ANNUAL PRODUCT QUALITY REVIEW

Guide to the Ultimate Product Improvement Tool

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MANAGEMENT SUMMARY

The annual product quality review (APQR) process is a requirement for manufacturers of drug products to comply with Good Manufacturing Practice (GMP) regulations and maintain high-quality products.

However, data aggregation tasks and siloed analysis can plague APQR preparation often hindering product quality decisions, leading to inefficiencies and errors in the process.

By applying the latest digital technology to automate the process end-to-end, drug manufacturers can streamline their data collection, analysis, collaboration and approval processes. This supports increased operational efficiencies, improved regulatory compliance and reduced costs.

Companies that modernize their APQR process will also benefit from electronic collaboration, review and compilation of required regulatory reports as well as eliminating time-consuming tasks and improving data analysis. This white paper will review how automating the APQR process can help organizations simplify their product quality review process and make informed product quality decisions quicker and on a more routine basis.

WHAT IS APQR?

APQR (also known as annual product review (APR) in FDA and product quality review (PQR) in EU good manufacturing practice (GMP) guidelines) is a requirement for pharmaceutical and biotechnology companies to comply with pharmaceutical GMP regulations. APQR is required to be conducted annually for every product to determine the need for changes in drug product specifications or manufacturing or control procedures

THREATS TO CONDUCTING EFFECTIVE APQRS

One of the major challenges facing APQR preparation is siloed systems and data sources that result in disconnected information. Unfortunately, this is a common issue in the Life Sciences industry, where different departments and functions can often work in isolation, using different systems of record to manage their data.

This can create significant difficulties when conducting an APQR, as multiple cross-functional resources are needed to extract data from these siloes manually. This manual process is time-consuming, increases the risk of errors and is costly for organizations; taking an average of 1 to 3 months to collect the necessary data and then conduct a manual review, analysis and approval.

AUTOMATING APQR WITH HONEYWELL PRODUCT QUALITY REVIEW (HPQR) SOFTWARE

By eliminating time-consuming tasks and improving data analysis, pharmaceutical companies can significantly enhance the APQR process. An automated APQR process can help organizations simplify their product quality review process and make informed product quality decisions.

Honeywell product quality review (HPQR) automatically ingests required data through a secure, cloud-based, connective data fabric that accesses the data needed from a company's existing data architecture (data lakes, etc.) and systems of record. HPQR provides capabilities that include:

- **Automated Data Collection:** HPQR eliminates paper-based processes and automates data collection from different record systems. The ease of this report will help you get closer to proactive quality.
- **Auto PDF generation:** Today's process is "copy and paste," but users can generate anything they need with the click of a button.
- **eSignature:** Supports eSignature in compliance with regulatory guidelines.
- **Audit Trail:** The data, interaction, collaboration and comments within HPQR are all part of the audit trail and in compliance with regulatory guidelines.
- **Cross-Functional Department Collaboration:** Users can see what they've been assigned, and various department users can contribute and collaborate on PQR. Users can send all approvals at once, receive email notifications and sign them, add notes or comments, and respond and make changes based on those notes.
- **Configurable Approval and Notification Workflows:** When a PQR is initiated, assigned users are notified of their tasks and can contribute to the PQR. The system then validates data to ensure it is adequately formatted for analysis. Finally, approvers are assigned the report for review and approval or to return with comments.

HPQR RESULTS IN:

- **Improved Operational Efficiency and Data Integrity:** Users can quickly collect and access data from multiple systems of record to help increase operational efficiency in a central system while reducing manual errors and redundancies.
- **Anytime Reviews:** By simplifying and automating the process, users can create virtual or interim PQRs, allowing them to routinely assess the state of their processes and review the progress of their continuous improvement initiatives.
- **Simplified Report Creation:** Users can automatically conduct complex analyses of quality data. Collaboration with cross-functional groups lets users assess and address product quality issues anytime.

