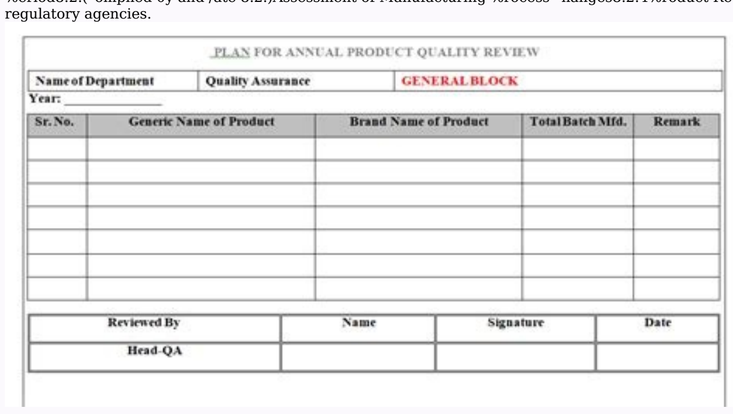
Annual product quality review report example

Annual product quality review. Annual product quality review format. Annual product quality review report sample.

PURPOSE: 1.To evaluate the performance of manufactured product versus the approved specificationsand expected quality attributes.2.To identify trends in product quality or changes in Active Raw Material═s!" #n$%rocess" or &inished 'oods performance.(.To propose the need for changes in product specifications or manufacturing processes or control procedures.).*omply with 21 *&R %art 211.1+, ═e!. SCOPE: This procedure is intended to describe the minimum requirements of 21 *&R %art 211.1+, ═e!regarding evaluation of the batches and the batch records on an annual basis in order toassure the quality standard requirements of the product. This procedure covers the approvedmar-eted products manufactured for commercial distribution. Page 1 of 8 RESPONSIBILITY ACTION ═A1.,/uring the beginning of each calendar year" ═A will obtain a list of approved products from Regulatory Affairs ═RA!. Refer to Attachment # $ A%R &low *hart for reference.2.,0ased on this list" ═A will generate a schedule of the Annual %roduct Reviews ═A%R! due for the year.2.1The schedule will include" as a minimum═ product" strengths" product codes"the review period and approval due date. 2.2The review period is determined by each product═s approval date. &or example" a product whose approval date is 3une 14" 2,,2 will contain datafrom batches manufactured5dispositioned within the 3une 14" 2,,2 to 3une1)" 2,,(reporting period. The review period encompasses 1 year of datafrom manufactured5dispositioned lots. A%Rs for different strengths of thesame product with similar approval dates may be combined.2.(A%R pac-ages will not be compiled for products for which there were no lotsmanufactured or products that have been discontinued during the reviewperiod. Although those products were not manufactured" product quality willbe monitored and documented throughout their shelf life through thefollowing systems═ stability study programs" customer complaints" andretention samples review.(.,═A will coordinate preparation of the A%R report" which consists of two parts═ the6xecutive 7ummary and the /ata &ile.).,The 6xecutive 7ummary consists of the following sections. 7ee section 8., for detailed information that will be included in the 6xecutive 7ummary.).1*over %age).2Approval %age).(Abstract).)Active Raw Materials).4%roduct Review).9*hange *ontrol).8/eviations5%lanned :ariances).+;aboratory #nvestigation Reports ═<<75<#n addition" charts5graphs must have >%repared 0y5/ate═? and>:erified 0y5/ate═? as a footer and be initialed and dated by the preparer andthe verifier. *harts5graphs will be generated if there are five or morelots5entries available" otherwise no charts5graphs are required. This does notapply to the /ata &ile.9.21,,@ of the manufactured lots within the review period will be reviewed.9.(&or /eviations5%lanned :ariances" ;#Rs and 7tability investigationsaddressing product with multiple actives" specify which active is involved.9.);ist the 7tability lots and the purpose of study.9.46nsure a statistical analysis is conducted to determine trends.8.,*ompile the 6xecutive 7ummary. The summary will include the following sectionswith the indicated requirements.8.1*over %age8.1.1%roduct name and strength8.1.2Application number 8.1.(Application approval date8.1.)Review %eriod8.2Approval %age 8.2.1%roduct name" strength" and product code8.2.2Review %eriod8.2.(*ompiled 0y and /ate 8.2.)Assessment of Manufacturing %rocess *hanges8.2.4%roduct Review8.2.9Approval 7ignatures and /ates Page 3 of 8 Skip to Content Researched by Consultants from Top-Tier Management Companies Copyright © 2023 SlideTeam. All Rights Reserved. Annual Product Review (APR) is the requirement of various regulatory agencies.



