

# PeopleSoft Enterprise Learning Management: Achieving FDA 21 CFR Part 11 Compliance

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**PEOPLESOFT ENTERPRISE**

# PeopleSoft Enterprise Learning Management: Achieving FDA 21 CFR Part 11 Compliance

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# PeopleSoft Enterprise Learning Management: Achieving FDA 21 CFR Part 11 Compliance

**ELM 9.0 is our solution for organizations  
providing learning in a regulated industry**

## **EXECUTIVE OVERVIEW**

Food and Drug Administration Title 21 Code of Federal Regulations (CFR) Part 11 sets the criteria for how electronic records and signatures should be evaluated by the FDA. Organizations doing business in a regulated industry are seeking solutions from their strategic technology partners to enable efficiency and effectiveness in meeting business requirements.

PeopleSoft Enterprise Learning Management (ELM) 9.0 is our solution for organizations providing learning in a regulated industry. Organizations can use PeopleSoft ELM to meet specific 21 CFR Part 11 and predicate requirements, plus general corporate learning needs, with one robust, integrated solution.

This whitepaper describes the need for compliance with FDA 21 CFR Part 11 requirements and specifically describes how PeopleSoft ELM helps customers meet these compliance requirements. The capabilities described herein are contained in PeopleSoft ELM 9.0, which became generally available in April 2006.

## **INTRODUCTION**

The global regulatory climate imposes a burden on corporations to validate that employee performance is in compliance with multinational statutes and regulations. The Food and Drug Administration 21 CFR Part 11, the Occupational Safety and Health Act (OSHA), the Health Insurance Portability and Accountability Act (HIPAA), and recently added scrutiny by the Security and Exchange Commission (SEC) on corporate accounting practices are just a few examples of the growing impact of the cross-industry regulatory environment on businesses.

Failure to adhere to these compliance rules in some cases can result in heavy fines, sanctions, and potentially the dissolution of the organization. As such, certification tracking is seldom optional for organizations, and in many cases is central to the way they do business.

Organizations doing business in a regulated industry are seeking solutions from their strategic technology partners to enable efficiency and effectiveness in meeting business requirements.

PeopleSoft ELM enables you to reduce learning costs and improve productivity

## WHAT IS PEOPLESOFT ELM?

PeopleSoft ELM is a Learning Management System that dramatically improves workforce performance.

Part of the PeopleSoft Human Capital Management (HCM) product family, PeopleSoft ELM is an internet-based solution that automatically recommends intelligent learning to people based on business goals and events. It is designed from the ground up to deploy the right learning to the right person at the right time, in any learning medium, via a single user interface. PeopleSoft ELM enables you to reduce learning costs and improve productivity by streamlining your learning process and embedding learning into all your critical business processes.

### All Learning

All Learning is a list of the activities you are enrolled in or completed and curricula and certifications for which you are registered or completed. You can view details, progress status, and schedules by clicking on the name of the activity or program.

\*Search Filter:

My Learning				
Title	Type		Status	Date
<a href="#">A Manager's Primer</a>	External Vendor Self Paced	<input checked="" type="checkbox"/>	Completed	02/07/2006
<a href="#">Business Fundamentals I</a>	External Vendor Self Paced	<input checked="" type="checkbox"/>	Completed	02/07/2006
<a href="#">Business Fundamentals II</a>	External Vendor Self Paced	<input checked="" type="checkbox"/>	Completed	02/07/2006
<a href="#">A Manager's Primer</a>	External Vendor Self Paced	<input checked="" type="checkbox"/>	Completed	02/07/2006
<a href="#">Business Management</a>	Certification	<input checked="" type="checkbox"/>	Completed	02/07/2006
<a href="#">Manage Development Level 01 Curriculum</a>	Curriculum	<input checked="" type="checkbox"/>	Completed	02/07/2006

[My Learning](#) [Search Catalog](#) [Browse Catalog](#) [Request New Learning](#)