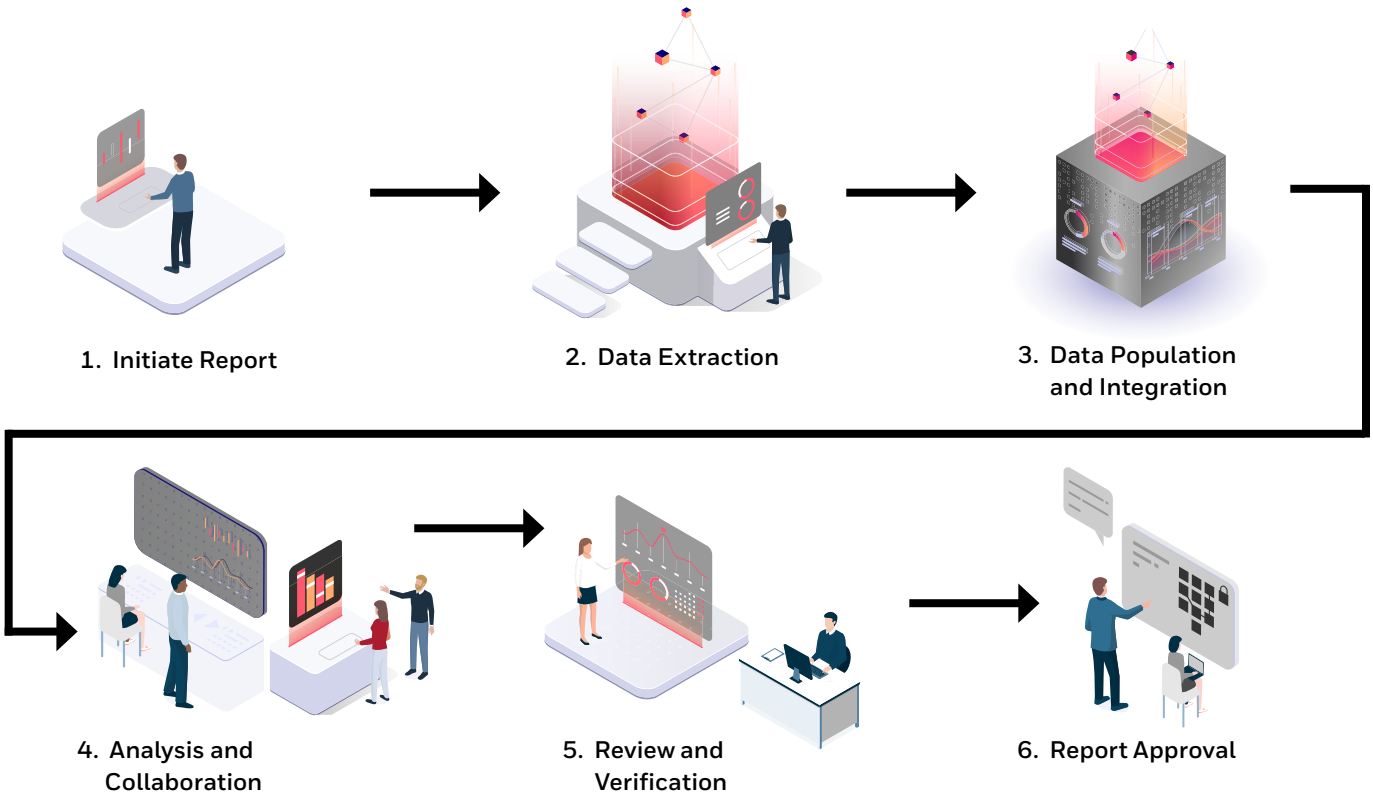
OPTIMIZE YOUR APQR PROCESS

With secure, cloud-based access to data, Honeywell Product Quality Review simplifies and streamlines the process for all stakeholders.

HPQR automates the collection and analysis of product quality data from multiple systems of records, facilitates collaboration among various functions and streamlines the collation and approval of annual reports for compliance needs.

HPQR provides a scalable solution and a modern approach for pharmaceutical companies to go beyond checking the regulatory compliance box. The result is a significantly improved user experience, efficiency and effectiveness of their product quality review process.

MODERN APPROACH TO PRODUCT QUALITY REVIEW



For more information

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