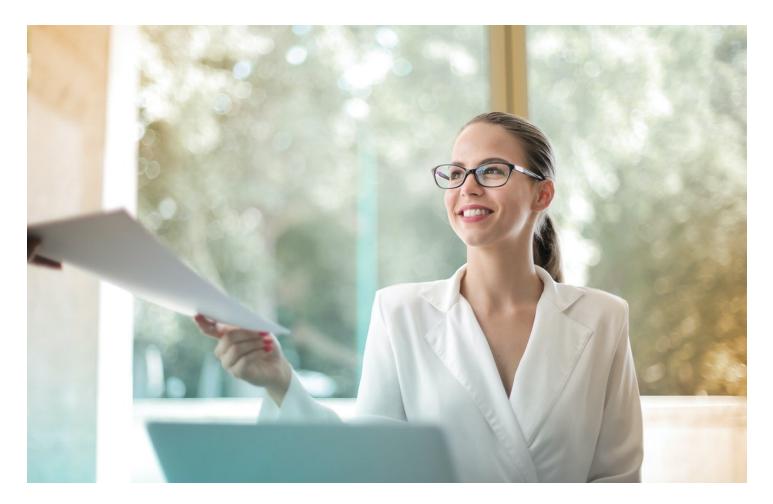# A Guide to Creating Annual Product (APR) Reports

White Paper | July 2020

Every year, the processes involved in the various stages of manufacturing pharmaceutical products undergo an evaluation known as the Annual Product Review (APR). The objective of scrutinizing APR reports is determining whether any of the process or product components require any alteration and quality improvement. Analyzing APR reports help to minimize product defects and any other potential risks that come with the manufacturing of pharmaceutical products, medical devices, among others. APR reports (when properly created) are valuable tools from an administrative standpoint. For any Quality Management System (QMS) to be effective, regular reviews are necessary and they are also necessitated by regulatory authorities. In the United States, these review reports are referred to as Annual Product Reviews, while in the EU they are referred to as Product Quality Reviews (PQRs). The general structure of both reports is rather similar.

Avoid CAPA & Compliance Risks with Document Automation Software

Poor quality and delay in APR reports and documentation can lead to compliance risks and the implementation of CAPA (Corrective and Preventive Actions). You can get rid of these issues by taking advantage of document automation software like Windward. It can quickly connect to your existing data sources and your company's quality experts can create templates (without the need for any coding) in familiar platforms like MS Word and populate it with the right content to generate reports. You can create hundreds of APR reports in a matter of few minutes and save thousands of dollars in the process. You can share these reports in a wide range of formats including PDF, DOCX, among others.

Rationale

It is important to make formal reviews on the quality and information relating to the compliance of pharma products regularly. Doing so helps you to monitor the performance of various processes and the quality of the products. You can point out any improvements that may be required in the manufacturing processes or on the product itself. Compliance risks and changes to be made during the control or manufacturing stages or even the product specifications can also be identified when carrying out reviews.

With the proper document automation software, your pharma company employees can create flawless APR reports to maintain compliance with regulatory bodies.

This review process provides a better understanding of the process and product. It also helps to inform the assessment of potential cumulative impacts of any changes to the product quality or any of the manufacturing processes. Manufacturers are therefore able to improve their processes while decreasing product-line-related deviations.

Every commercial product requires APR reports to ascertain the consistency of processes, assess trends, determine the necessity of changes in production, specification, control, and, or, manufacturing procedures as well as evaluate the necessity for revalidation.

APR reports when generated on time foster the improvement of quality-related processes by acting as a communication conduit for those involved in the manufacturing of the products and those in quality and regulatory affairs. It is therefore important to establish the content and the management of APR reports and document automation software ensures you can generate them fast and error-free. Even an individual employee can create these reports with basic knowledge of APR documentation when you engage Windward.

APR Requirements

Every site is required to have clearly indicated procedures that act as guidelines during Annual Product reviews. APR reports should account for one-year periods, however, these rolling periods do not necessarily have to be calendar years. It takes about 60 calendar days to complete a review. However, some review processes can take up to three months (90 calendar days) from the end of the rolling period. Where production is below three (3) batches annually, APR reports are still required. Here, reviews may include reviews conducted on 2 to 3 prior production years.

Periodic reviews are carried out on the various production documents of a given product, its release data, stability data, any product complaints, among other parameters. This is important in the establishment of trends as well as the determination of any issues. The senior site managers must be issued with final review reports on an annual basis.

Although they are annual, they need to be perfect and you can ensure just that by implementing document automation to generate these reports and submit them on a timely basis.

Applicability

APR reports apply to all commercial products. This is true for medical devices as well as drug products. All product batches regardless of their status (i.e. accepted, destroyed, or rejected) must be included in the APR. Data assessment as well as all electronic or otherwise documentation must be reviewed and addressed in an APR. APRs of pharmaceutically active ingredients must include critical steps in the manufacturing process. Previous reviews must also be considered.