Figure 1. PeopleSoft ELM Learner interface

## WHAT IS 21 CFR PART 11?

CFR Title 21 is a set of Food and Drug regulations and Part 11 sets the criteria for how electronic records and signatures should be evaluated by the FDA

The U.S. Department of Health & Human Services (HHS) is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The Food and Drug Administration (FDA) is the part of HHS that focuses on food and drug safety. Code of Federal Regulations (CFR) Title 21 is a set of Food and Drug regulations and Part 11 sets the criteria for how electronic records and signatures should be evaluated by the FDA. These regulations were written in 1997.

21 CFR Part 11 does not require that organizations begin using electronic records and signatures, but only that they regulate such usage. The FDA measures compliance using the rules outlined in Part 11 for the organizations that use electronic records and electronic signatures in addition to, or in lieu of, handwritten documents and handwritten signatures.

**21 CFR Part 11 relies on predicate rules such as GMP, GLM and GCP**

Because regulation enforcement history is very short, many of the rules that 21 CFR Part 11 has set forth are up for interpretation by the organizations falling under the compliance standards and the persons performing the audit from the FDA. Many organizations do not know the full extent of the meaning of compliance for these regulations until they are audited.

21 CFR Part 11 does not set the rules from the ground up. Instead they rely on “predicate rules,” with which organizations already operate, as a basis. These rules can include good manufacturing practice (GMP), good laboratory practice (GLP), and good clinical practice (GCP) rules.

The predicate rules define to what data, or to what records, 21 CFR Part 11 applies. For example, Part 11 does not state that there is a need for a reason code in certain places when a change is made to a record, but the GxP, predicate rule might require that a reason be given for the change. Another example is the predicate rules may also state where an electronic signature is needed. 21 CFR Part 11 builds guidelines around how electronic records and signatures are to be handled, but not necessarily where they need to be used.

## **Definitions**

This section covers PeopleSoft’s definitions for some of the terms and phrases used in defining the requirements for 21 CFR Part 11. The requirements cover several major areas: electronic records, electronic signatures, system security, and computer system validation and procedural issues.

### **Electronic Records**

Part 11 defines an electronic record 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. As a general rule electronic records are those records required for submission or in support of the data that is submitted to the FDA. Records that are submitted typically deal with anything that affects the quality of the product. Examples of electronic records are bills of material, routings, and container and lot information.

### **Electronic Signatures**

Part 11 defines an electronic signature as: a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature.

### **Digital Signature**

A digital signature is an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity for the signer and the integrity of the data can be verified, typically using a public and private key pair.

**Handwritten signature**

A handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate writing in a permanent form. The act of signing with a writing or marking instrument, such as a pen or stylus, is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices to capture the name or mark.

**Open system**

An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

**Closed system**

An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

**PEOPLESOFT ELM'S FDA 21 CFR PART 11 COMPLIANCE STRATEGY****Meeting Industry Needs**

The life science industry is unique in many aspects. A software company looking to build an IT infrastructure for a life science customer needs to look at many functions of the organization and what they focus on—functions like government regulation, lot management, container management, serial control, and all the functions that go with a manufacturing execution system (MES), or batch/recipe management systems. PeopleSoft will continue to focus on regulatory and other drivers of functionality for this industry.

No vendor can claim that his or her software products are certified Part 11 compliant. A vendor, instead, can say that all of the Technical Controls for 21 CFR Part 11 compliance are built into the product. Remember, it is the responsibility of the user to implement the Procedural and Administrative Controls and to use products with the correct Technical Controls for overall Part 11 compliance.

