

VL-2000
Veriteq vLog
Qualification Protocol

For Veriteq vLog Version 4.10

Veriteq Instruments, Inc.

Prepared For:
Pharmaceutical Company, Inc.

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1 DOCUMENT OVERVIEW

The purpose of this IQ/OQ protocol is to provide assurance that the Veriteq vLog Data Logging and Reporting System has been set up properly, is functional, and operates with a high degree of integrity, security and reliability.

The Installation Qualification (IQ) protocol template has been designed to ensure that the system, composed of both the hardware and the software, has been installed correctly at the point of use. The Operation Qualification (OQ) protocol template has been designed to ensure that each component of the system performs as intended.

VL-2000 loggers use Coordinated Universal Time (UTC) to create a base time in every logger file. This provides an absolute reference that the Veriteq vLog software uses to display the logger information using the computer's local time zone. Sample files for multiple time zones have been included on the *Veriteq vLog Qualification Protocol CD* in the `\samples\<<timezone>\` directory. When implementing this protocol, use the sample files located in the directory corresponding to the time zone of the computer being used.

The appendices contain printouts of both sample graph files and tabular data listings. For your reference, **Appendix A** lists the passwords for all Veriteq vLog sample files that are supplied on the *Veriteq vLog Qualification Protocol CD*.

A text and binary file editor will be required to complete Section 7.3.2 of this protocol. In the event that such an editor is not available to you, UltraEdit, a text and binary file editor, has been provided with a Single User license on the *Veriteq vLog Qualification Protocol CD*, in the directory `\UltraEdit\`. The file *RegInfo.txt*, located in the same directory, contains the user name and software key for the Single User license. For instructions on using this program, refer to the help file that comes with the UltraEdit software.

This document is provided in Word document format for customization, and is located on *Qualification Protocol CD* in the directory `\Qualification Protocol\`.