



LogTag[®]

**21CFR Signature Suite
Brochure**

Version A

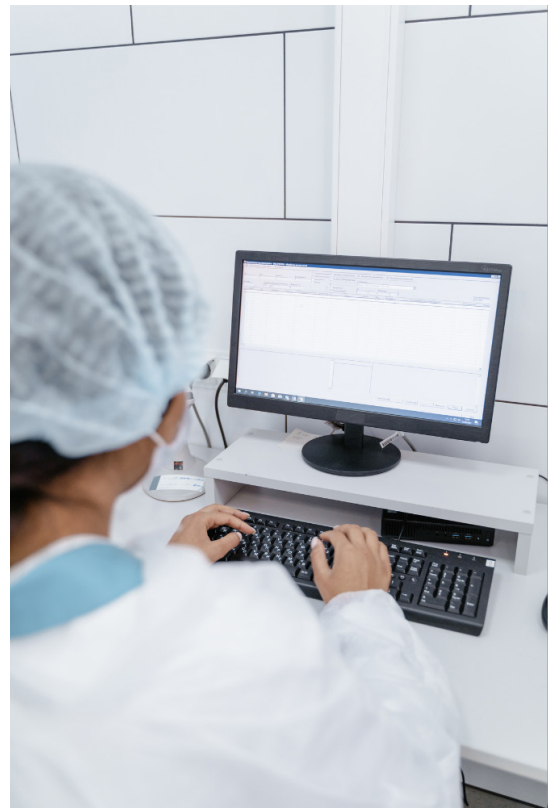
<https://logtag.com>

What is FDA 21 CFR Part 11?

21 CFR Part 11 is a regulation set forth by the U.S. Food and Drug Administration (FDA) that governs the use of electronic records and electronic signatures in the pharmaceutical, biotechnology, and healthcare industries. This regulation ensures that digital documents, electronic records, and electronic signatures are as reliable, trustworthy, and legally binding as traditional paper records and handwritten signatures.

Key Elements of 21 CFR Part 11:

- **Electronic Records:** The regulation ensures that electronic records are trustworthy, reliable, and equivalent to paper records.
- **Electronic Signatures:** It mandates that electronic signatures be used in a manner that ensures their authenticity and integrity.
- **Audit Trails:** Systems handling these records must have secure audit trails that document changes or modifications.



Compliance with 21 CFR Part 11 is critical in ensuring that electronic records and signatures used in the manufacturing, testing, and distribution of regulated products (e.g., pharmaceuticals, biologics, and medical devices) meet regulatory standards.

How LogTag Complies with 21 CFR Part 11

LogTag provides full support for 21 CFR Part 11 compliance through its Digital Signature Suite, which enhances the functionality of LogTag Analyzer to meet all the necessary regulatory requirements.

LogTag Digital Signature Suite

The LogTag Digital Signature Suite is a powerful tool that ensures that LogTag Analyzer complies with FDA 21 CFR Part 11. It facilitates secure, authenticated, and traceable digital signatures on all data files handled by the LogTag Analyzer, ensuring that these files meet the highest regulatory

Key Features of LogTag Digital Signature Suite:

- **Secure Signatures:** Reduces the risk of signature fraud and ensures all digital signatures are authentic and reliable.
- **User Authentication:** Requires unique usernames and passwords for users, ensuring only authorized personnel can access and sign data files.
- **Audit Trails:** Maintains a comprehensive audit log of all user activities, ensuring full traceability and accountability for each action taken within the system.
- **Permanent Signatures:** Once a digital signature is applied, it becomes a permanent part of the file and cannot be removed, ensuring data integrity.
- **Multiple Signatures:** Supports the application of multiple signatures on a single file, allowing for different stages of review and approval, enhancing the approval process.
- **Regulatory Alignment:** The suite is specifically designed to adhere to FDA regulations governing electronic records and electronic signatures, ensuring compliance in regulated environments.

What the Digital Signature Suite Applies to LogTag Analyzer

The **Digital Signature Suite** integrates seamlessly into **LogTag Analyzer**, providing enhanced functionality for managing electronic records and signatures. Here's how it works:

- **Electronic Records Management:** LogTag Analyzer manages and stores data files from LogTag temperature loggers. When the Digital Signature Suite is enabled, it allows users to sign these files digitally, ensuring compliance with 21 CFR Part 11.
- **Signature Information:** Each digital signature applied to a LogTag data file includes:
 - The printed name of the signer
 - The date and time the signature was applied
 - The reason for the signature (e.g., review, approval, or authorship)
- **User Authentication:** To apply signatures, users must log in using a unique username and password, ensuring only authorized individuals can sign data files. This user authentication system is robust, preventing unauthorized access to the system.

Scan the QR codes below to access the **Digital Signatures** page or **LogTag Analyzer**. There, you will be able to download the relevant user guides and access the LogTag Analyzer software or the Digital Signatures Suite User Server.

LogTag Digital Signature Suite
(User Server)



LogTag Analyzer
(Software)



Setting Up the Digital Signature Suite

LogTag have ensured integrating the Digital Signature Suite into LogTag Analyzer is a straightforward process:

- 1. Install the LogTag User Server:** This software manages user authentication and signature tracking across all instances of LogTag Analyzer in your network. The server can be installed on a central server or even on the same machine as LogTag Analyzer.
- 2. Configure LogTag Analyzer:** Once the User Server is set up, LogTag Analyzer can be configured to connect to it. This enables all the signature and user authentication functionality required for 21 CFR Part 11 compliance.
- 3. User Login and Authentication:** Each user must log in with a unique username and password. All actions, including signatures, will be tracked and recorded in the audit logs.
- 4. Audit Trails and Signatures:** As data files are processed, digital signatures can be applied. The audit trail records all user actions and signature applications, ensuring traceability and compliance.

Digital Signatures User Guide

For instructions on how to install and set up the LogTag Digital Signature Suite, please scan the QR code to access the full LogTag Digital Signatures User Guide. Here, you'll also find detailed information on how LogTag ensures compliance with FDA 21 CFR Part 11.



**Digital Signatures
User Guide**