PeopleSoft is committed to supporting FDA regulations and helping our customers validate for compliance. The commitment includes the development of solutions for 21 CFR Part 11 requirements, including:

**PeopleSoft is committed to supporting  
FDA regulations and helping our  
customers validate for compliance**

**Meeting Electronic Records Requirements**

PeopleSoft stores electronic records and maintains an audit trail with an electronic signature and time stamp. The stored and maintained electronic records are the ones needed and submitted to the FDA for compliance as outlined by the predicate rules. As a general rule, any record in the system that affects regulatory submissions, safety, or quality, will be traced back to production sources to satisfy business requirements such as recall of a product for medical reasons. For example,

during an audit, the electronic records, signatures, and an audit trail that deals with bills of material, routings, and lot and container information might be submitted.

PeopleSoft provides an archival process to handle the amounts of data that will need to be stored and retrieved for audit purposes. Reporting and query tools can be used for retrieving the data.

**Electronic signatures are attached to each electronic record where mandated and stored in the audit file with the executable time stamp**

### **Meeting Electronic Signature Requirements**

PeopleSoft requires the user to enter a password to act as a valid electronic signature for that user when required. When the user is entering data that requires an electronic signature, PeopleSoft will prompt the user for their password. Electronic signatures will be attached to each electronic record where mandated and stored in the audit file with the executable time stamp. In some cases multiple signatures will be required. PeopleSoft uses automated workflow functionality to capture multiple signatures and write to an audit file.

PeopleSoft requires that user ID and password combinations are unique to each user. Using our standard PeopleTools-delivered software, system managers can use a user ID/password workbench to ensure that reassignment of passwords and user ID combinations are forbidden.

### **Meeting System Validation Requirements**

The FDA does not validate the software providers that provide software to life science organizations, but they do require the organizations being audited to validate the software they are using. The organizations being audited need to ensure and show documentation that computerized systems conform to the FDA's established requirements for completeness, accuracy, and reliability, and are consistent with the intended use and development purpose.

System documentation should be readily available at the site where the audit is being performed. Such documentation should provide an overall description of computerized systems, and the design of the system, and the reason for the design (intended purpose).

PeopleSoft documents the entire life cycle process for the development of our software. We document the business reasons for a design change, the functional purpose, and the technical specifications or changes to the system that will be needed. We also document the testing aspects of our development, and we provide full documentation of the product (user manual) and how it is intended to work.

If an organization chooses to modify the intended use of the software to perform other functions, this needs to be documented by the organization making the modifications. Any changes or upgrades to the software system need to be documented for validation purposes. Software validation is intended to be ongoing, and the PeopleSoft development process supports this level of recurrent audit and control.

To meet the requirements of those organizations in FDA-regulated environments, PeopleSoft assesses our compliance against standards such as GaMP 3 (Good Automated Manufacturing Practices) regulations.

### **Meeting System Security Requirements**

For almost any type of business application, security is critical. This is especially true in core business applications, such as PeopleSoft applications. PeopleSoft provides you with security features, including components and PeopleTools, to ensure that your sensitive application data is secure. Most likely, you will use other security tools for your network and RDBMS. All these tools work together to protect your PeopleSoft system from unauthorized access.

With PeopleSoft you can divide users according to roles. A role is an object that has properties, such as name, description, permission lists, and so on. One of the properties assigned to a role is the list of users assigned to it. For instance, there might be an employee role, a manager role, or an administrator role. Users who belong to a particular role require a specific set of permissions, or authorizations, within your system so that they can complete their daily tasks.

### **Meeting Procedural Regulations**

Some requirements outlined in 21 CFR Part 11 are procedural requirements that an organization manufacturing pharmaceutical drugs, providing clinical trial services, or manufacturing medical devices should follow and thus are outside the scope of the software system.

## **21 CFR PART 11 REQUIREMENTS AND PEOPLESOFT'S RESPONSES**

The statements below will show each requirement for 21 CFR Part 11 and PeopleSoft's response to each. Our responses are based on current functionality primarily in PeopleSoft ELM.

