21 CFR Part 11 Information

U. S. Food & Drug Administration

Overview Information

In April '02, the Food & Drug Administration (FDA) published an update to their final rule for electronic records and signatures. The final rule is known as '**21 CFR Part 11**' where the '21 CFR' refers to Title 21 of the **Code of Federal Regulations**.

The objectives of the final rule are: i) capability to prevent unauthorized changes to electronic records, ii) retention of electronic records, iii) authentication of users with access rights to data, and iv) monitoring of all electronic signatures, In a nutshell, the FDA wants a comprehensive electronic record audit trail that reveals who did what, where, when, and for what reason.

The content of the rule explains under what conditions the FDA will consider electronic signatures and electronic records to be trustworthy and reliable. It defines the conditions under which an enterprise must operate to meet record keeping and record submission requirements.

Implications for IT management

When an organization under the jurisdiction of 21 CFR Part 11 elects to begin using electronic records and electronic signatures, the requirements of the final rule must be met in full for all relevant electronic records. 'Electronic record' is defined as any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Important data integrity-related benefits realized by implementing 21 CFR Part 11 requirements include:

- **Risk avoidance** – *the enterprise is always well prepared for FDA inspections and is therefore able to avoid fines and penalties. This is achieved because computer systems, controls, and attendant documentation subject to, FDA inspection will be readily available for such an inspection.*
- **Improved quality** – *the enterprise saves the waste/cost associated with unreliable data quality.*

Although the use of electronic records as well as their submission to the FDA is currently voluntary, the benefits provide an eloquent argument for embracing early 21 CFR Part 11 implementation.

How Unbeaten Path can help

- ☑ **Bill of Health**™ provides 50 robust assessment reports describing your iSeries security status together with a competent prescription to address each identified vulnerability.
- ☑ **Stitch-in-Time**® **Data Integrity Software** quickly and decisively responds to audit challenges about the security of your data. If an unauthorized change was executed in a critical file, Stitch-in-Time provides comprehensive information to enable analysis of that change.
- ☑ **Stocking Stuffers**™ **for SOX** are a collection of products designed to work with BPCS software that can help internal or external auditors to gather evidence about the integrity of your internal control environment.

Enterprises under the jurisdiction of 21 CFR Part 11

Compliance is required of FDA-regulated companies involved in the development, manufacturing and marketing of life sciences products, including pharmaceuticals, diagnostics, biotechnology, and medical devices. It applies both to the manufacturer and to the suppliers who are selling materials to the manufacturer; should a supplier not be in compliance, then both the vendor and the manufacturer face penalties as specified in the final rule.

21 CFR Part 11 jurisdiction also includes all companies operating under GMP, GLP, or GCP guidelines.

Interesting excerpts from the final rule

The rules define a 'closed system' as an environment in which system access is controlled by persons who are responsible for the content of electronic records stored on the system. Enterprises who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:

a. *Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.*

b. *Protection of records to enable their accurate and ready retrieval throughout the records retention period.*

c. *Limiting system access to authorized individuals.*

d. *Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.*

e. *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. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records … .*

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

f. *Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.*

g. *Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).*

The entire content of the final rule

The Food & Drug Administration web site provides access to the full text of the final rule. **go-see-it**