Standard Operating Procedure

Title: Quality Assurance Change Control Procedure

Department	Quality Management		Document no		QMS-180
Title: Quality Assurance Change Control Procedure					
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

1. Purpose

The purpose of this Standard Operating Procedure is to describe the process that must be followed when implementing a change that will impact the product or any process within the quality management system.

2. Scope and Application

This procedure applies to any change that may affect:

- Starting material
- Product component
- Process Equipment
- Process environment (or site)
- Method of production or testing
- Computer software
- Product data/integrity
- Any other change that may affect product quality or reproducibility of the process.

This procedure does not apply to:

- The manufacture of experimental batches for process development
- Unplanned deviations
- Batch Rework
- Documentation changes
- Printed Packaging

The Change control procedure will ensure that there is sufficient data to support the change and that the change will result in a product of the desired quality, consistent with the approved specifications. The impact on facilities, systems and equipment will be evaluated. The risk assessment will determine the need for validation or qualification of equipment.

3. Safety and Process Specific Information

All safety requirements for relevant areas at any GMP facility must be followed at all times.

4. Environmental Health and Safety

The impact on Environmental Health and Safety must be considered when implementing any change control.

5. Reference Documents

1. Quality Risk Management Techniques (QMS-135)
2. Risk Assessment Register (Form 930)
3. Change Control Tracking Form (Form 920)
4. Change Review Form – Toll Customer (Form 925)

7. Impact Assessment - A comprehensive review of the impact of the change. Section two of the change control form guides the impact assessment. The risk assessment should complement the impact assessments.

8. Major change – a change that potentially affects a product:
   - Purity, Identity, Safety or Efficacy during any validated manufacturing process step.
   - Change in a facility that supports the manufacturing process of registered product.
   - Change in manufacturing equipment or process-validated state.
   - Variation of formulation.
   - Change in conditions of registration as notified by regulatory body or contractor.
   - Change in approved shelf life.
   - Change in validated testing method or contractor.
   - New Product Introduction – completed at the contractor or at a GMP facility.
   - Changes in label conditions.

9. Minor change – any change that does not fit the major definition.

Section 2 – Change Control Package Review

8.8 A formal meeting will be chaired by the Quality Assurance Associate for the change control panel to discuss the change and agree on implementation tasks (including those identified in the risk assessment).

8.9 At the meeting, all change control panel members will sign and date the change control panel review page (if all agree) of the change control.

8.10 For each implementation task, the relevant department designee will nominate the staff member responsible for completing the task and the date by which it will be completed.

8.11 No changes are to be made to the agreed implementation plan unless approved by the QA Manager (or delegate.)

8.12 If any member of the change control panel does not approve the change, a meeting with the QA Manager (or delegate) and the Change Champion is held to resolve the issues.

Section 3 – Implementation

8.13 Upon approval of the change Control Package. The QA Associate will:

- Enter Implementation tasks into the database (including dates and persons responsible).
- Notify all staff of their delegated tasks.
- Update the Change Control folder with signed documentation.

Section 4 – Review and Closure

8.14 The change champion will supply evidence of closure of all implementation tasks (agreed to in section 3 by the change panel) to the Quality Assurance Associate.

Evidence of completion of the proposal may include updated SOP, training records of relevant staff in updated SOP, photographs, test results to support change, stability data (real-time / accelerated or both), validation data, inventory printouts, etc.

8.15 The Quality Assurance Associate reviews the closure evidence.

8.16 If extra information is required, the Quality Assurance Associate will liaise with the Change Champion to ensure all evidence of closure is provided.

8.17 The Quality Assurance Associate will review the complete package and approve the closure.

8.18 Upon approval, the Quality Assurance Associate will:

- Record the first batch where the change occurred (if applicable)
- Update change control database.
- PDF all documentation supporting the change (change package, worksheets, approvals, change summary) into the change control folder.
- Notify the change control panel and change champion.

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APPENDIX 1: Suggested participants of the Change Control Panel

Change Type / Approval	Engineering Manager	Formulation Manager	IT Manager	Logistics Manager	Process & Development	Production Manager	QA Disposition	QA Manager	QC Manager	Regulatory	Validation Manager	Safety Representative
Raw Material (specification, source, storage, testing)				Y	Y	Y	Y		Y	Y	Opt	Opt
Testing (test method, expiry, specification, reagents)		Y (2)			Y (1)	Y			Y	Y		
Manufacturing Process (sterilisation, filtration, batch sizes, cleaning)	Y	Y (2)			Y (1)	Y	Y			Y	Y	Y
Equipment (alterations, replacement, construction, control units)	Y					Y				Y	Y	Y
Methods (3) (changes)			OPT (4)	Y (4)	Y (4)	Y (4)	Y (4)	Y (4)	Y (4)	Y	Opt	
IT (Hardware, Software, LAN, automated systems, Plant software)			Y (5)			Opt	Y (5)				Y	

Appendix II. (1) Biological or immunological reagent change approval
(2) Pharmaceutical change approval
(3) Major Facility or equipment modifications approval
(4) Approval of SOP in area of expertise
(5) Relative to impact on department

NB: The above is a guide only. The Quality Manager can decide that an individual is not required to approve a change proposal based on content and can also add additional persons to the approval list as required.

In the absence of the nominated approver, authorized delegates can approve on their behalf as long as relevant expertise has been attained in that area.

3. Risk Assessment – as per company Risk Assessment Procedure (refer to PQA-SOP-167 document series)

Outcome of Change Control Risk Assessment	Major / Minor	Champion (initial/date)	DD / MMM / YYYY
Attach risk assessment to change control		Champion (initial/date)	DD / MMM / YYYY
Comments	If any list below		

Section 2 – Change Control Package Review

All Changes			Departments Required as Defined by Change Implications					
Department		Sign	Department		Sign	Department		Sign
Quality	☐		Commercial	☐		Finance	☐	
			Formulation	☐		Information Technology	☐	
			Logistics	☐		Maintenance	☐	
			Process Development	☐		Production	☐	
			Purchasing	☐		Quality Control	☐	
			Regulatory	☐		Safety	☐	
			Validation	☐		Warehouse	☐	

Section 4 – Review and Closure

1. Information Provided for change closure

List the first batch where change will occur		
Quality Assurance Associate reviews package and all evidence provided as per plan	YES / NO	**Sign & Date**
Comments	If more detail is required to close the change control progression, then state it in the comments field.	
Quality Assurance Associate closes change control in the database	YES / NO	**Sign & Date**
Quality Assurance Associate distributes closure notice to the Site review team	YES / NO	**Sign & Date**
Change Control file marked as closed and archived appropriately	YES / NO	**Sign & Date**
Comments	Include the list below; otherwise, mark it as Not Applicable.	