



ComplianceWire®

Learner's Guide

Updated: September 2018

Version: 2.4

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Document Version Updates

| Date | Version | Update Details |
|----------------|---------|---|
| June 2016 | 1.0 | Initial Release |
| October 2016 | 2.0 | What's New in this version - 2016R2 |
| April 2017 | 2.1 | What's New in this version - 2017R1 Course Credit. |
| October 2017 | 2.2 | What's New in this version - 2017R2 <ul style="list-style-type: none">▪ Browser Auto-Complete Prevention▪ Updates to Privacy, Privacy, Copyright & Terms of Use Statements▪ Support for Microsoft Edge▪ Added FAQs section |
| May 2018 | 2.3 | What's New in this version - 2018R1 <ul style="list-style-type: none">▪ Forgotten Password Retrieval via Email▪ Platform documents in other languages |
| September 2018 | 2.4 | Updated the Password Security questions section |

What's New in this Version for 2018R1 Release

Forgotten Password Retrieval via Email

If your instance of ComplianceWire in Production had the ability to request a forgotten password via email from the login screen, you will no longer be able to do so after the 2018R1 release.

The system administrator for the ComplianceWire instance may request you to set up answers to password security questions. Upon setting up answers to the security questions, you can then reset the passwords through these security questions. Alternately, you can also submit a request to your system administrator outside of the system.

Platform Documents

With the 2018R1, the ComplianceWire Learner's Guide will be available in Simplified Chinese, Japanese and Korean (if these languages are included in your ComplianceWire instance).

To access the Quick Reference Guides in one of the available languages mentioned above, set the Preferred Language from the Preferences screen and then select **Tools > Platform Documentation**.

The Quick References guides in the language selected will be listed.

Introduction

ComplianceWire is a fully-validated knowledge and Learning Management System (LMS) that facilitates the management of training activities, learner proficiency and compliance status in industries such as *Pharmaceutical, Medical Device, and Biologics*. The software ensures compliance with 21 CFR Part 11 requirements.

System Requirements

| | Support Applications | Notes |
|----------------|--|---|
| Browser | <ul style="list-style-type: none"> Internet Explorer Version 8-11¹ Google Chrome Mozilla Firefox Version 20 & higher² Safari Version 9² Microsoft Edge | <ul style="list-style-type: none"> Course narration is not available for HIP2 CBT Training Type in Firefox and Chrome. Browser must be set to allow cookies. All pop-up blockers should be turned off for best performance. iPhones (or any other types of phones) are not supported at this time. Although not officially supported, we are unaware of any issues running the ComplianceWire software application when using Microsoft Edge or on mobile browsers such as Chrome, Firefox, and Internet Explorer. <p>¹ For Internet Explorer, each user's browser must be set to include .compliancewire.com as a "trusted site." In many cases, an organization's IT department includes the ".compliancewire.com" web address as a trusted site for all users within the organization.</p> <p>² the Auto-complete prevention feature is not supported for Safari browsers (all versions) and Firefox version 52 and beyond. We recognize that browsers can provide upgrades at any time, and our team at UL will continue to monitor these upgrades and their potential impact on our browser auto-complete prevention functionality. In order to maintain 21 CFR Part 11 compliance, we strongly recommend that your IT policies regarding browser upgrades reflect appropriate testing of the browser auto-complete prevention feature.</p> |
| Connectivity | Broadband | Application responsiveness is directly related to the speed of your network and the connection to the internet. Faster internet connections will yield better application performance. |
| Other Software | Adobe Acrobat Reader 1 Shockwave 11 Flash 10 | Acrobat Reader is only necessary when accessing downloadable files. The full version of shockwave is required for some courses. Required for course interactions. |

Browser Auto-Complete Prevention

Clients have historically relied on their company's browser policies to disable the auto-complete feature and maintain Code of Federal Regulations (CFR) Part 11 compliance. This new ComplianceWire feature will help make it easier for clients to adhere to the requirement in Part 11 that states: "... 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." (21 CFR Part 11, Subpart C, Sec. 11.200)."

Although industry standards that govern search engines and website design dictate that auto-population is preferred, we recognize that it presents our clients with challenges maintaining (CFR) Part 11 compliance. In addition to the SOP's, Guidelines and Browser policies that a company may have in place, UL is taking measures to prevent browsers from auto-completion of Username and Password fields in ComplianceWire for native login, change password, and e-signature pages.

