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DATE EFFECTIVE:
SUPERSEDES
SUBJECT: VL-Series Product Design & GMP / CFR 21 Part 11 Compliance

1. Objective

To document the level of compliance of the Veriteq VL-series data logging system and vLog Software products with the Good Manufacturing Practice (GMP) regulations under “1998 CFR Title 21 Part 11 Electronic Records/Electronic Signatures”.

2. Scope

Applies to Veriteq VL-series data loggers (VL-1000 and VL-2000) and vLog Software products.

3. Overview

Pharmaceutical companies are required to validate and monitor their various systems and processes to comply with GMP requirements. Before using the VL-series products, companies must determine whether the system will produce records that they can submit to the FDA. The primary concern is how the VL-system uses electronic records and how this use compares to the FDA requirements for electronic records laid out in CFR 21 Part 11.

4. Responsibility

It is the responsibility of the persons using the VL-series products in FDA-regulated environments to fully understand the VL-series product operation, the applicable GMP documentation requirements, and to follow approved operating procedures.

5. Product Description

- 1) The VL-series data logger and software system is a set of temperature and humidity recording tools that have been designed for use within the framework of a company’s GMP-compliant record-keeping and documentation system.
- 2) The VL-series system is designed to produce paper-based data logging records that can form part of a GMP-compliant documentation package. As a part of this process, the system creates secure electronic records that are subject to the requirements of 1998 CFR 21 Part 11 requirements.
- 3) The electronic records that the VL-series system generates are not required to be maintained or submitted to the FDA as part of a documentation package. The electronic records are, instead, used to

create paper records that are reviewed, approved, archived, and submitted by the responsible individuals. The unalterable electronic records must be archived to support future FDA reviews.

6. Summary of Compliance

- 1) The following table summarizes the key GMP requirements and how the VL-series system meets those requirements.

Requirement	Reference	VL-Series Features
All records shall be prepared, dated and signed (full signature, handwritten) by one person and independently checked, dated and signed by a second person.	<i>GMP 211.186</i>	<ul style="list-style-type: none"> • Password-protected system outputs paper-based records with appropriate form for review and approval sign-offs.
Electronic records may be considered trustworthy and reliable and be used in lieu of paper records provided that the electronic records have proper security controls.	<i>CFR 21 Part 11; Subpart A – Sec. 11.1 Scope</i>	<ul style="list-style-type: none"> • Software produces secure password-protected and encrypted electronic records that are used to produce printed documentation • Software recognizes invalid or altered logger files and renders them completely unusable
Ensure the authenticity and integrity of the electronic records such that the person responsible for the electronic record cannot readily repudiate the record as not genuine	<i>CFR 21 Part 11; Subpart B – Sec. 11.10</i>	<ul style="list-style-type: none"> • Tamper-proof data logger (no switches or buttons) • Password-protected calibration record verifies integrity of recorded data • Password protection ensures that person who created electronic record is the same person who outputs a paper record
Ensure that the system can discern invalid or altered electronic records	<i>CFR 21 Part 11; Subpart B; Sec. 11.10 (a)</i>	<ul style="list-style-type: none"> • Software recognizes invalid or altered logger files and renders them completely unusable
Ensure that complete and accurate records in both human readable and electronic form are available for review and inspection by FDA	<i>CFR 21 Part 11; Subpart B; Sec. 11.10 (b)</i>	<ul style="list-style-type: none"> • Original raw electronic record is never modified and can be printed for review and inspection

Questions and Answers about Veriteq vLog Software

Does Veriteq have a secure “audit trail” function?

An audit trail is, in simple terms, a record showing who has accessed a “computer system” and what operations he or she has performed during a given period of time. Audit trails are vital both for maintaining file security and for recovering lost data.

The Veriteq vLog/VL data logging system is based on the creation of secure data logger files that cannot be modified (without rendering the files completely unusable). Because of this unmodifiable nature, there are no operations that are possible to be performed on the electronic data logger record after, or during, file creation. Consequently, the “audit trail” associated with a Veriteq vLog/VL data logger file is confined to one set of entries. All data associated with the electronic data logging record is captured in the data logger file. This data includes:

- the time and date the file was created
- the ID of the creator of the file
- a description of the data logger file
- the serial and model number of the data logger
- the status of the logger file (secure and verified)
- when the logger was last calibrated
- who the logger was last calibrated by
- when the logger is next due for calibration

Can users disable the recording of “audit trail” data in the data logger record?

No. Users cannot disable or modify the content or the way data is written to the electronic record nor can the information be edited or deleted any time during or after the record is created.

Can users change data logger parameters after starting an electronic record?

Any changes made to data logger operating parameters in the middle of a recording session results in the creation of a completely new electronic record. Data in the logger is cleared.

What kind of protection is built into the secure logger files?

The vLog data logger system utilizes distributed encryption to protect files from modification of any type. The Logger (.spl) files contain a 32 bit encryption key (4.3 Billion combinations). The Graph (.spg) files also contain a separate (and different) 32 bit encryption key. The Download password has a separate 160 bit key (1.46E+48 combinations). The Calibration data has a separate 96 bit key (7.92E+28 combinations) stored in the loggers itself. Also, the data is stored in the logger files and graph files as raw binary values - not in a human readable format. All of the keys must be correct before vLog will display VERIFIED and SECURE.