Role	Responsibilities
Change Requestor	- Initiating the change by creating a Change Request; - Specifying the details of the change, including a description of the proposed change, a justification and an estimated completion date; - Obtaining agreement from the Department Manager of the area affected by the change; - Ensure adequate supporting data is provided to facilitate approval.
Department Managers	- Assessing any Change Request initiated for their area to ensure that it is value adding and that all supporting (System Owners) information has been provided; - Approving each change for implementation.
Change Request Coordinator	- Administering the Change Management procedure; - Monitoring the Change Request created; - Advising the Plant Technical Team when changes are ready for review; - Coordinating the Plant Technical Team Meetings; - Reviewing the deliverables for completed Change Request; - Closing the Change Request record;
Plant Technical Team	- Attending the periodic meetings; - Conducting the Impact Assessment for each Change Request; - Recommending the deliverables and activities required to support the implementation of each change; - Assigning a Project Leader and Project Team.
Quality Assurance/Compliance Manager	- Approving each change for implementation in the Pre-Approval stage of Change Request; - Approving completion of each change in the Post-Approval's stage of Change Request;
EH&S Coordinator	- Approving each change for implementation in Pre- Approval's stage of Change Request.
Project Leader	- Coordinating the project team activities to meet required deliverables as assessed in the impact assessment; - Extending the Estimated Completion Date of the Change Request when required using *Overdue Change Request Notification;* - Compiling the supporting documents to address deliverables required; - Notifying the Change Request Coordinator when all deliverables are complete and change can be closed.
Project Team Members	- Completing all activities required to successfully document and implement the approved change.

5.0 PROCEDURE

5.1 First discuss the proposal with the manager of the area affected by the change to determine if the change is feasible.

5.1.1 **Initiate a Change Request using appropriate Change Request Form**. (For example, **Form-365** Master Document Change Control Form)

5.1.1.1 Change Request Form

- **Title/Short Description** – Enter a short description of the Change Request. This description must be direct and relevant to the content of the record. A short change description is required. For example: "Reduction of calibration frequency for HPLC 453".

- **Responsible Person** – Identify the responsible person to coordinate the implementation of the Change Request.

Request. They should also identify any concerns or special considerations regarding the approval and implementation of the change. This assessment should also take into consideration any impact to regulatory commitments.

5.2.1.3 At the site technical review team meeting, the team should discuss any issues that arise during completing the Impact Assessment of the Change Request. The deliverables will be determined and recorded at this time.

5.2.1.4 The status of the change will be determined in the Pre-Approval stage with reference to the table below:

Status	Required Details
Approved	- Project Leader assigned to coordinate the activities - Project team members assigned to execute the activities - The recommended deliverables required supporting the change have been determined - Any special comments have been considered and documented in the pre-approval comments stage.
More Assessment Needed	- Any additional information required in order to assess the change and the initiator is responsible for needed collating that information - A date for the status of the change to be reassessed
Cancel	- Write the reason and any comment for the cancellation in the Pre-Cancel Approval stage

5.2.1.5 Once the status is determined in the Pre-Approval stage, a date and meeting number is will be recorded in Pre-Approval comments section by the Change Request Coordinator.

5.2.1.6 Approval to proceed is granted once EH&S and Quality Operations complete their approval under the Pre-Approval section.

5.2.1.7 A Change Request where More Assessment is needed should be returned to the initiator to provide. The Change Request Coordinator can do this on the Change Request record. Once the requested information has been collated, the form should be re-submitted for assessment. (Return to Section 5.1.3)

5.2.1.8 When a Change Request is cancelled the Change Request Coordinator must endorse the cancellation and archive the cancelled form appropriately.

5.3 Implementing a Change

5.3.1 The assigned Project Leader must call a project meeting with the team to fully scope the activities required to implement the change. The team should assign suitable actions and realistic time lines for all activities.

5.3.2 The Project Leader should then co-ordinate the activities that have been identified as required for the Change Request and ensures that the change is implemented prior to the Due Date.

5.3.3 Once a change is open past its Due Date it is considered to be overdue. If for any reason, an extension of the Due Date is required, this must be formally requested and approved by completing "*Overdue Change Request Notification".*

5.3.4 The relevant members of the assigned project team should complete each assigned activity, in line with the relevant guidelines and procedures in their departments.

Appendix 1 – Activities Included for Each Change Type

Change Type	*Included Activities*
Documentation	A **Documentation** change covers a change to any registered document including but not limited to: • Registered Specifications
Facility / Utility / Equipment	A **Facility / Utility / Equipment** change covers any modification to the equipment, or the environment of equipment operation (e.g. Relocation, modification, new equipment, new components or consumables) and facility changes in the manufacturing area or office area. The changes include, but are not limited to: • Manufacturing equipment (blenders, tanks, mills, sieves, compressing machines, encapsulators, etc.) • Packaging equipment (vision systems, cappers, labellers, shrink tunnels, pharmacode readers, etc.) • Equipment PLC's • Tooling (compressing and packaging) • Water system • Test equipment (Analytical instruments, calibration instruments) • Environment (HVAC, pest control, etc.) • Construction • Demolition
IT Systems	An **IT Systems** change covers any change to a GMP computer system, including: • Hardware • Software • Data integrity • Operation • Storage / back-up • Traceability
Manufacturing Process	A **Manufacturing Process** change covers any change to a Blend, Tablet, Capsule or Liquid production or packaging process including, but not limited to: • Manufacturing process instructions (processing times, order of addition, critical parameters) • Packaging process instructions (set up, critical parameters) • Cleaning processes (time, temp, agent, method) • Introduction of new products • Deletion of products • Transfers of products into, or out of, the facility. • Lot traceability • Storage requirements

