1.0 Purpose

The purpose of this procedure is to define the process for initiating, assessing, approving, executing, and closing change requests.

2.0 Scope

This procedure applies to all change requests involving revised SOPs, Forms, Test Methods, Raw Material and Packaging Component Specifications, Finished Product Profiles (Product and Packaging) and Test Tickets, Protocols, Reports, Master Batch Records, Label Masters, Equipment, Validated Software, and any other cGMP parameter/document that is under Document Control responsibility. This procedure does not apply to the creation of new documents.

3.0 Responsibility

3.1 It is the responsibility of all employees who become aware of the need for a change in the system to initiate a change request or to inform their supervisor of the need for a change request.

3.2 It is the responsibility of Quality to review and approve all change controls that have been proposed for implementation.

Note: There shall be a time limit of 48 hours for the approval of any change request by any person acting as a reviewer/approver.

3.3 It is the responsibility of DC to assign change control numbers and follow the change control throughout the review/approval process. DC is also responsible for closing the change control once approved and for following all other steps outlined in this

procedure.

4.0 Definitions

4.1 **DC** – Document Control

4.2 **QC** – Quality Control

4.3 **R&D** – Research and Development

5.0 References

5.1 C-501, SOP, Document Control Procedure

5.2 C-502, SOP, Record Storage, Retention, and Destruction

5.3 QS-112, SOP, Core Quality System and Quality Events

5.4 QS-112-F2, Form, Quality Event Cancellation Request

5.5 C-403-F1, Form, Change Control Request Form

6.0 Overview

6.1 Change Control is one of a number of Quality Systems governed by SOP QS-112 Core Quality Systems and Quality Events. SOP QS-112 manages the following aspects of all quality events:

- Assignment of unique event numbers
- Logging of events with DC
- Assignment of event due dates
- Event due date extensions
- Event cancellations

- Monitoring of open events

7.0 Permanent Change Requests

7.1 The change control initiator will complete **Section 1** of form C-403-F1 Change Control Request Form. If needed, a draft of the proposed document will be prepared and attached to the change control, along with any other supporting documentation related to the proposed change. At a minimum, the requested changes must be outlined in the change summary section of form C-403-F1.

7.2 The change control initiator will submit the electronic change control file to DC, and will also submit a hard copy of form C-403-F1 Change Control Request Form with all associated documents attached. DC will review and assess the change request packet for completeness and accuracy, ensuring that no other change request is in process that will affect the same document or change. If approved, DC will sign/date Change Request Approved By/Date section of form C-403-F1 Change Control Request Form.

7.3 Once the change control has been approved to proceed, DC will assign an event number and record it onto form C-403-F1 Change Control Request Form, as well as the Quality Events Log.

7.4 DC will prepare the change control packet by printing the current version of the document that a change has been requested for. The current version and proposed changes will be added to the change control packet.

7.5 DC will inform the initiator of any additional information or documentation required to complete the change control packet.

7.6 If product quality will be affected by the change, customer notification is required.

7.7 DC will submit the change control packet to the person who will be responsible for the change. Once the change has been made, the person who made the change will sign and date "Initial changes made by/Date", attach the revised document to the change control packet, and return the packet to DC.

7.7.1 Any electronic documents that have been changed will also be returned to DC via any suitable electronic data sharing method.

7.8 DC will assign appropriate reviewers/approvers (refer to Attachment 1 for guidance) in **Section 3** of Form C-403-F1 Change Control Request Form and submit the change request packet to the first reviewer.

7.9 Reviewers/Approvers will assess the change and, if necessary, indicate any additional requirements/documents that are affected by the change in **Section 2** of Form C-403-F1 Change Control Request Form. DC is also authorized to complete Section 2 as needed.

7.10 After review and approval of the change request packet, the reviewer/approver will initial and date **Section 3** of Form C-403-F1 Change Control Request Form, and will provide any necessary signatures as required to the changed documents. The packet will be returned to DC upon completion.

7.10.1 The last approval for any change control request will be Quality Management.

7.10.2 DC will ensure that the change request has been reviewed and approved by all assigned departments and verifies that no comments have been entered by reviewers/approvers without rerouting for approval.

7.10.3 DC will ensure the implementation of the proposed change indicated in the change request by assigning the effective date on any required pages of the approved document (when applicable) and in **Section 4** of form C-403-F1 Change Control Request Form. The effective date will also be entered into the Quality Events Log. DC will distribute copies as required, following SOP C-501 Document Control Procedure.

