

## New Comet Cloud Feature: Audit Trail

Full control over every change – a step toward 21 CFR Part 11 compliance

The Audit Trail feature in the Comet Cloud system enables complete tracking of all user and system actions. Every login, device configuration change, modification of user permissions, or alarm setting adjustment is automatically recorded and included in the audit report.

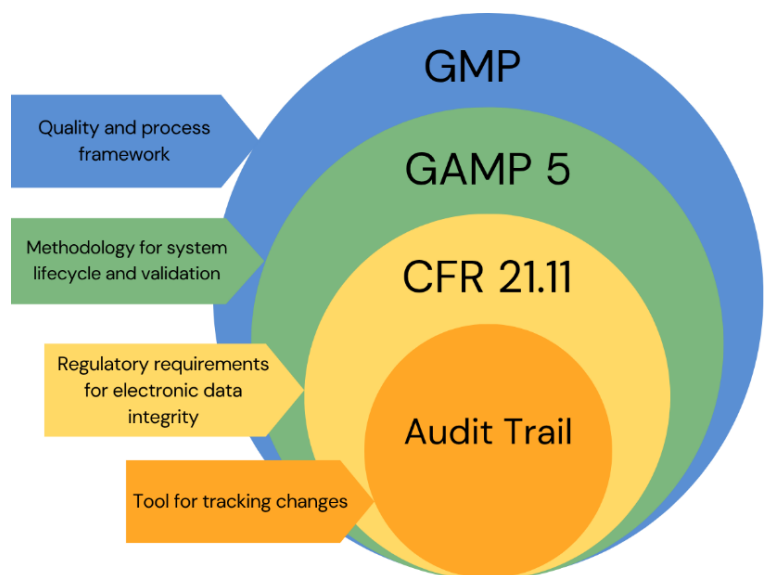
This feature ensures full traceability and transparency of system operation – key requirements for validation in regulated environments.

### Key Audit Trail Features

- **Automatic recording of all changes** – Every action is logged, including timestamp and event type.
- **Login and permission change tracking** – Overview of who accessed the system and when.
- **Data immutability** – Audit records cannot be modified or deleted, ensuring information integrity.
- **Storage in Comet Cloud** – Audit reports are available within the user profile.
- **Report regeneration capability** – After the retention period, reports can be regenerated by specifying a time range.
- **Email delivery of reports** – Users receive summary reports at defined intervals.
- **Data export** – Audit records can be exported in PDF format for audit, validation, or internal control purposes.

### For Regulated Environments (Pharmaceutical Industry, Laboratories)

- **Simplified system validation** – Complete documentation of all changes simplifies qualification and validation processes according to GMP/GAMP 5 principles.
- **Audit readiness** – Evidence is always available showing who made changes, when, and what was modified.
- **Support for 21 CFR Part 11 requirements** – Automatic records support compliance with electronic records and traceability requirements.



### Support for 21 CFR Part 11 Compliance

Requirement	Description	Compliance in Comet Cloud
Section 11.10(e)	Audit records must contain information about data changes, time, and user	✓ Every action is recorded with user identification and timestamp
Section 11.10(c)	Data must be protected against modification or deletion	✓ Audit reports and records are cryptographically protected and immutable
Section 11.70	Data must remain readable and accessible throughout the retention period	✓ Reports are available online and can be regenerated for any selected period