### **General Questions**

#### **Is PeopleSoft considered an Open or Closed system as defined by the FDA?**

PeopleSoft ELM, depending on the implementation, can be considered an open or a closed system. Access controls are created within the system by assigning user IDs and security roles. If only employees use the software with no outside access granted, it will be considered a closed system. Even if users log into their system via WAN or VPN, that system still qualifies as a closed system. If PeopleSoft ELM is deployed and access is granted to outside partners, suppliers, or customers via a portal, for example, the subsystem affected will be considered an open system.

#### **Can using PeopleSoft eliminate the need for handwritten signatures?**

According to regulation 11.2 (a), "For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part,

**PeopleSoft provides you with security features, including components and PeopleTools, to ensure that your sensitive application data is secure**

provided that the requirements of this part are met,” so PeopleSoft ELM users can use electronic signatures in lieu of handwritten signatures.

### **How does PeopleSoft use Electronic and Digital Signatures?**

PeopleSoft uses digitally signed application messages for integrating to third-party systems. We leverage PKI technology to provide these capabilities, including digitally signing web transactions to verify the authenticity and integrity of transaction data, and provide non-repudiation and public key encryption to help address confidentiality.

PeopleSoft ELM requires a user to sign on the system using two distinct components in the ID and password combination. When PeopleSoft ELM requests an electronic signature, the user is re-prompted for their ID and password, or just password to sign an electronic record during a system transaction and during a continuous period of controlled system access.

**When PeopleSoft ELM requests an electronic signature, the user is re-prompted**

### **Verify Identity**

To protect your privacy, verify your identity by typing your password. If you are not this user, click **Sign Out**.

User ID: LMLELM\_TOM\_OUREN  
Password:

*Figure 2. PeopleSoft ELM Electronic Signature prompt*

## **Specific Questions**

### **11.10 Controls for Closed Systems**

**Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed records as not genuine. Such procedures and controls shall include the following:**

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

PeopleSoft follows a documented software development life cycle process, which includes testing and documentation during each build and release cycle.

Customers will be responsible for validation of the software in their environment to ensure it performs for their intended use.

#### **11.10.b The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.**

Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

Reports and queries can be used to display data.

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

PeopleSoft provides an archival process due to the amounts of data that will be collected. This archived data can be retrieved and inquiries and reports can be generated based on this data.

**11.10.d Limiting system access to authorized individuals.**

PeopleSoft's system access security covers the requirement of limiting system access to authorized roles and individual system users.

**11.10.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 and shall be available for agency review and copying.**

PeopleSoft provides audit trail records

PeopleSoft provides audit trail records that capture user ID, time stamp, action (create, delete, modify) and if modify, capture the old and new value. If a predicate rule requires that a reason be given when a change is made to a record, PeopleSoft ELM can capture a reason code

If a predicate rule requires that a reason be given when a change is made to a record, PeopleSoft ELM can capture a reason code

**Status Details**

Curriculum Name:	<a href="#">Basics of Management</a>	Type:	Curriculum
Curriculum Code:	BasMgmt01	Contact:	Allan Martin

Drop Charges of 100 USD will apply. Are you sure you want to drop Margaret Tucker from this program? Please note that the learner will not be dropped from any learning activities in which the learner has enrolled to complete this program -- the learner will need to drop these separately.



**Figure 3. PeopleSoft ELM Reason Code prompt**

**11.10.f Use of operations system checks to enforce permitted sequencing of steps and events, as appropriate.**

PeopleSoft provides an option to enforce permitted sequencing of key system steps and events.

**11.10.g 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.**

PeopleSoft requires a user to sign on the system using two distinct components in the ID and password combination. PeopleSoft calls the electronic signature function to re-prompt the user for their password to sign an electronic record during a system transaction and during a continuous period of controlled system access.

**11.10.h Use of device (e.g. terminal) checks to determine, as appropriate, the validity of the source of data input or operations instruction.**

PeopleSoft has user level security for each signon location.