Learners and Administrators must manually type in their User ID and Password login credentials in the areas described below.

Learner Functions

- Login page
- Change Password page
- Class Sign-in sheet for an ILC
- All forms that require e-Signatures
- All Training Type completions that require e-Signatures

Browser Support

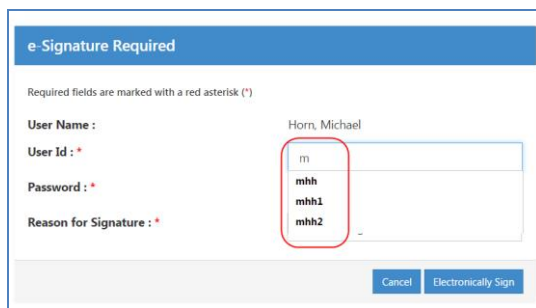
The auto-complete prevention is supported on the following browsers:

- Microsoft Internet Explorer versions 8 through 11
- Microsoft Edge
- Google Chrome

Mozilla Firefox Note: The Apple Safari browser is not supported by the auto-complete prevention feature.

More Information - Browser Auto-Complete Prevention

- The SAML SSO Login and Custom Login pages are not impacted and will continue to function as is with existing capabilities.
- The auto-complete prevention feature does not prevent third-party tools that may be used to store and populate login and e-signature pages.
- The browser will present a suggestions drop-down list for the User ID field as shown in the example below. However, it is necessary to enter the password.



The screenshot shows a web form titled "e-Signature Required". It contains several fields: "User Name" (filled with "Horn, Michael"), "User Id" (with a dropdown menu showing suggestions: "m", "mhh", "mhh1", "mhh2"), "Password", and "Reason for Signature". The "User Id" field is highlighted with a red box. At the bottom of the form are "Cancel" and "Electronically Sign" buttons. A note at the top states "Required fields are marked with a red asterisk (*)".

Logging In

Launch a compatible browser and then enter the supplied web address in the Address field to launch ComplianceWire.

The Login screen displays.

You **must** enter the **User ID, Password,** and **Company Code** to access the system.

Note: Passwords are case-sensitive. If your password has lowercase or UPPERCASE letters, they must be entered in the appropriate case to be able to log in successfully.



First-time access

When you login to ComplianceWire software for the first time, the system prompts you to change the temporary password assigned by the Administrator. Enter the temporary password and then provide a new password. You must **Confirm New Password**.

Note: A password must be greater than 3 characters and less than 12 characters long.

Security Questions

If your Administrator has set up security questions related to your password, you will be prompted to provide answers.

Note: Answers to the security questions are case sensitive. For example, “New york” is not the same as “New York.”

Expired Password

If your password has expired, the system prompts you to change your password before being given access to the system.

After changing the password select **Continue Login** to bring up the Knowledge Center screen.

Forgotten password

Click the **Forgot your password** link to answer security questions for a password reset. When all questions have been answered correctly, you will be logged in and then forced to provide a new password. Answers to the security questions are case sensitive.

Note: This is an optional feature. If you do not see this feature on the Login screen, then it may not be available for your instance of ComplianceWire.

Action Center

Click **I Accept** on the Login screen to display the Action Center.

| Item | Items Due |
|---|-----------|
| "Curriculum Title update" "Curriculum code update" | 29 |
| "cv" "cv" | 25 |
| Assignment via Roster Assignment via Roster | 1 |
| Direct Assignment Direct Assignment | 15 |
| Elective Elective | 1 |

The **Action Center** is available to all users and provides access to training and compliance-related tasks.

The **Training Dashboard** in the above example displays five Training Items that requires the learner's attention (overdue or due soon).

Note: The Date displayed in the header will be based on the user's Operative Time Zone and preferred date format. The UTC offset will be displayed if it is selected as the date format, else the offset is visible when hovering over the date.

Click on the Training Item to launch the course.



Expand or Collapse the Dashboard by clicking the **ACTION CENTER**.



Show or hide the Status Dashboard by clicking on these icons. The Status Dashboard provides an overview of the total Training Items; Assignments that are Overdue, Due Now (within 1 day) or Due Soon.

Tool Bar

The options on the toolbar gives you access to various useful tools about your assignments as shown below.



