Audit Trail Review

Building the Bridge
between Business and IT

Why reviewing Audit Trails?

The last published Data Integrity Guidelines (FDA, MHRA, EMA) as well as the corresponding inspector praxis in the last couple of years has put dramatic focus on Data Integrity and as part of it on the Audit Trail Review process.

In this context, it is important to have a clear understanding of what is an audit trail, distinguish between system and data audit trails and accordingly define the optimal and most efficient process for the audit trail reviews in the different systems.

What we offer

- Analysis of your current audit trail review strategy
- Process optimization & data analysis to recognize important aspects to focus on
- Supporting the automation of your review process (generating specific report per system for the important exceptions).

This means increasing efficiency by generating maximum value from your data while securing GxP compliance.

Step by step:
How wega increases your Audit Trail Review (ATR) maturity level

Analyze Current Audit Trail Review Strategy

considering the following aspects and focusing on the most critical systems & data

- Governance related to CSV and Data Integrity
- Audit Trail Review procedures and tools (e.g. reports)
- Audit Trail and Audit Trail Review considerations in system validation (e.g. as part of system design)

Optimize Audit Trail Review Process

- Identify Critical Data
- Use Data Visualization approach for fast Identification of relevant Exceptions
- Compile, Configure and Run relevant Exception Reports
- Improve Process (when to review what and how)

Setup Audit Trail Review Automation

- Setup proactive event based monitoring to raise exceptions
- Confirm exceptions and trigger actions at runtime