

How InfiniVault™ Meets FDA 21 CFR 11 Requirements

The InfiniVault Archive Appliance from ProStor Systems provides significant economic advantage in archiving of information and meets multiple regulatory compliance requirements. FDA 21 CFR 11 is one of the compliance regulations that InfiniVault can automate for customers.

In March of 1997 the Food and Drug Administration issued regulations that provide criteria for acceptance by the FDA of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records.

The regulations were intended to permit the widest possible use of electronic technology. The Food and Drug Administration's concept is that an electronic record is not created until it is stored on durable media. Subsequent to issuance, the FDA has published a compliance policy guide, enforcement guide, and additional detailed guidance documents.

Information Storage Requirements for FDA 21 CFR 11

The elements of FDA 21 CFR 11 that pertain to information and how the ProStor InfiniVault meets the requirements are noted in the following table:

Action	InfiniVault Solution
Limit system access to authorized individuals	InfiniVault requires that authentication be established to allow authorized access to information contained within the InfiniVault archive. Passwords are required for identification and for access to administrative functions InfiniVault and will be timed-out due to inactivity.
Audit Trail of Access	InfiniVault keeps an audit trail log of every action taken on a file. The audit trail includes information about the ingestion, every access subsequent, the cartridges and locations where the file resides, and the retention period and actions performed and the final disposition of the file. The FDA regulations also specify the audit trail be time-stamped which the InfiniVault provides. The audit trail provides a complete chain-of-custody for all financial records that are archived.
Retention of records	Ingested files are put into independent archives within InfiniVault and with the archives multiple folders may be configured. Each folder within an archive has a retention period setting. Files will be retained until that retention period expires.
Authenticity - protect from alteration or destruction	InfiniVault stores archived financial data in WORM (Write Once Read Many) mode both in the Active Archive and on the RDX® removable cartridges. The hardware enforced WORM on the cartridges ensures that the data cannot be altered or deleted until the retention period has expired. Additionally, a hash algorithm is performed on the data to product a unique Content Address that is used to verify that no data has been changed during any transmission or storage operation.
Data security of system	InfiniVault ensures authenticity and integrity of the data through protections using WORM and a content address has code. In addition confidentiality is assured when required with encryption of the data.

Summary

The FDA 21 CFR 11 was instituted to enable the transition from paper to electronic records and still maintain the integrity and accuracy that was required. The enforcement was graduated to allow for companies institute complying systems. At this point, enforcement has become a focus for the FDA and compliance is no longer a tomorrow issue.

InfiniVault provides a very simple means to meet all the legal requirements while providing significant economic benefits for archiving of data. The excuses of cost and complexity to meet the legal requirements cannot be used when a solution such as the ProStor InfiniVault is available.



InfiniVault™ Product Family