Principles of Software Validation and 21 CFR Part 11 Compliance

By Daniel Bolland and Justin Miller

Editor's Note: Daniel Bolland and Justin Miller have collaborated on this article to bring us a dual perspective in this primer on how PeopleSoft EnterpriseOne® addresses the ever-increasing requirements for accountability in our enterprise applications. This article discusses the regulations for both automated and manual procedures and gives us an introduction to the mechanics of EnterpriseOne's Audit Management features.

*Food for thought: This EnterpriseOne feature is useful to meet **Sarbanes-Oxley** requirements. For that matter, the audit functionality is useful to serve standard audit practices that existed prior to all the recent legislation. While this article addresses the audit functionality in EnterpriseOne, It should also be noted that there is an equivalent audit feature for World® users.*

What is 21 CFR Part 11?

Issued by the US FDA (Food & Drug Administration) in 1997 the 21 CFR Part 11 final rule is intended to permit the widest possible use of electronic technology.

21 CFR Part 11 establishes the criteria under which electronic records and electronic signatures will be considered equivalent to paper records and handwritten signatures. The rule applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in FDA regulations.

The regulations set forth in 21 CFR Part 11 have eight main requirements, which can be summarized as: **Computer systems must be validated to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.** This includes software used in implementation of the device manufacturer's quality system (e.g., software that records and maintains the device history record) - labeling, packaging, distribution, complaint handling, etc. Computer systems that create, modify, and maintain electronic records and to manage electronic signatures are also subject to validation requirements.

The FDA expects companies to, at a minimum, perform a review of all systems and a plan of action to bring its sites into compliance with the regulations.

The 8 main points of the regulations are:

1. Validation is required for all systems. Validation is “a process of verification and qualification conducted throughout the life of a computer system that results in the establishment of documented evidence that provides a high degree of assurance that the system will consistently fulfill requirements”.

2. Accurate reproductions of original records.

3. Access controls on the system.

4. Computer-generated, time-stamped audit trails of electronic record “actions”. This requires that information relative to a data transaction (such as a person performing the transaction, the date/time, and reason) be linked to original data for all transactions involving data modification.

5. Sequence, location, and authority checks.

6. Adequate training for developers.

7. Written discipline policies.

8. Document control & life cycle methodology.

What do I have to do to ensure that my software is Validated, and secondly, complies with the FDA's 21 CFR Part 11?

The FDA is looking for companies to review all systems and create a detailed plan describing how you will come into compliance with the regulation. Remember, validation is the organization's responsibility; all an ERP package can do is to offer tools that are designed to make validation easier. Here are some of the typical contents of a good validation plan:

- Risk Assessment
- Validation Team
- Validation Plan
- Development Analysis
  - Issue Log
  - Requirements Definition
  - Systems Design Document
- Risk Assessment Update
- Manuals/ Procedures
- Users Manual
- Operators Manual
- Training
- Qualification
  - Installation Qualification (IQ)
  - Operational Qualification (OQ)
  - Performance Qualification (PQ)
- Qualification Documentation
- Qualification Test Cases
- Qualification Reports
- Traceability
- Validation Final Report
- Validation Package
- On-Going Use and Maintenance
- Periodic Audits
- Change Control Procedures
- Decommissioning

What does Peoplesoft EnterpriseOne offer to help validate and become 21 CFR Part 11 compliant?

1. Required validation for all systems.
   Validation became a much more (yet not totally) automated with AutoPilot / Solution Modeler / Scripting Tool. With questions, scripts, image capture, and custom reports, users can detect missing, incorrect, or altered data from many of Peoplesoft's files.

2. Accurate reproductions of original records.