Lab Instrument Upgrade Package
21 CFR Part 11

Lumetics Inc. specializes in advanced software solutions for the pharmaceutical industry.

The **Lumetics LINK™** platform is a 21 CFR Part 11 compliant data management, analysis, and reporting system designed to process and store large volumes of data produced by laboratory instrumentation.

Development and Analytical Teams:
Use LINK to gain deeper insights and achieve significant time savings by:

- Automating data extraction directly from instrument files
- Applying advanced, proprietary analysis algorithms
- Compiling results into fully customized, client-specific reports

The platform also provides interactive access to project charts, tables, and images, supporting detailed data interrogation, and advanced analytical development.

IT/Automation Teams:
Use LINK to deliver a fully automated ELT (Extract, Load, Transform) solution capable of processing data from all laboratory instruments, with seamless integration into existing LIMS/ELN systems and specialty analytics tools such as SAS JMP and Spotfire.

Instrument Vendors:
Use LINK White-Label APIs to rapidly achieve regulatory compliance for their instrumentation, and/or equip their platforms with the entire suite of LINK data visualization, analysis, interrogation and reporting capabilities.

Lumetics White-Label API

Full 21 CFR Part 11 compliance for laboratory instruments within 2–4 weeks, leveraging a proven solution that has been successfully validated and deployed across the pharmaceutical industry.

Instrument software will be upgraded to include:

- Secure end-user authentication utilizing on-premises LDAP and Windows Active Directory (AD)
- User group management and role-based access control, with a fully configurable User Privileges Matrix encompassing all critical instrument features and functions
- Electronic signatures (e-signatures) compliant with regulatory requirements
- Change control functionality to track and manage system and data modifications
- A comprehensive audit trail that is fully searchable and exportable

Value Recipient

Instrument Vendors: Vendors with non-compliant instrumentation seeking to rapidly enter the pharmaceutical market or expand the use of early-stage R&D instruments into cGMP-regulated environments.

Pharmaceutical Quality & Development Teams: Organizations aiming to transition entire laboratories—or specific product characterization assays—into cGMP compliance in order to meet FDA regulatory requirements.

Solution Overview

Lumetics provides a local, on-premises LINK server and database instance that interfaces with one or more instruments via a RESTful API. This integration enables instrument software to leverage the full Lumetics LINK 21 CFR Part 11 compliance feature set.

As part of the implementation, Lumetics supplies:

- Integration-ready syntax examples written in instrument software source code covering all key compliance elements
- A preconfigured LINK server/database, including a User Privileges Matrix with five user group levels and their access privileges to all requisite instrument configuration and operational functions
- A fully featured, browser-based User Privileges Matrix and Audit Trail interface, which can be launched directly from within the instrument software

Next Steps

1. Provide Lumetics with details of key instrument functions that require user group access control, along with sample data file outputs
2. Implement the code snippets provided by Lumetics within the appropriate functional areas in the instrument software
3. Deploy a 21 CFR Part 11 compliant instrument upgrade to your customers

Contact Lumetics to discuss your application

www.lumetics.com • info@lumetics.com • 1.613.417.1839

Additional Compliance Details...

Secure End-User Login

Instrument software users are authenticated using on-premises LDAP/LDAPS via Windows login, with software access controlled through membership in Windows Active Directory (AD) user groups.

Configurable User Group Levels

Precisely control access to instrument setup, operation, analysis, and reporting functions for each user group (e.g., Administrator, System Owner, Scientist, Analyst, Reviewer). The User Privileges Matrix enables full customization of each installation to align with specific laboratory workflows.

Lumetics LINK Permissions Matrix (Default Settings)

Area	Topic	Action(s)	Administrator	System Owner	Scientist	Analyst	Reviewer
Audit Trail	Access	Access Audit Trail	Y	Y	Y	Y	N
	Export	Export Audit Trail	Y	Y	Y	Y	N
	Reset	Reset Audit Trail	Y	N	N	N	N
	Optimization	Record	N	N	N	N	N
Data Collection	Run Experiment	Run Experiment Results	Y	Y	Y	Y	N
	Run Method Experiment	Record Method Experiment Results	Y	Y	Y	N	N
	System Suitability	Record System Suitability Results	Y	Y	N	N	N
Data Recording	Save Experiment	Save Experiment Data	Y	Y	Y	Y	N
	Save Method Experiment Data	Save Method Experiment Data	Y	Y	Y	N	N
	Save Optimization	Save Optimization Data	Y	Y	Y	N	N

Electronic Signatures

Require users to provide their password and rationale for any changes that could impact analytical results, ensuring compliance with regulatory requirements.

Audit Trail Traceability

Capture all relevant system activity requiring traceability, including e-signature events, within a fully searchable and exportable audit trail.