LVS-95XX Series

21 CFR Part 11 Compliance Explained

CFR is an abbreviation for Code of Federal Regulations and is used by the U.S. government to define legal regulations. 21 CFR is the general classification within the regulation. Part 11 is the part that defines what we are concerned about in 21 CFR. Part 11 refers to the entire 21 CFR Part 11; it defines the record keeping of testing as it relates to the process of making drugs, medical equipment, etc. 21 CFR Part 11 covers the paperwork trail necessary in tracking the production life cycle of items being manufactured, including the signatures of the Quality Control representatives, indicating that a process was completed and tested, and either meets the standards or does not meet the standards. In the past, these records were on paper, which became the permanent part of the records required by the Food and Drug Administration (FDA) should they need to examine the production process for any reason.

Now, record processing is performed electronically so there is no paper trail for the FDA to examine. Part 11 addresses this issue by providing an electronic signature of the test performed.

The LVS-95XX and 21 CFR Part 11

On the LVS-95XX Barcode Verifier, user names and passwords must be entered, which constitutes an electronic signature. There are a number of requirements the LVS-95XX also meets, such as keeping track of detail records, audit trails of the changes, and more, all of which are required by Part 11. Omron Microscan states that our systems are Compli-ant READY. We do not say they are COMPLIANT; there is a big difference between the two statements. If an item is COMPLIANT, it must be registered with the FDA and meet extensive requirements that are not the remit of the LVS-95XX product. The LVS-95XX is a Commercial Off-The-Shelf product (COTS), meaning it is not customized to any system; it is as it is. Buyers of the system are responsible for the integration and validation of the LVS-95XX product into their compliant system.

National Guidelines

The buying organization of the system with FDA compliance is responsible to the FDA for validation; they need to have in place the procedural and administrative controls as required by cGMP, ISPE GAMP®, FDA or other National guidelines. The LVS-95XX has the required abilities to meet the requirements to make the system compliant by the purchasing organization. This includes, but is not limited to the following:

- Ensures accuracy, reliability and consistent intended performance
- The ability to generate accurate, complete copies of records in human readable and electronic form suitable for inspection, review, and copying
- Limiting system access to authorized individuals
- Use of secure, computer-generated, time -stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records
- Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, or perform operations at hand
- Record changes shall not obscure previous recorded data

Omron Microscan has available for separate purchase a Validation Procedure Outline that covers Installation Qualification (IQ) and Operational Qualification (OQ) protocol. The outline is available for purchase and use by the buying organization to customize for their validations protocol.

About Omron Microscan

Omron Microscan designs, develops and manufactures print quality vision inspection systems, leveraging our patented methodology in barcode imaging and ISO (ANSI) barcode grading. Omron Microscan has installations in over 40 countries and maintains a commitment to our customers, to the print industry, and to the excellence of the vision products we produce. Omron Microscan is ISO 9001:2008-registered and is proud to be a GS1 US Solution Partner.

GS1 US Solution Partner

TÜV USA Member of TÜV NORD Group ISO 9001 Registered

OMRON MICROSCAN