These reports must address site-specific water quality grade. Where one product makes use of only one water quality, data about the water may be part of the APR for the product's APIs. In the case of critical utilities, separate APRs are recommended. Where this is not feasible, a chapter within the APR should be dedicated to the utilities APR.

You can create standard templates using Windward to include in all your APR reports and even create special templates to include information that is specific as mentioned above. The advantage of Windward is you can create these templates in a fraction of the time in comparison to other solutions available in the market. You can utilize query wizards and simplified logic sequences to incorporate all relevant data into these templates.

Reviewing APR Reports

Statistics

The first thing to be considered should be reviews of recommendations from prior reports and any resultant actions. After this is done, basic statistics are then reviewed. These include the number of manufactured batches and their yields (these are inclusive of batches that were partially completed). Other statistics to be reviewed include:

- The number as well as the percentage of all rejected batches giving reasons for their rejection
- The number as well as the percentage of all reprocessed or reworked batches giving reasons as to why
- Important control measures taking place within the various processes, the results of the finished products, as well as important results from API tests.
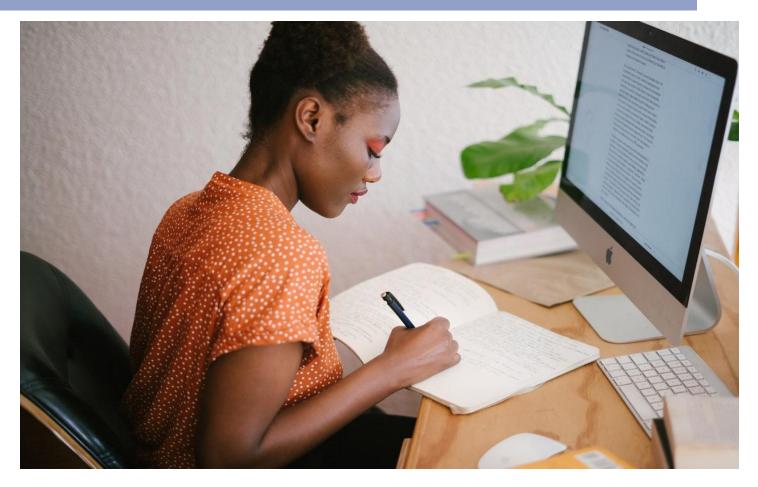
Deviations

It is important that deviations from product line validated states are analyzed. This analysis typically includes reviewing every batch that was not up to par with established specifications as well as their resulting investigations. Important deviations, as well as any outlier specification results and any investigations of failures, need to be analyzed. Here, of importance is the efficacy and adequacy of preventative and corrective measures taken.

Other important aspects that require reviewing include any complaints about the product quality that result in products being returned, any recalls, important regulatory issues, the quality of salvaged goods, and any changes made to the product quality or the manufacturing process, changes made to the product specifications, and the status of process validation.

Trend Analysis

Consideration of trend analysis data is key. Emphasis should be placed on critical in-processes, release testing data, graphic representation as well as basic statistics. This includes the review of results from programs aimed at monitoring product stability and the analysis of trends presented by the stability data.

Product Line Summary

Product summaries are typically comprised of an analysis of observations as well as recommendations made. This analysis includes observations and recommendations made by official inspectorates on issues directly relating to the products being reviewed as well as fresh recommendations from the current review.

Completing the Report

Senior site quality management, senior site management, and site production management are responsible for reviewing, assessing, and approving APR reports. Regulatory authorities seeking to carry out an audit, in-house or external, should be able to gain access to approved APRs from at least eleven (11) years prior.

For an APR report to be deemed a meaningful document, it should focus on evaluating and assessing information and data. It should also entail meaningful lists of data and facts. Reviews should also pay attention to mid-term as well as long-term trends, both between and within batches, as it may be difficult to observe clear trends from a single batch's data. This is where the analysis of previous reports is beneficial. Lastly, meaningful reviews should serve to verify select original documents such as test and batch records.

When gathering APR information, it is important to differentiate between Module and Product-specific information, so have a team to help efficiently compile the necessary information, employ the use of an annual information collection strategy, and lastly, link APRs to other ongoing validation programs, risk management, and CAPA.

A Guide to Creating Annual Product Review (APR) Reports

With all the information that needs to be included in an APR report, you can't let errors creep in, especially when it is about quality control and compliant reviews in the pharma industry that deals with the lives of human beings. By taking advantage of Windward, you can create APR reports quickly and error-free by simply designing the templates and tagging the relevant data to populate the templates and generate them in required output formats. You don't have to hire a programmer or developer to help you set up the document automation software. All it takes is a few clicks and even an individual employee in your company (with no coding knowledge) can create them and share it with others to review and submit to relevant authorities.

Deciding which document automation software to use can be tricky, as no one solution suits all use cases. That's why Windward Studios put together a handy guide of what to look for.