

Enhancing Compliance and Quality Review Efficiency: A Comparison of Monthly vs. Daily Assessments

Utilizing Qualio

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Abstract

This study investigates the effectiveness of monthly compliance assessments versus daily quality reviews in ensuring regulatory adherence and operational excellence. It specifically examines the impact of Qualio, a quality management tool, on addressing findings and improving efficiency compared to traditional paper-based methods.

A comparative analysis was conducted, tracking indicators such as Sponsor Monitoring Visit findings and Non-Conformance rates before and after implementing daily checks. Additionally, the impact of Qualio-enabled digital reviews versus paper-based processes on Protocol Deviations was examined.

Results show that daily quality reviews led to earlier detection and resolution of compliance issues, resulting in decreased Sponsor Monitoring Visit findings and Non-Conformance rates. Staff reported higher satisfaction with Qualio's interface and workflows. The study highlights the benefits of daily reviews for proactive compliance management and the significant enhancement of the review process through Qualio.

Introduction

- Objective:** To evaluate the efficiency of monthly versus daily compliance assessments and quality reviews in achieving regulatory adherence and operational excellence.
- Significance:** This research focuses on the impact of Qualio, a digital quality management tool, on addressing compliance issues and improving operational efficiency compared to traditional paper-based review methods.
- Context:** Ensuring consistent compliance and operational quality is crucial for regulatory adherence. Traditional paper-based methods may lag in detecting and resolving issues, potentially impacting overall efficiency.

Methodology

- Comparative Analysis:** A comparative analysis of compliance assessments and quality reviews was conducted to evaluate their effectiveness.
- Indicators Tracked:** Sponsor Monitoring Visit Findings: Tracked before and after implementing daily checks.

Non-Conformance Rates: Monitored to compare the effectiveness of daily versus monthly reviews.

Protocol Deviations: Assessed the impact of Qualio-enabled digital reviews versus traditional paper-based processes.

- Tools:** Qualio: A quality management tool used to facilitate digital reviews.

Traditional Paper-Based Methods: Used for comparison with Qualio-enabled processes.

Results

- Earlier Detection and Resolution:** Daily quality reviews led to earlier detection and resolution of compliance issues compared to monthly reviews.

- Impact on Indicators:** Sponsor Monitoring Visit Findings: Decreased significantly with daily reviews.

Non-Conformance Rates: Showed a notable reduction after the implementation of daily checks.

Protocol Deviations: Early detection and reporting observed with Qualio-enabled digital reviews compared to paper-based methods.

- Efficiency Improvements:** Streamlined Review Process: Implementation of Qualio facilitated real-time collaboration and efficient issue resolution.

Staff Satisfaction: Increased satisfaction with Qualio's intuitive interface and automated workflows.

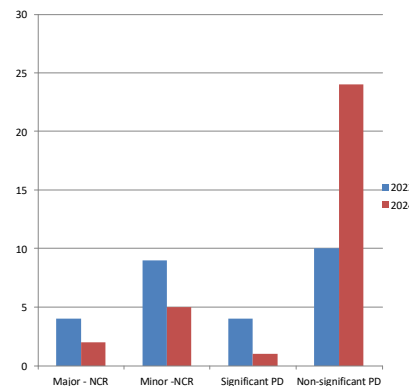


Chart 3. Comparison of Non-Conformance and Protocol Deviation '23, '24

PD breakdown

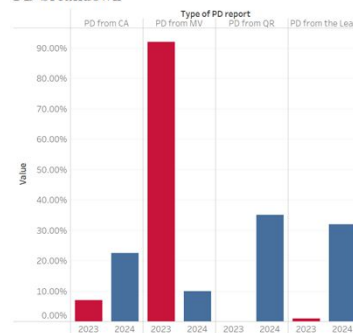


Chart 4. Breakdown of Protocol Deviations in terms of reporting

Conclusion & Discussion

- Summary of Findings:** Daily compliance assessments are more effective than monthly reviews for early detection and resolution of compliance issues, resulting in improved regulatory adherence and operational efficiency.
- Impact of Qualio:** The use of Qualio significantly enhances the review process by streamlining workflows, enabling real-time collaboration, and increasing staff satisfaction.
- Future Implications:** The study supports the transition to daily assessments and digital quality management tools for better compliance management. Organizations should consider integrating such tools to achieve higher levels of operational excellence and regulatory compliance.
- Final Recommendation:** Moving from monthly to daily compliance reviews and adopting digital tools like Qualio can lead to significant improvements in regulatory adherence, efficiency, and overall operational performance.



Figure 1. Traditional Paper based workflow.

Figure 2. Qualio based Workflow.

2023



Chart 1. Cumulative number of PD, CA, NCR of 2023 (6 months).

2024



Chart 2. Cumulative number of PD, CA, NCR of 2024 (6 months)

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