5.6 **Quality Event** – An event that triggers the use of a CQS and that is subject to cGMP regulations.
- 5.7 **cGMP** – Current Good Manufacturing Practices as defined by regulations associated with the manufacture, testing, holding, etc. of a food, dietary supplement, drug product, or device manufactured by Ion Labs.
- 5.8 **OOS** – Out of Specification –a result for a test performed does not meet established acceptance criteria.
- 5.9 **OOT** – Out of Trend – a result for a test performed that meets established acceptance criteria, but is not statistically consistent with historical trends.
- 5.10 **AR** – Aberrant Result – a result for a test performed that meets established acceptance criteria, but is considered atypical, abnormal, anomalous, deviant, irregular, questionable, or unexpected.
- 1.1 **Adverse Event** – Any health-related event associated with the use of a cosmetic, dietary supplement, or OTC that is adverse.
- 1.2 **Serious Adverse Event** – Results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly/birth defect, or one that requires medical or surgical intervention to prevent such serious outcomes.

## **6.0 Procedure**

### **6.1 CAPA Sources**

6.1.1 Initiate CAPA in response to exception data (i.e. Quality Events that negatively affect the quality of components, materials, products, procedures or systems). These CAPA sources include, but are not limited to:

6.1.1.1 Complaints – SOP QS-101

6.1.1.2 Deviations – SOP C-201

6.1.1.3 OOS – SOP D-105

6.1.1.4 Audits (including technical and laboratory system audits) or FDA Inspections

6.1.1.5 Product rejections / non-conformities

6.1.1.6 Recalls

6.1.2 Initiate CAPA in response to non-exception data such as:

6.1.2.1 Data trending and holistic data reviews

6.1.2.2 Continuous improvement projects

6.1.2.3 Industry and regulatory surveillance

6.2 CAPA Process

6.2.1 Root Cause Analysis

6.2.1.1 Effective root cause analysis is critical before an effective CAPA is determined. SOP QS-111, Root Cause Analysis, provides instruction for conducting Root Cause analysis.

6.2.1.2 Root Cause analysis may identify multiple causes in addition to finalizing on a root cause. Generate separate CAPA to address multiple causes as applicable.

6.2.2 Risk Management / Risk Assessment

6.2.2.1 Use risk management tools as applicable to prioritize possible causes, and potential CAPA. SOP QS-114 provides instruction and tools for conducting Risk Management activities.

6.2.3 CAPA Plan

6.2.3.1 A CAPA plan identifies actions that eliminate and/or minimize risk associated with identified causes of a non-conformity or other undesirable event.

6.2.3.2 Assign effort, resources, and timelines proportional to identified risk levels.

#### 6.2.4 Effectiveness Check

6.2.4.1 Assign an Effectiveness Check to CAPA as applicable, even if a CAPA number is not required. SOP QS-113, Effectiveness Checks, provides instruction for conducting Effectiveness Checks.

### 6.3 CAPA Documentation

6.3.1 Laboratory CAPAs must follow section 6.3.4. The CAPA must be documented and assigned a the unique CAPA number.

#### 6.3.2 CAPA Immediately Executed

6.3.2.1 For CAPA executed immediately and/or closed before closure of the source event, the CAPA does not require a CAPA number.

6.3.2.2 Assign a CAPA number only if it is helpful to have the CAPA number for reference and documentation purposes (see Section 6.4 for assignment details).

#### 6.3.3 CAPA Pending Execution

6.3.3.1 For CAPA that are not complete before closure of the source event, a CAPA number must be assigned (see Section 6.4 for assignment details)

6.3.3.2 Detail the CAPA plan on form QS-108-F1 and assign the CAPA to an individual / department for completion

#### 6.3.4 CAPA To Be Determined

6.3.4.1 For CAPA that are not complete before closure of the source event and / or if the CAPA plan is not determined, a CAPA number must be assigned (see Section 6.4 for assignment details)

6.3.4.2 Assign the CAPA to an individual / department for completion using form QS-108-F1.

6.3.4.3 Instead of a CAPA plan, indicate the need to complete root cause analysis and to identify a CAPA plan in the CAPA plan section of the form. For Laboratory CAPA's the plan section of the form will include the evaluation for the need for action to ensure that nonconformities do not recur, and where warranted determines a corrective action that will eliminate the root cause(s), thereby ensuring

that the problem does not recur or occur elsewhere. Appropriate error-proofing methods (including those preventing human error) are applied, as applicable.

6.4 CAPA Assignment / Closure

6.4.1 Initiate / Assign a CAPA by submitting form QS-108-F1 to DC.

6.4.2 Close a CAPA by submitting form QS-108-F2 to DC.

6.5 Additional Requirements from QS-112

6.5.1 This procedure is considered a Core Quality System (CQS) that is also controlled by the CQS and Quality Events SOP (QS-112).

6.5.2 The term “event” is a generic reference to any of the CQS covered by SOP QS-112. The term “event” is used interchangeably with specific CQS events as applicable (i.e. “CAPA” here).

6.5.3 SOP QS-112 provides instructions common to all Ion Labs CQS including the following topics which are not be duplicated here:

- Assignment of unique event numbers (i.e. CAPA numbers)
- Logging of events with Document Control
- Assignment of event due dates
- Event due date extensions
- Event cancellation
- Event Revision / Amendment
- Monitoring of open events
- Record management and retention instructions

6.6 Laboratory CAPA Trend Reporting

6.6.1 The Quality Manager submits information regarding corrective action activities for management review. Such information may include a description of actions taken; the processes from which they originated, the status of such actions, and may include further review of their effectiveness. Where there are too many actions for individual review a summary will be presented.

6.6.2 Management Review will also be used to assess the overall process for timeliness of actions initiated and timeliness of actions taken for corrective actions in the Laboratory Management System.

## 7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/23/14	New.	14-0521	D. Popp
1	02/09/15	Revise to include 21 CFR 210 and 211.	15-0055	D. Popp
2	02/09/15	Added reference to quality system extension request form.	17-0916	S. Millar
3	01/14/20	Revise to reflect forms QS-108-F1 and QS-108-F2 and reference QS-112.	19-0603	K. Burris
4	11/04/21	Added requirements for ISO 17025:2017 for laboratory CAPAs.	CC-21-0412	J. Sassman



**Corrective And Preventative Action (CAPA) Assignment**

Form: QS-108-F1      CCR No. CC-21-0412      Revision: 2

**CAPA Number** *(assigned by Document Control after the rest of this form is completed)*

	Revision #	
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**CAPA – Title / Description**

CAPA Source / Reference (i.e. RPT #, DEV #, INV#, etc.)	

Event Dates

CAPA Open Date

CAPA Due Date

**CAPA– Owner (i.e. Assigned to)**

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**CAPA Plan / Comments**

<input type="checkbox"/> N/A	<input type="checkbox"/>	
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Title / Name	Signature	Date
<b>Completed By:</b>		
<b>Assignment Accepted By:</b> <input type="checkbox"/> N/A if same as completed by		
<b>Approved By (Quality):</b>		



**Corrective And Preventative Action (CAPA) Closure**

Form: QS-108-F2      CCR No. CC-21-0412      Revision: 2

**CAPA Number**

Revision #

**CAPA – Title / Description**

CAPA Source / Reference  
(i.e. RPT #, DEV #, INV#, etc.)

**DATE INFORMATION**

**Closed Date**

**CLOSURE SUMMARY**

Include as applicable: Evidence and/or statement of closure, cross references to supporting documentation, general conclusions / outcome, etc.

Title / Name	Signature	Date
<b>Completed By:</b>		
<b>Approved By (Quality):</b>		