**11.10.i Determination that persons who develop, maintain, or use electronic record/signature systems have the education, training, and experience to perform their assigned tasks.**

It is the responsibility of the customer's standard operating procedures to ensure there are policies in place to determine that persons, who develop, maintain, or use electronic record/signature systems, have the education, training, and experience to perform their assigned tasks. Security can then be established based on such determination to ensure compliance.

**11.10.j The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification**

It is the responsibility of the customer's standard operating procedures to ensure there are policies in place that hold individuals responsible for actions initiated under their electronic signature.

**11.10.k Use of appropriate controls over systems documentation include:**

**Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.**

It is the responsibility of the customer's standard operating procedures to ensure there are policies in place to control the distribution of, and access to, and use of documentation for system operation and maintenance.

**Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.**

It is the responsibility of the customer's standard operating procedures to ensure there are policies in place for revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation

### **11.30 Controls for Open Systems**

**11.30 Persons who use open 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 from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in Sec. 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.**

PeopleSoft uses digitally signed application messages for integrating to third-party systems. We leverage PKI technology to provide these capabilities, including digitally signing web transactions to verify the authenticity and integrity of transaction data, and providing non-repudiation and public key encryption to help address confidentiality.

### **11.50 Signature Manifestations**

**11.50.a Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:**

**1) The printed name of the signer.**

PeopleSoft requires the password of the person signing the record.

**2) The date and time when the signature was executed.**

A time stamp is generated and captured during the electronic signature and stored in the audit file.

**3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.**

Where appropriate, PeopleSoft uses workflow to capture approvals and reviewers' signatures or will capture both signatures at data entry time. Both are stored in the audit file.

**11.50.b The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).**

Information captured in a.1, 2, 3 is displayed in inquiry displays and report printouts.

## 11.70 Signature/Record Linking

**Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.**

PeopleSoft automatically links electronic signatures to their respective electronic records. For handwritten signatures, operating procedures call for a process to identify handwritten signatures and match that identity with a corresponding identity on an electronic record. Actual handwritten signatures or documents are not stored in the database.

## 11.100 Electronic Signatures General Requirements

**11.100.a Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.**

PeopleSoft security ensures that all user ID and password combinations create a unique signature.

**11.100.b Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.**

It is the customer's responsibility to put in place operating procedures to verify the identity of the individual.

**11.100.c Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be a legally binding equivalent of the signer's handwritten signature.**

PeopleSoft relies on the customer's operating procedures to ensure persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be a legally binding equivalent of the signer's handwritten signature. It is the customer's responsibility to put in place operating procedures to verify the identity of the individual.

**1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lance, Rockville, MD 20857**

PeopleSoft relies on the customer's operating procedures to ensure certification is submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lance, Rockville, MD 20857 .

**2) Persons using electronic signatures shall, upon agency request provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature**

PeopleSoft relies on the customer's operating procedures to ensure persons using electronic signatures will, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

**11.200 Electronic Signature Components and Controls**

**11.200.a Electronic signatures that are not based upon biometrics shall:**

**1) Employ at least two distinct identification components such as an identification code and password.**

PeopleSoft security ensures that all user ID and password combinations create a unique signature, using two distinct components with the ID and password.

**When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.**

PeopleSoft requires a user to sign on the system using two distinct components in the ID and password combination. PeopleSoft calls the electronic signature function to re-prompt the user for their password to sign an electronic record during a system transaction and during a continuous period of controlled system access.

**When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all the electronic signature components.**

PeopleSoft security can be used to log off a user after a certain period of inactivity.

**2) Be used only by their genuine owners; and**

PeopleSoft ELM requires a password to sign an electronic document. It is the responsibility of the customer to implement procedures for distribution and dissemination of these elements.

**3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals**

PeopleSoft ELM requires a password to sign an electronic document. It is the responsibility of the customer to implement procedures for sharing of these elements.