Note: Any new or changed SOP or form will not be considered effective until all training has been conducted and documented by the appropriate designee. Authors and approvers of the change do not require training. Only laboratory methods are excluded from this requirement (D-700 / D-

1000 SOP number series). Training is not required for laboratory methods prior to implementation.

7.10.4 DC will ensure compliance of all additional requirements for closure that have been documented in **Section 2** of Form C-403-F1 Change Control Request Form and will complete **Section 5** of the form. DC will inform the initiator and any other concerned departments of the completed change, preferably by email.

7.10.5 When completed, the change control packet will be scanned and electronically filed here: F:\Doc Control Only\Forms and Logs\Change Control\Closed Change Controls.

7.10.6 Change requests can be cancelled at any time by the initiator, DC, or Quality. A reason for the cancellation must be documented on Form QS-112-F2 Quality Event Cancellation Request (refer to SOP QS-112 Core Quality Systems and Quality Events). If the change request is cancelled, DC will void the change control request number and will stamp VOID or write Cancelled on form C-403-F1.

7.10.6.1 The voided form will be scanned and filed electronically here: F:\Doc here: Control Only\Forms and Logs\Change Control\Closed Change Controls.

7.10.7 Quality may, at its sole discretion, make the following (but not limited to) types of corrections after the document has been approved or made effective, as long as these changes are not altering the significance of the document:

7.10.7.1 Correction of Typographical Errors

7.10.7.2 Correction of any cross referenced document numbers

7.10.7.3 Correction of page numbers called out within the text portion of the document

7.10.8 These changes must be initialed and dated on the original document. Editorial changes will be updated during the next official revision of the document.

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/05/10	New	-	-
1	04/04/12	Made SOP more detailed. Changed both attached forms.	-	-
2	11/19/12	Clarified and reorganized SOP. Revised form C-403-F1. Added change request reviewer/approver matrix.	-	-
3	10/16/13	Changed 72 hours to 24 hours in responsibility section. Replaced Director of Quality & Regulatory Affairs with Manager of Quality & Regulatory Affairs in Section 5.5.	-	-
4	11/06/13	Changed number format in Section 5.6.1.	13-1014	K. Burris
5	01/22/15	Added necessity for customer notification for changes that will affect product quality. Updated SOP format.	14-1018	D. Popp
6	02/11/16	Removed C-403-F2. Added electronic request log. Changed responsibilities.	16-0137	K. Burris
7	11/15/17	Added procedure for new temporary change request.	17-1461	K. Burris
8	03/02/20	Added reference to QS-112. Removed temporary change control process and form.	19-0606	K. Burris
9	12/20/22	Minor edits to format and wording throughout. Changed logo. Added note that lab test methods do not require training to be considered effective.	CC-22-0477	K. Burris

9.0 Attachments

9.1 Attachment 1 – Suggested Change Request Review/Approver Matrix

ATTACHMENT 1 – SUGGESTED CHANGE REQUEST REVIEWER/APPROVER MATRIX

Type of Change	Suggested Reviewers/Approvers
Master Batch Record	R&D, Production, Sales, Purchasing, Quality
Standard Test Method/Specifications	QC Laboratory, R&D, Quality
Labeling	R&D, Quality
SOP, Form, Protocol, Report	Affected Departments, Quality
Product Profile/Specification Sheets	QC Laboratory, R&D, QC, Quality

ION LABS	Change Control Request Form		
	Form: C-403-F1	CCR No. CC-22-0477	Revision: 8

CCR No _____ Rev _____ Due Date _____

SECTION 1 – Change Proposal (Initiator)				
Type of Change[1]	**Description**	**Document No.**	**Revision No.**	**Initiated By/Date**
Change Summary				
Rationale				

[1] (i.e. Standard Operating Procedure, Forms, Standard Test Methods, Specifications, Product Profiles, Protocols, Reports, Master Batch Records, Materials, Packaging Components, Labeling, Equipment, Suppliers)

Change Request Approved By/Date: _____

1. Initial Changes made by/Date: _____
2. Additional Changes made by/Date: _____
3. Additional Changes made by/Date: _____

SECTION 2 – Change Control Review and Impact Assessment/Requirements for Closure (DC/Reviewer/Approver)				
No.	Activity	Responsible	Assigned By/Date	Complete
1.				☐
2.				☐
3.				☐

CCR No _____ Rev _____ Due Date _____

Customer Notification Required: ☐ Yes ☐ No Date of Notification: _____ (attach evidence)

SECTION 3 – Approvals [Reviewed/Approved (Y) Yes or (N) No-Initials/Date. If No, provide explanation

Department	Print Name	First Routing			Second Routing		
		Y / N	Initials	Date	Y / N	Initials	Date

SECTION 4 – Change Control Implementation (DC)

Document Effective Date		By		Date	

SECTION 5 – Change Control Closure (DC)

☐ All requirements included in the change control verified as complete and closed	By		Date	

Comments _____