PLAN FOR ANNUAL PRODUCT QUALITY REVIEW

Name of Department	Quality Assurance	GENERAL BLOCK

Year: _____

Sr. No.	Generic Name of Product	Brand Name of Product	Total Batch Mfd.	Remark

Reviewed By	Name	Signature	Date
Head-QA			

APR roots the monitoring of product quality as well as to find out the scope of quality improvement by controlling the critical process parameters (CPP).

cGMPs

Make the Most of Annual Product Quality Reviews

Now advanced by global regulators, the APR offers an opportunity to better understand and improve processes

By Ajay Pazhayattil,
Director, Quality and Regulatory Affairs, Jarvis Street Pharma, Inc.

FDA'S CURRENT good manufacturing practices (cGMPs) require that the quality standards of a drug product be evaluated each year to determine whether there is a need to adjust drug product specifications, manufacturing and control procedures. Subpart J of 21 CFR 211.180 mandates establishing a written procedure for the annual product review process, and recommends the review of a representative number of batches, both approved as well as rejected. These guidelines stress the importance of analyzing the results of investigations, any deviations found and product complaints received. The APR report must explore, in depth, the reasons for any product recalls and returns.

No doubt, FDA's goal with the APR is to get manufacturers to look at their processes thoroughly and systematically, and to focus on areas where they might be improved. Other regulators are also on board with APR's.

Canadian GMP's were updated in 2009 to include an explicit section for Annual Product Quality Review (C.02.011). Health Canada's regulations require manufacturers to analyze previous reviews, examine finished product testing results and critical in-process controls, and review: failed batches, deviations, CAPA effectiveness, changes, stability studies, returns, complaints, recalls, critical equipment qualifications, and quality agreements. CAPA's from annual product reviews need to be communicated to senior management and completed in a timely and effective manner, with effectiveness verified via self-inspections.

In the EU, Product Quality Review, as well as the PIC/S GMP guide, requires a review of:

- starting materials including packaging materials used
- marketing authorization variations
- post-marketing commitments.

They also make the qualified person at the facility responsible for the review's accuracy and timely completion. Although these requirements are "harmonized" and, for the most part, somewhat similar, there are a few unique exceptions, as shown in Table 1.

STRUCTURE OF AN APR REPORT

The structure of a review report may vary, based on the products involved and manufacturer's documentation requirements. However, companies should follow a standard

DIFFERENCES IN GLOBAL APR REQUIREMENTS

US FDA	Health Canada	EU
Management review/notification Review of returned or salvaged drug products Review of regulatory GMP observations	Nonprescription Category IV drugs not exempted	Review of starting materials including packaging materials Review of Marketing Authorization variations Assessment of whether revalidation should be undertaken

Table 1.

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APR – Annual Product Review also known as APQR – Annual Product Quality Review and PQR – Product Quality Review, below the SOP and formats for APR preparation. Annual Product Report (APR/APQR/PQR): Annual product report is a documented evidence for assuring that the various manufacturing parameters are controlled enough which results into a finished product meeting all predetermined specification and other quality attributes. Also acts as an indicator to identify requirement of changes in specifications or manufacturing processes or control parameters with the help of statistical review of trend. SOP for Annual Product Quality Review (APR / APQR / PQR) Purpose: The purpose of this sop is to describe the detail procedure for preparation, review and approval of annual product report/ product quality review (APQR / APR /PQR) with the objective of verifying the consistency of the process, equipment and system for meeting predetermined specifications and other quality attributes of a finished product. Scope: This procedure applies to all drug products manufactured to understand and review the process, Specification and adherence to specified standards. Note: APR / APQR / PQR, all are same but the terms are differently used in guidelines. Procedure – Annual Product Review (APR): Preparation of Annual Product Quality Review (APQR):Annual product report shall prepare for all finished products manufactured.APR to verify the consistency of the existing process, the appropriateness of current specifications forRaw materials.Packing materials.Intermediate product andFinished product to identify any emerging trends as also to identify product / process related improvements.APR shall prepare for drug Products as per below time line and acceptance criteria:Time Line to prepare the Annual Product Quality Review : Yearly+ 3 months. APR shall prepare for all products manufactured in a year.If more than fifteen batches manufactured during the review period, Prepare graphical presentation of analytical trend data of in-process and finished product.In case of less than fifteen batches, instead of graphical presentation, minimum/maximum value of trend shall be prepared and reported.APR tracking register shall be maintained.Preparation of APR consists of three stages:Collection of data / information,Review of data / information andGeneration of review report.Annual Product Reports shall contain data of all the batches manufactured for a product during calendar year from January to December.Separate APR / APQR shall generate in case a product is produced using different manufacturing process.Review shall cover all the markets where the product is being sold.In case of a product that is manufactured in multiple strengths or different packs, combined APR report can generate. however each pack or strength shall evaluate in separate manner.Preparation of APQR / APR / PQR of all products shall complete till the end of first quarter of product anniversary.To manage the preparation of APR of all products and to divide the work load throughout the year,APR of different products shall plan in different months i.e. as per product anniversary.Suppose 120 products are manufactured in year, then every month approx.

