

## **Summary - Annual Product Records Review**

Data from Production Batches/Lots of all APIs and Marketed Drug Products, including Quarantined-HOLD and Rejected batches/lots, should be summarized on, at least, an annual basis. The criteria used to identify the first and last batch in the review period should be defined in Site procedures [e.g., Manufacture Date, Quality Control (QC) testing date, final disposition].

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.

**[Read More](#)**