

# Standard Operating Procedure

## Title: Annual Product Review

- The QA manger or the delegate will provide a summery report of Deviation Reports. In addition the QA department will provide any reworks/ reprocessed / returned drug products and salvaged materials for the review period, number of lots produced, rejected or uncompleted (including partial lot rejection) and the list of lot numbers reviewed in the APR.
- The laboratory manager or delegate will provide the raw materials control information, all finished product release and stability test results, Deviation report summaries and retention sample review results. The laboratory manger will also provide information on all relevant method validation activities.
- The technical service manager or delegate will provide a summery of the manufacturing /packaging validation activities and an evaluation of critical equipment changes during the review period. These evaluations must assess the impact of changes on the product. Technical service will also be responsible for summarizing change control information and investigations not captured in the discussion of Deviation reports.
- The engineering manager or delegate will provide summery data on equipment evaluation carried out by engineering department. This data must be accompanied by an assessment of the impact on the product.
- The operations manager or delegate will provide information on all recalls executed and product complaints received during the review period for the product under evaluation together with a summery of correspondence conducted with regulatory bodies.
- The Operations manager or delegate will provide a list of lots assigned for manufacture during the review period, lot yielded data, in-process results and product reconciliation information
- The regulatory manager will provide a summery of regulatory changes or requirements for the review period that affected the product.

### 3. APR report evaluation and final Report retention- Responsibilities

- The QA staff will circulate the APR draft report to the appropriate department manager or designee for review and comments as follows
  - QA
  - Regulatory
  - Manufacturing
  - Technical Service
  - Laboratory
  - Other support department as applicable
- Comments and/or recommendations must be addressed to the QA staff on or before the next scheduled quality meeting. The recommendations will be assessed in the meeting and included in the APR if necessary.
- A summery of the APR report should be presented to the management team for review and approval. The summery should be attached to the final report for filing.
- The QA department should track completion of the recommendations.