To change the manufacturer of an excipient, validation requirements to demonstrate the change will have no adverse impact on finished drug products or process will be assessed based on risk and documented.

**Raw Material Review Team Members:**

- Coordinate all evaluation activities within their relevant department to assist with the evaluation process.
- Communicate within own department of meeting outcomes, priorities, strategies and status of the change/s.

**Manufacturing Compliance:**

- Maintain regulatory and in-house requirements for the proposed material to be used in drug product manufactured in the site.

**Quality Assurance:**

- Ensure no drug products manufactured using proposed material are released for sale until all relevant evaluation and validation requirements are met.

**Third Party Contract Manufacturing QA Group:**

- Obtain relevant supporting documents from affiliate users using the proposed materials.
- Ensure the Manufacturer/Supplier of the proposed material meets the Supplier Audit Rating of Acceptable Supplier as per **QMS-045** *Vendor Selection and Evaluation Procedure*.
- Ensure the use of the proposed material have no adverse impact on drug products (semifinished or finished goods) manufactured by Third Party Contract Manufacture.

**Quality Control Laboratory:**

- Review and approve Raw Material Specification and Test Report (RMSTR) of current and proposed material.
- Perform relevant evaluation testing of proposed material and review test results against the RMSTR.
- Ensure the proposed material meets the RMSTR requirements prior to the release of the proposed material for manufacturing of drug products.
- Assign 'Completed' status for evaluation material upon complete successful full testing to RMSTR.

**Validation / Technical Services:**

**Co-ordinator:**

- Convene the Raw Material Review Team meetings.
- Communicate project status to Raw Material Evaluation Team Members, Stakeholders and Sponsor for each raw material evaluation.

**Validation Engineer / Project Chemist:**

- Perform validation requirement assessment for each raw material evaluation.
- Manage qualification / validation studies based on the outcome of the qualification validation requirement assessment for each raw material evaluation.

 

5.3.2.2 Review of the RMSTR for the current material shall be conducted to ensure the current material is compliant to the applicable current monograph. Any differences identified should be documented and addressed prior to proceeding to **Step 5.3.2.3**.

5.3.2.3 Review of C of A for the proposed material shall be conducted to ensure it is compliant with the applicable current monograph and existing Raw Material Specification Test Report. Any differences identified should be documented and addressed prior to proceeding to **Step 5.3.2.4**.

5.3.2.4 Create the RMSTR for the proposed material and ensure it is compliant with applicable current monograph and existing RMSTR.

5.3.2.5 Assess PCP / PCR submissions requirement and complete the relevant section in the RME document (Form **725**).

5.3.2.6 Stability requirements shall be verified against market requirement and recorded.

5.3.3 **Quality Assurance**

Ensure no drug products manufactured using proposed material are released for sale until all relevant evaluation and qualification / validation requirements are met.

5.3.4 **Third Party Contract Manufacturing Quality Assurance Group**

5.3.4.1 Obtain all relevant supporting documents from affiliate users using the proposed materials.

5.3.4.2 Verify the manufacturer and/or supplier of the proposed material has been audited for manufacturing and/or supplying the proposed material. Record audit detail in the relevant section in the RME document (Form **725**).

5.3.4.3 Verify the proposed material is used by Third Party Contract Manufacturer and Verify the proposed material is used in Semi-finished goods at SITE, Site followed by further processing by Third Party Contract Manufacturer. Record the outcome in the RME document (Form **725**).

5.3.4.4 Communicate qualification/validation and stability requirements with the Third Party Contract Manufacturer, Procurement and Supply Planner.

5.3.4.5 Ensure qualification/validation studies have been completed by the Third Party Contract Manufacturer.

5.3.4.6 At the completion of all validation studies by the Third Party Contract Manufacture, Third Party Contract Manufacturing Quality Assurance Group informs all relevant departments that the validation has been completed.

5.3.4.7 If this material is currently used or evaluated by other sister site manufacturing facility then only one site must perform an evaluation.

 

5.3.7.3 Technical Services Project Chemist raises Technical Service Alert Form (TSAF) for all batches under validation evaluation. Validation of the proposed material should be performed as per SOP **VAL-115** *Process Validation for Liquids and Solid Dose Manufacturing*.

5.4 **Evaluation Document Closure**

5.4.1 Any recommendations for completing the evaluation (including PCR submissions, validations) may be entered into database and the commitment numbers clearly stated in the RME document (Form **725**) in the Recommendations section.

5.4.2 The RME document (Form **725**) is circulated to the Procurement Manager, Validation / Technical Services Manager, Quality Assurance Manager, Quality Control Manager for approval of the evaluation outcome.

5.4.3 Completion of the RME document (Form **725**) indicates one of the following:

5.4.3.1 The evaluation is complete with no additional recommendations. The proposed material is suitable for use at SITE, Site for the drug products listed in Section 1 of the RME document (Form **725**). Or,

5.4.3.2 The proposed material is suitable for use in additional evaluation activities detailed under Section 8 of the RME document (Form **725**); e.g. validation.

5.4.4 The Change Control cannot be closed until all recommendations listed in Section 8 of the RME document (Form **725**) are completed.

5.5 **Implementation**

5.5.1 Supply Planner orders a commercial quantity of the proposed material for validation (if required) and/or manufacturing. Supply Planner shall make a note in the material database defining the Purchase Order (PO) as an evaluation material then alert the Receiving Dock / Warehouse.

5.5.2 Upon receipt of the delivery, the Receiving Dock / Warehouse shall check the PO notes and receipt the material against its RMSTR. The delivery shall be sub-lotted with an “Evaluation” and coloured “Evaluation” labels shall be applied to the Goods Received Report and each container of the delivery.

5.5.3 Upon successful testing by the Quality Control Laboratory, a ‘Complete’ status is assigned in the material database to the delivery.

5.5.4 Supply Planner shall perform lot management allocations to the assigned batches.

5.5.5 Schedule validation batches and issue Manufacturing Instructions (MI) and/or Packaging Instruction (PI) as per process validation requirement for the change.

5.5.6 Distribute TSAF to relevant departments to inform validation activities with relevant departments.

5.5.7 Submit Stability Request Form with MI / PI when requested by Quality Control Laboratory.

 