

Audit Trail Review



In the life sciences sector, compliance with regulatory requirements is mandatory, and managing GxP audit trails can be one of the most inefficient and complex tasks. Although audit trails are meant to ensure data integrity and traceability, most companies still rely on manual, periodic reviews that are time-consuming, error-prone and resource intensive. This is where Audit Trail Review helps. It turns audit trail review into a real-time, automated process, reducing workload, improving compliance, and keeping teams focused on what matters most : data integrity and product quality.

Main benefits



Standardization

Defining key parameter changes and critical data enables fully standardized audit trail reviews across systems, regardless of the user.



Continuous Monitoring

Continuous monitoring and real-time alerts highlight record gaps instantly, reducing compliance and product risks.



Automation

Automate data transfer and near real-time detection of incomplete or non-attributable records.



System & User Tracking

Our software gives full visibility of registered GxP systems and assigns responsible owners via a secure, configurable registry.



Compliance

Switching to automated monitoring keeps you always audit-ready and reduces non-compliance risk.



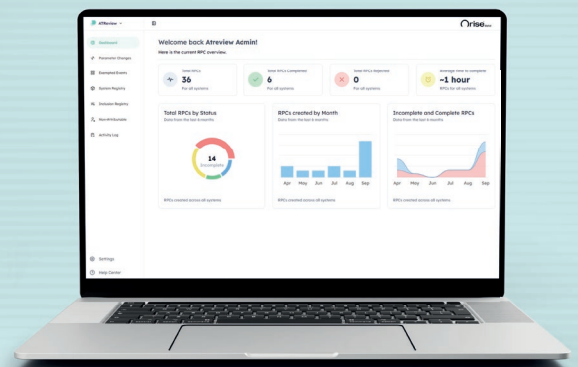
Tamper Proof & Secure

Audit Trail Review logs all actions in real time with secure e-signatures, supporting data integrity compliance.

Our technology

Orise Digital Audit Trail Review allows organisations to eliminate manual audit trail reviews of GxP systems with smart automation. Our fully configurable application connects all your GxP audit trail data in one user friendly interface.

Our cloud technology allows each GxP system to send audit trail records automatically and instantly to Audit Trail Review where all relevant parameter changes can be analyzed, reviewed, and approved in real-time.



From periodic to continuous

Organisations select which GxP systems to gather audit trail data from and determine their own relevant parameter changes from these systems. Audit Trail Review will then automatically detect actionable items and alert the necessary users.

With continuous, near real-time monitoring of your audit trail data, managing unwieldy periodic reviews and retrospectively tracking down data is no longer required. Access to audit trail record data is controlled via securely assigned privileges within the Audit Trail Review application and all actions within Audit Trail Review are recorded in near real-time activity logs allowing for a fully contemporaneous and fully compliant audit trail.

A validated industry solution

Demands are high from regulators and industry bodies such as:



ISPE

SHAPE THE FUTURE
OF PHARMA



U.S. FOOD & DRUG
ADMINISTRATION



Medicines & Healthcare products
Regulatory Agency

A validated application built on our own qualified infrastructure, Compliant Cloud Platform, Audit Trail Review is specifically designed with these regulations, standards and guidance in mind.

Case Study: A leader in the pharma industry achieved over 80% reduction in audit trail effort




Challenges


- High Risk caused by incomplete audit trails
- Insufficient, poorly executed or unfulfilled audit trail reviews
- Current process is labour intensive and time consuming
- Unmanageable amounts of audit trail records (excel spreadsheet)


Solution


- Critical thinking-based risk profiling assessments
- Standardised parameters, removing subjective evaluation
- Single source of truth-audit trail reviews
- Digitalize, continuous monitoring, automatic detection & notification
- 21 CFR Part 11 compliant
- e-Signature approval

Outcomes

 Reduces risk, always
audit-ready

 >80% reduction in effort

 Cost saving direct/indirect

 Near real-time data

Orise Digital is the digital innovation arm of Orise, built to connect and optimize the entire digital process and system landscape. With deep expertise in automation, system integration, and process optimization, we deliver industry-proven tools that enhance connectivity, streamline operations, and turn data into actionable insights. Orise Digital helps enterprises integrate technologies seamlessly, boost efficiency, and stay compliant. As the final link in the digital chain, we turn digitalization from vision into reality—empowering smarter, faster, and more informed decision-making through structured, visualized data.