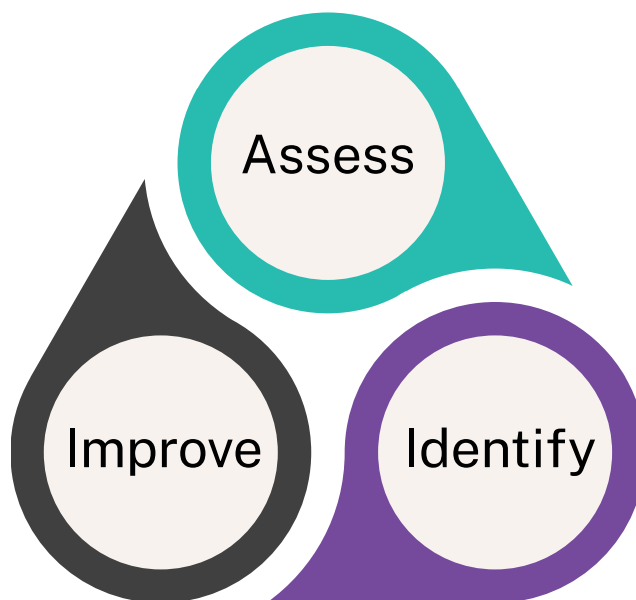


# How to Implement a Compliant Audit Trail Review Process

Regulatory agencies are increasing their focus on audit trails. In 2024, FDA Warning Letters mentioning audit trail reviews more than doubled [1]. Updates to EU Annex 11 (2026) will further emphasize audit trails [2].



## Key Steps for Compliance

1.

### Assess GxP-Relevant Systems



- Identify GxP-critical systems through risk assessment and maintain an inventory.
- Ensure systems capture necessary audit trail data – if it's not recorded, it can't be reviewed!
- When implementing new equipment, integrate audit trail requirements early to avoid compliance issues later.



**2.****Identify Critical Data & Gaps**

- Perform risk assessments to pinpoint critical data and review priorities.
- Assess gaps in systems and processes regularly – regulatory expectations evolve!
- Example gaps:
  - Audit trail functions are not available or require manual saving.
  - No clear criteria for review, either missing critical data or including too much irrelevant data.

**3.****Plan & Implement Improvements**

- Prioritize system improvements - manual workarounds are increasingly not accepted by regulators!
- Establish distinct Audit Trail Review Plans for each system based on risk.
- Filter or sort audit trail data to highlight high-risk events (e.g., manual changes, unusual user activity).
- Train relevant staff (QA, manufacturing, lab, IT) to ensure compliance and efficiency.

**Looking for Support?**

GxP-CC provides expert consulting on audit trail compliance, data integrity, and quality management. Contact us at [www.gxp-cc.com](http://www.gxp-cc.com)!

**References**

[1] FDA, "Warning Letters," 14 March 2025. [Online]. Available: [FDA Warning Letters](#).

[2] European Medicines Agency, "Concept Paper on the revision of Annex 11," 19 September 2022. [Online]. Available: [EMA Annex 11](#).

