Annual Product Quality Review

Product quality review is an annual evaluation of a pharmaceutical preparation, which looks back at production and quality control data to assess changes, trends and weaknesses.
In other words it is a structured procedure in which all information, changes and dependencies that have arisen during a calendar year with regard to the manufacture and control of a preparation are detected, evaluated and documented and in which suggestions for improvements are recommended.

Importance of PQR in Pharmaceuticals

1. PQR is a regulatory requirement
CFR 211.180 (e) basically specifies that the quality standard of every product must be evaluated at least once a year based on the current specifications and records to determine whether modifications to product specifications, manufacturing instructions or control procedures are required.
Chapter 1 (Pharmaceutical Quality System) of EU guidelines also recommends to evaluate the consistency of existing process annually through PQR.
2. PQR is an effective quality improvement tool to enhance the consistency of the existing process & overall quality of the product (PQR helps to highlight any trends and to identify product & process improvements).
3. PQR will provide a broader view of product data & it can serve as a historical document.
4. PQR will capture trends & will help to determine the need for revalidation and changes any.
5. PQR offers the opportunity to critically examine the functions of internal systems, such as change controls, documentation, storage, investigation of deviations, OOS procedures and the processing of complaints.
6. In short product review serves as "ongoing validation" and, on the other hand, the data and results obtained are important prerequisites for continuous improvement (CIP).

PQR Preparation Procedure

PQR preparation should typically be carried out for each product manufactured in the previous year.
All documents which directly or indirectly refer to the manufacture and control of a preparation in the period concerned must be investigated.
Data should be presented in tabular form or in graphical form (i.e., charts or graphs), when applicable.

What data must be given in the product quality review?

A review of starting and primary packing materials used in the FPP, especially those from new sources.

All analytical results obtained from the certificates of analysis must be recorded and evaluated. The results must be included as averages or individual values, depending on the test item.

A tabulated review and statistical analysis of quality control and in-process control & finished product results.

Yield control - The yields at the individual manufacturing stages must be recorded. Losses at critical production stages must be evaluated for possible risk. Yields that fall below the tolerance range must be explained.

Qualification status of critical equipments, facilities & utilities.

Change to starting material & product specifications.

A review of all critical deviations or non-conformances and related investigations.

A review of all changes carried out to the processes or analytical methods.

Details of stability testing & process validations etc.

A review of the results of the stability-monitoring program

A review of all quality-related returns, complaints and recalls - All internal and external complaints, as well as the affected measures must be presented in order to prevent complaints of a similar kind in the future.

Consequences of PQR

Process optimisation

Revalidation

Adaptation of manufacturing or control procedures

Amendments in current specifications

Strict change control programs

Improvement of complaint processing

The author is an experienced pharmaceutical blogger.