

HONEYWELL PRODUCT QUALITY REVIEW (HPQR)

Modernize the Annual Product Quality Review (APQR) Process

Annual product quality review (APQR) reports, also known as PQR or APR, are a requirement for manufacturers of drug products to comply with good manufacturing practice (GMP) regulations and maintain high-quality products.

APQRs consist of a set of chapters that focus on specific aspects of the product. Each chapter typically includes explanations and commentary accompanied by visualizations, such as charts and statistical calculations. The manual effort required has turned this into a burdensome “check the box” activity.

Creating an APQR report is a collaborative process between various department personnel who work on individual APQR chapters related to their expertise, and a report project manager (RPM), who is responsible for overseeing the report process, ensuring its completion and delivery.

The Honeywell product quality review (HPQR) app streamlines this process by providing a single, digital location where the APQR report is taken through its process workflow; from accessing required source data to generating a draft report with chapters that undergo multi-user reviews and onto the approval and generation of the final APQR.



FEATURES



Configurable Workflows

Automate the approval workflow with notifications when actions are required by a user



Concurrent Collaboration

Various departments can contribute and collaborate on the report simultaneously



Analytics Toolkit

Statistical analysis and control charts using familiar tools to quickly identify outliers and focus areas



Auto PDF generation

With the click of a button users can generate a final APQR in PDF format



Audit Trail & eSignature

Remain compliant with 21 CFR Part 11 by sending documents electronically for approvals

BENEFITS

- **Improves Operational Efficiency and Data Integrity:** Users can quickly obtain data from multiple systems of record to increase operational efficiency in a central system while reducing manual errors and redundancy.
- **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.
- **Simplifies Report Creation and Collaboration:** Users can automatically conduct complex analysis of quality data. Collaboration with cross-functional groups enables users to assess and address product quality issues at any time.
- **Regulatory Compliance:** The data, interaction, collaboration and comments within HPQR adhere to regulations like 21 CFR Part 11, ICH Q7, EudraLex, WHO Annex 2 and ALCOA+.

AUTOMATE PRODUCT QUALITY REVIEWS

Connect to any data source to automatically generate reports in minutes not months, increasing efficiency, effectiveness and driving continuous improvements in process and product quality.



For more information

To learn more, visit
www.spartasystems.com

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