**11.200.b Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.**

PeopleSoft does not intend to provide support for biometric signatures, but this capability may be added by third-party implementation partners in the future.

### **11.300 Controls for Identification Codes/Passwords**

**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:**

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

PeopleSoft security ensures that all user ID and password combinations create a unique identification.

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

PeopleSoft security has the capability to force user ID passwords to be changed periodically.

**11.300.c Following loss management procedures to electronically de-authorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices ... and to issue temporary or permanent replacements using suitable, rigorous controls.**

PeopleSoft relies on the customer's operating procedures to ensure loss management procedures are in place to electronically de-authorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices ... and to issue temporary or permanent replacements using suitable, rigorous controls.

**11.300.d Use of transaction safeguards to prevent unauthorized use of passwords an/or identification codes and to detect and report ... attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.**

PeopleSoft detects attempts to access the system and lock access IDs from use, and provides workflow functionality to notify management when these transactions take place.

**11.300.e Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code and password information to ensure that they function properly and have not been altered in an unauthorized manner.**

PeopleSoft relies on the customer's operating procedures to ensure initial and periodic testing of devices, such as tokens or cards, which bear or generate identification code and password information to ensure that they function properly and have not been altered in an unauthorized manner.

PeopleSoft ELM helps to achieve and maintain regulatory compliance by automating the delivery of mission-critical learning, and by tracking the completion of certifications and the review of standard operating procedures

## Benefits

Failure to adhere to 21 CFR Part 11 requirements can result in fines and business disruption. PeopleSoft ELM helps to achieve and maintain regulatory compliance by automating the delivery of mission-critical learning, and by tracking the completion of certifications and the review of standard operating procedures. Organizations can mitigate risk and increase compliance by ensuring that their policies and procedures are disseminated and understood through PeopleSoft ELM.

The screenshot displays the 'Section Details' and 'Item Details' sections of the PeopleSoft ELM certification administration interface.

**Section Details:**

- \*Section Name:** Business Fundamentals
- Instructions:** Complete the self-paced activities for these courses.
- \*Section Order:** 1
- Items to Complete:** 2

**Item Details:**

Order	Required	Item	Allow Waiver	Historical Credit	Credit Period	Allow Equivalent	
1	<input checked="" type="checkbox"/>	Business Fundamentals I	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
2	<input checked="" type="checkbox"/>	Business Fundamentals II	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	

[+ Add Catalog Item](#)

**Expiration Information:**

- Validity Period:** 0 Days
- Grace Period:** 0 Days
- Expiration Date:**
- Expiration Warning Period:** 0 Days
- Recertification Period:** 0 Days

**Figure 4. PeopleSoft ELM certification administration**

Organizations doing business in a regulated industry are seeking solutions from their strategic technology partners to enable efficiency and effectiveness in meeting business requirements. Utilizing PeopleSoft ELM is one way customers can solve these regulatory challenges, while at the same time benefiting from an integrated learning and HCM solution.

## CONCLUSION

This whitepaper described how PeopleSoft ELM 9.0 helps customers meet their FDA 21 CFR Part 11 compliance needs. Functional capabilities, such as access control, audit capability, flexible certifications, and electronic signatures, allow

customers to meet the technology requirements, while customer-defined processes can complete a regulatory compliance system and process.

PeopleSoft ELM is the result of our extensive experience in the management of human capital assets, customer relationships, supply chain automation, and learning solutions. Built upon this expertise, PeopleSoft ELM gives you powerful technology and the flexibility you need to develop your organization's human capital to its fullest potential and to meet your industry compliance requirements.



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March 2007  
Author: Jonathan Vinoskey

Oracle Corporation  
World Headquarters  
500 Oracle Parkway  
Redwood Shores, CA 94065  
U.S.A.

Worldwide Inquiries:  
Phone: +1.650.506.7000  
Fax: +1.650.506.7200  
[oracle.com](http://oracle.com)

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