## Procedure

## 1. General

- The APR will determine the need for revalidation of processes or methods, changes in product specifications, manufacturing and control procedures as well as evaluation of the need for regulatory notification supplements to regulatory submissions.

- For the analysis, in process control results as well as the finished product laboratory results from all lots manufactured or tested during the review period should be considered unless the total number of lots is equal to or exceeds fifty. If this is the case the data for evaluation should be a representative sampling of the lots produced. Selection of lots should be based on a predetermined frequency (e.g. first four lots manufactured each month) in order to eliminate effect of seasonal changes on product characteristics and allow the inclusion of released as well as rejected lots.

- If less than three batches of a product are manufactured in the review period, the APR will be delayed until at least 3 lots are available for the review or until the next review period where two years of data will be reviewed.

- The first and last batch in the review period will be determined by the final disposition date of each batch. The QA department will determine the lots included and list sent to all departments.

- The management will present recommendations for preventative and corrective actions related to any trends observed at quality team meeting for discussion and approval.

- The QA staff will maintain an update calendar, which establishes the yearly schedule for all product belonging to the site.

- All data provided must be inclusive of a source document reference and the issue/effective date in order to assure traceability of the incorporated information.

- All partial batch rejection must be reported in the APR as well as total batch rejections.

- A schedule for the complaint of APR data and completion of APR reports should be compiled and reports reviewed in a timely manner. Any overdue reports should be notified to the quality meeting.

## 2. Responsibilities

The following responsibilities apply to the preparation, coordination and review of the APR's

- The QA department is responsible for overall coordination and administration of the APR's, ensuring that the reports are issued in a timely manner after collection of the data, tracking of any action items arising from the review and for review of the data supplied prior to finalizing each APR. The QA department is responsible for the compilation and collation of the APR document by ensuring that all departments supply the required data and time lines for the receipt of data are met.

 

- The QA department should track completion of the recommendations.
- The APR final report will be filed in the QA office. The APR final report should be retained for a minimum of seven years.

## 4. Procedure Steps

| Section | Data source | Applicable statistical analysis/ Quality tools | Report format |
|---|---|---|---|
| **General information (introduction)**<br>• Review period<br>• Product name<br>• Packaging configuration<br>• Description<br>• Approved manufacturing, Packaging, release and stability testing sites<br>• Manufacturers of actives | • Batch documentation<br>• Packaging records<br>• Master file documents<br>• APR calendar<br>• Regulatory submission<br>• Registration documents<br>• Certified product details | None | Tabulate and/or summarize |
| **Batch Size**<br>• Product batch size<br>• Specification numbers for intermediate, bulk and finished products<br>• Packaging components<br>• Changes in components<br>• BPN numbers that were reviewed in the APR<br>• Total or partial lot rejection numbers | • Master file documents<br>• Bill of materials | None | Tabulate and/or summarize |
| **Approved product Changes**<br>• Change requests associated with the master file documents | • Approved change | None | Tabulate and/or |

 

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|---|---|---|---|
| | for critical equipment during the review period form the Technical Service and engineering department. | | summarize |
| **Regulatory compliance**<br>• Review any commitment pending from the previous period<br>• Evaluate corrective actions for closure | • Review available information regarding regulatory filing changes, inspection observations, Product certifications as applicable. | None | Tabulate and/or summarize |
| **Evaluation/recommendation and/or comments**<br>• Evaluate all information obtained during the APR preparation<br>• Present if product quality characteristics shows a particular trends<br>• Comment on activities, accomplishments, enhancement conducted during the review period, if any<br>• Determine the need for changes, if any based on the report evaluation<br>• If changes are recommended as a result of this evaluation they should be minimally agreed by the site management team. | • Previous APR<br>• Documents reviewed<br>• Management evaluation | N/A | Tabulate and/or summarize |

## 5. Summary of Changes

| Version # | Revision History |
|---|---|
| QMS-060 | New |

 