

Annual Product Records Review

- Adverse trends in the data are identified and investigated;
- Findings and conclusions in the Annual Product Records Review are summarized;
- Review date schedule is adhered to;
- Action items identified throughout the year as well as outstanding issues from the previous year are reviewed;
- Recommendations for preventive or corrective actions that would lead to product quality improvements are provided; and
- Action plan which includes responsibilities and a target completion date for each recommended action is completed.

The Site Quality Team should sign the Annual Product Records Review as the preparer.

5.

Each Production and Quality Department Head should be responsible for:

- Providing Annual Product Records Review Supporting Data generated in their departments to the Site Quality Team for inclusion in the Annual Product Records Review;
- Ensuring that the data is trended, if applicable; and
- Ensuring that any departmental-level conclusions based upon the data are accurate.

6.

The Site Quality Head should:

- Review the Annual Product Records Review;
- Make or endorse recommendations, if necessary, for preventive or corrective actions that would lead to product quality improvements; and
- Identify or endorse an action plan, if necessary, which includes responsibilities and target completion dates for each recommended action.

7.

The Site Quality Head and the Production Team should review and approve the Summary of the Annual Product Records Review and forward the approved Summary to the Site Quality Team for distribution and follow-up.

Where required by local regulations, the Qualified Person should also review the Summary of the Annual Product Records Review to ensure that the reviews are performed and the data are accurate.

8.

The Site Quality Team should:

- Forward a copy of the approved Annual Product Records Review to the Site Quality Head and Key Site Principals;
- Track progress on any recommendations; and
- Provide periodic notification of status of recommendations to the Site Quality Head