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Changes from previous version:

Section	Summary of Changes	Change Control Number
ALL	1. New document	

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1. PURPOSE

This document describes the formal Change Control Procedure at Synoligo. This SOP is to define the control requirements and systems that shall be used to ensure that data quality, data integrity, and processes are not adversely affected by change. This standard process ensures that all planned changes are reviewed, assessed for impact, approved by management and Quality Assurance before implementing the change

2. SCOPE

The scope of this SOP includes but is not limited to the following – environment, machine, method, manpower, material, measurement. Preventive maintenance work, routine inspections/adjustments, or repairs involving the replacement of like-for-like or functionally equivalent parts and components to either maintain an equipment/system or return it to its previous operational status are out of scope.

3. INTERNAL REFERENCES

Document ID	Title
QA001	Quality Policy

4. EXTERNAL REFERENCES

Document ID	Title
ISO9001	Quality management

5. RESPONSIBILITIES

Job Function and/or Department	Responsibility
All Personnel	Ensures that all changes (see scope) are reported before implementation. Any member of staff can initiate a Change using Change Control Request Form.

6. DEFINITION

Term	Definition

7. PROCEDURE

7.1. Requestor identifies a proposed change and consults the Operational Management.

7.2. The Requestor initiates Change Control Request Form.

7.3. Type of Change

7.3.1. Indicate which system is affected of the proposed change

7.4. Change Description

7.4.1. Provide a detailed summary of the proposed change

7.4.2. Include the location, material, system, and/or equipment. Involved in the change.

7.5. Change Justification

7.5.1. Describe the background driving the reason for the change(s) (i.e., equipment failure, process improvement, etc.).

7.5.2. Itemize the proposed changes and include a justification for each.

7.5.3. State the criticality of the change or if a formal risk assessment is required.

7.6. Supporting Documentation

7.6.1. List and attach documents as applicable in support of the proposed changes or impacted by the

proposed changes, e.g., SOP, master batch records, validation reports, etc.).

7.7. Change Implementation Actions

7.7.1. Implementation actions must specify whether the actions are pre or post implementation, the specific actions, and responsible persons or department for each action.

7.8. The requestor requests a change control number from Quality Assurance.

7.9. The requestor and the affected department operational management signs and dates.

7.10. If the change impact client program or a notification is required as per quality agreement, the change need to be approved by the sponsor.

7.11. Quality Assurance determines the potential impact of the requested change.

7.12. Quality Assurance determines whether the change is approved or rejected.

7.13. Once a change request has received approval, requestor perform and document the completion of each pre-implementation action.

7.14. Submit the completed change implementation documentation to the reviewers, along with the summary of the completed actions on the change control request.

7.15. Quality Assurance verify that the implementation actions were performed as specified in change control request and/or there is appropriate justification for any change to the implementation plans.

7.16. The change control request remains open, pending final approval until all pre and post implementation requirements are completed and approved according to this procedure.

7.17. Document final approval of the change on the change control request form once all pre and post implementation actions have been completed satisfactorily.

7.18. Management of Changes and Documentation Storage

7.18.1. The completed / signed Change Control Request Form and supporting documentation related to the Change Control will be filed with Quality Assurance.