

Standard Operating Procedure

Title: Change management system

- **Due Date** - Identify a realistic due date for the Change Request.
- **System Owner** – Identify the owner of the business area.
- **Department(s) Affected** – Enter the relevant department(s) of impact.
- **Area(s) Affected** – Enter the relevant area(s) of impact.
- **Urgency** - Enter either Emergency/Critical, Expedited/Urgent or Standard/Routine to determine the priority. A critical change will potentially affect quality, regulatory and/or safety. An urgent change will improve cost, customer service and/or marketing ability. A routine change will improve productivity and efficiency.

Note: Emergency/Critical approvals will only be granted in exceptional circumstances and should not be considered a normal part of the change management.

- **GMP Change** – Enter Yes or No, depending on the impact on GMP.
- **Change Type** – Enter either Major or Minor. A minor change is a routine change of no product significance. These changes do not require re-validation. A major change may impact purity, safety and efficacy of a product. It may involve a change to a critical utility (e.g. HVAC, plant surveillance system, sterile compressed air, etc) or process that requires re-validation. Major changes usually require regulatory approval before implementation.
- **Impact Assessment Required** – Enter Yes or No. Write the rationale for the choice.
- **Change Classification** – Write either permanent / temporary changes to be made.
- **Description of Change, Reason for Change and Recommended Actions** – a detailed description of what the change is, why the change is required and how the change will be completed.
- **Attachment(s)** - Attach any relevant supporting files/documentation, risk assessments, feasibility studies, material specifications, registration documents etc., if applicable.
- **More Information**– Specific details of the change to be completed for items affected; Product, Documentation, IT systems, Process, Material, Packaging/Labelling/Artwork and Facilities/Utilities/Equipment. Status of the items can be updated throughout the life of the change.

5.1.2 Initiator to sign and date when all fields have been completed.

5.1.3 The Change Request Coordinator and the EHS approver must pre-approve the Change Request.

5.1.4 The Change Request Coordinator should prepare an agenda and site technical review team which new changes have been submitted for review and route the changes for impact assessment.

5.2 Assessing / Approving a Change Request

5.2.1 Routine and Standard Changes

5.2.1.1 Each member of the site technical review team should review the agenda and complete the Impact Assessment for each of the new changes.

5.2.1.2 Each member should consider the GMP and EH&S impact of the change and the deliverables required by their department, in line with the guidelines in the Impact Assessment section of the Change