

PeopleFluent Learning

CFR Installation Guide

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CFR Installation Pack

The CFR Installation Pack includes:

- CFR Installation Guide (this document)—instructions on how to run the database installation script and prepare the application to support CFR compliance.
- SQL script—a script that will create the database tables and triggers required for CFR auditing functionalities.
- CFR Overview—a document outlining the technical requirements of Title 21 CFR Part 11 and how the functionalities of the application help to meet them.

Notice to Users

This document is subject to revision based on external hardware and software changes; it may be updated periodically to reflect those changes.

PeopleFluent supports and provides defect fixes for PeopleFluent products under valid Support and Maintenance Agreements on only those operating systems and third-party systems that have been certified and published by PeopleFluent. PeopleFluent will not be responsible for providing any defect fixes for non-certified distributions.

Step 1: CFR License

You need a special license to enable CFR related features in the LMS. This document assumes that you have already acquired this license through sales channels and updated it in the *WEB-INF\conf* directory of the LMS application. Please proceed only when the license is in place.

Step 2: Enable Database Auditing

To enable database auditing, you must run the database script provided in the CFR Installation Pack.



Before running the script:

- It is recommended to back up your production database.
- You must install or update PeopleFluent Learning before running the CFR installation script for the same version.
- Stop the web server that is hosting the LMS.

Running the Script

On Windows Systems

1. Edit the db.username and db.password in the build.xml file with the authentication information for executing the database installation scripts.
2. Make sure the JAVA_HOME and TOMCAT_HOME environment variables are set correctly.
3. Execute `install.bat`.

On Linux/Unix Systems

1. Edit the db.username and db.password in the build.xml file with the authentication information for executing database installation scripts.
2. Make sure JAVA_HOME and TOMCAT_HOME environment variables are set correctly.
3. Set execution permission to `install.sh` and `ant` by running `chmod +x install.sh ant`.
4. Execute `install.sh`.

Reverting in Case of Failure

The CFR installation script takes a backup of the original database scripts present in the nschema folder of the installation directory to nschema.backup. In case of failure, the database can be recreated using these scripts and backed-up data can be restored. Please contact PeopleFluent, providing the details of the failure.

Step 3: Configuration

After enabling database auditing, restart the application, log in as a system administrator and configure the system for CFR using the settings described below.

Role Access Controls

- Ensure the access control for *Allow User Deletes* is disabled for all User Roles.
- Ensure that access to the API is disabled so that the application remains a closed system.
- Enable *Compliance Reports*, which provides access to:
 - R501 - Module Completion Target Status
 - R502 - Program Completion Status
 - R503 - Mass Distribution Program Compliance Status (ORG membership based)
 - R504 - Mass Distribution Program Compliance Status (DA-based)
 - R505 - Audit Trail Report
 - R506 - Audit Trail User Action Report
 - R507 - Learning Module Audit Report
 - R508 - User Transcript Audit Report
 - R509 - Module Completion Audit Compliance Report
 - R510 - Module Deadline Completion Percentage by Organization

System Configuration

The *eSignature* category is available for CFR-enabled licenses, under which is the *Learning program completion from* setting. Set this to:

- *Learner*, if programs should be marked complete by the learner, or
- *Instructor*, if programs should be marked complete by the instructor.

Organization Maintenance

PeopleFluent recommends enabling electronic signatures for all required places at the root organization level. If necessary, settings can be customized for individual organizations. The following eSignature settings are available per organization:

- eSignature legal name format
- Enable eSignature for course CSV loader
- Enable eSignature for program CSV loader

- Enable eSignature for when a learner withdraws from a course
- Enable eSignature for course update/delete
- Enable eSignature for course launch
- Enable eSignature for structured course importers
- Enable eSignature for course finish/completed
- Enable eSignature for exam launch
- Enable eSignature for change in question status
- Enable eSignature for question importers
- Enable eSignature for manual grading of test answer
- Enable eSignature when transcript details are modified by a reviewer
- Enable eSignature when transcript details are modified via the catalog editor
- Enable eSignature for transcript attendance details modification
- Enable eSignature when transcript details are modified via the enrollment wizard
- Enable eSignature when editing an external training record
- Enable eSignature for Certification update/delete
- Enable eSignature for awarding/deleting User Certifications

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