Product Quality Review

Annual Product Review

Presentation prepared by "Drug Regulations"
a not for profit organization.
www.drugregulations.org

ten products shall identifying for preparation of APR.The batches to be considered for APR review shall dependent on the APR period i.e. 01/01/14 to 31/12/14 or 01/02/14 to 31/01/15 or 01/03/14 to 29/02/15 so on.The next year review shall perform for next review period i.e. if in first year the period was selected the 01/01/14 to 31/12/14Then the next year APR shall prepare for the batches manufactured during the period from 01/01/15 to 31/12/15, for the products APR falling during this stated period and same shall follow for the rest.In-case of WIP for a product, APR shall complete after its final QA release.General Instruction for preparation of Annual Product Review – APR :Various data incorporated into the APR can present in tabulated form. Also graphs, flow chat, etc. can use as per the requirement.APR of all products shall kept with QA department.All relevant points shall discuss with the concern department/s.APR shall not destroy in case of product transfer, product discontinuation or banned from govt. Authority.If the APR is required to share with other locations,Then the "Uncontrolled copy" shall issue upon request.If the APR is not due,Than only raw trend data shall share with the new location.In-case a particular product is not manufactured during a particular year,Then the APR shall restrict to review of only relevant points.Annual product report shall prepare in accordance to the following points.Each APR shall have a covering page which includesThe Company Logo in the center of the page."ANNUAL PRODUCT REPORT" below the Logo.The table shall contain the product name, Year and APR number.Subsequent pages of the APR shall bear the Header and footer.Header shall bear the Sun Pharma Logo at the top right corner of each page."ANNUAL PRODUCT REPORT "shall be written at top center of each page.Header shall contain the table at top of each page which shall contain the page no., Product name, Generic name and market.Footer of each page shall contain the unique APR number on left corner of each page. Upper control limit: (Arithmetic mean + 3 X standard deviation (σ)). Lower controlled limit: (Arithmetic mean – 3 X standard deviation (σ)). In case the UCL or LCL falls out of specification limit, the minimum and/or maximum limit among all data for a particular parameter can consider aslimit for recommendation orthe root cause of such variation to identify to eliminate the same for future batches. Process performance and Process performance index can calculate as a part of further study of trend results. Process performance The process performance, or Pp, measures a process's performance, which is defined as the allowable spread over the actual spread. (Refer Diagram below) Process performance: Pp= USL-LSL/6σ Where Pp= process Performance, USL= Upper Specification Limit, LSL= Lower Specification Limit and σ= Standard deviation Interpretation of Pp Value:As Pp is inversely proportional to the standard deviation, higher the value of Pp, better is the process performance.Process Performance index (Ppk) value shall calculate for batch yield, and to key quantitative results (Assay, Related substances, residual solvents etc.).Below the formula for calculation of Two-sided specification. Formula- 1: Ppk=Pp-(m-x)/3S Where: Ppk = process Performance index m=Mean Point (USL+LSL/2) x= Mean value S: Standard Deviation Formula -2: Ppk= Minimum of (USL- X) / 3S or (X- LSL) / 3S Where: USL: Upper Specification Limit LSL: Lower Specification Limit X: Mean Data S: Standard Deviation Interpretation of PpK Value:If PpK ≥ 1Then the process is capable of generating 99.7 % of the product batches that are within the specification. If required, do the Further assessment.If PpK ≤ 1Then the process may generate some non-conforming batches over a period of time and needs assessment to identify and eliminate cause for variability.If required, do the Further assessment in this case.If PpK ≥ 1.33 :Then the process is capable, For normally distribution of population. For more details about Process Capability calculation (cpk ppk value calculation) Click here Review of status against previous APR:Check for any recommendations / actions stated in previous APR completed for the product.Compare the trends against those included in the previous APR for any similarities / differences, check whether any corrective actions completed in previous year have improved the trends during this year.Provide a brief summary in the APR report based on the above points.Conclusion:A suitable conclusion shall drawn by reviewing the above mentioned parameters.Recommendation:Based on logic and statistical review, recommendation for betterment of the product and system shall describe.Tools shall design to ensure the implementation of recommended action plan/s for betterment of future batches.Addendum Report:Annual product report can reopen for incorporation of further information under circumstance's as listed below.
An addendum report shall prepare for further updation.If any information found missing while review.To include the recommendation/suggestion of auditors. Annual Product Review Tracking Register References & Annexures: ReferencesGuideline for preparation of annual Product review of Drug Products.21 CFR Part 211.Good Manufacturing Practices issued By WHO.Australian code of cGMP for medical products issued by TGA.Annexures:Format for Annual Product Review Tracking RegisterFormat for APQR Skip to content