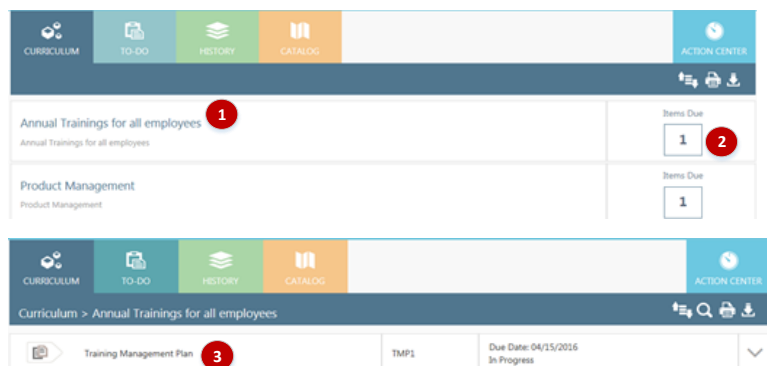
On the right-hand side there are action icons that support the tools:

| | |
|--|--|
| | SORT – arrange the assignment list by ascending/descending order. |
| | SEARCH – locate a specific assignment(s) from the list. The Advanced search allows you to locate an item by Keyword, Title, Course Code or Description. |
| | PRINT – print the assignment list. |
| | DOWNLOAD – save the assignment list to a local or network drive. You save the list as a .CSV or Microsoft Excel format. |

Curriculum View

This view provides a list of assignments due.

1. **Curriculum Title:** Click to list the Training Items due within a specific curriculum.
2. **Items due:** Displays the number of Training Items due for the curriculum title.
3. Click on a curriculum row to list the Training Items item due within a curriculum.



- Click on the Training Item to read more information about the Training Item or to launch, print or add it to your calendar.


The screenshot shows a detail view for a training item titled "Training Management Plan". At the top, it displays the item name, code "TMP1", and due date "04/15/2016" with a status of "In Progress". Below this, there are fields for "Training Type" (STANDARD OPERATING PROCEDURE), "Code" (TMP1), and "Version" (11.0). Further down, it lists "Due Date" (04/15/2016), "Assignment type" (Required Assignment), and "Additional Certificate Text". A "Description" section follows, stating that the document describes strategies for identifying training needs. A "Curriculum" section lists "Annual Trainings for all employees". At the bottom, there are three action buttons: "Launch", "Add to Calendar", and "Print". A red circle with the number "4" is placed over the "Print" button.

To-Do View

This view provides a list of Training Items that are assigned but incomplete.

- Click on an action button to sort items by date, download the "To-Do" list, search for a specific items, or print the list.

The screenshot shows the "To-Do" view of the training system. At the top, there are navigation tabs for "CURRICULUM", "TO-DO", "HISTORY", and "CATALOG". On the right, there is an "ACTION CENTER" with icons for sorting, search, and print. Below the tabs is a list of training items. The first item is "Develop Platform Documentation" with code "DPD1" and due date "03/29/2016". The second item is "Training Management Plan" with code "TMP1" and due date "04/15/2016" (status "In Progress"). Red circles with numbers "1" and "2" are placed over the action center icons and the dropdown arrow of the second item, respectively.

- Click the down arrow icon  to read more information about the Training Item or to launch, print or add it to your calendar.

This screenshot is identical to the one above, showing the detail view for the "Training Management Plan" training item. It includes the item name, code, due date, training type, code, version, due date, assignment type, description, and curriculum. The "Launch", "Add to Calendar", and "Print" buttons are visible at the bottom.

Navigation Controls:

When you launch a training item from either the To-Do list or the Curriculum View, you will be returned to the tab from which you launched it regardless of their Preferred View setting. This enhancement will be particularly beneficial when launching Training Items from a Curriculum to make the process of interacting with Training Items in ComplianceWire more intuitive for Learners.

For example,

1. Select a Curriculum from the Curriculum tab (for example, Curriculum > Sales Personnel Training).



2. Launch and complete a training item from the curriculum.
3. The “Return” button takes you to the Curriculum you launched the training Item from.

Note: This enhancement will work the same for those clients who have a post-login landing page.

History

This view provides a list of the completed Training Items.

The icons on each line indicate:

- Qualified completion
- Equivalent completion (the learner did not take the course but was given a completion because an equivalent Training Item was setup in the system)
- Effective version of the Training Item
- Retired (Training Item is no longer assigned to learners)
- E-signature
- Completion certificate

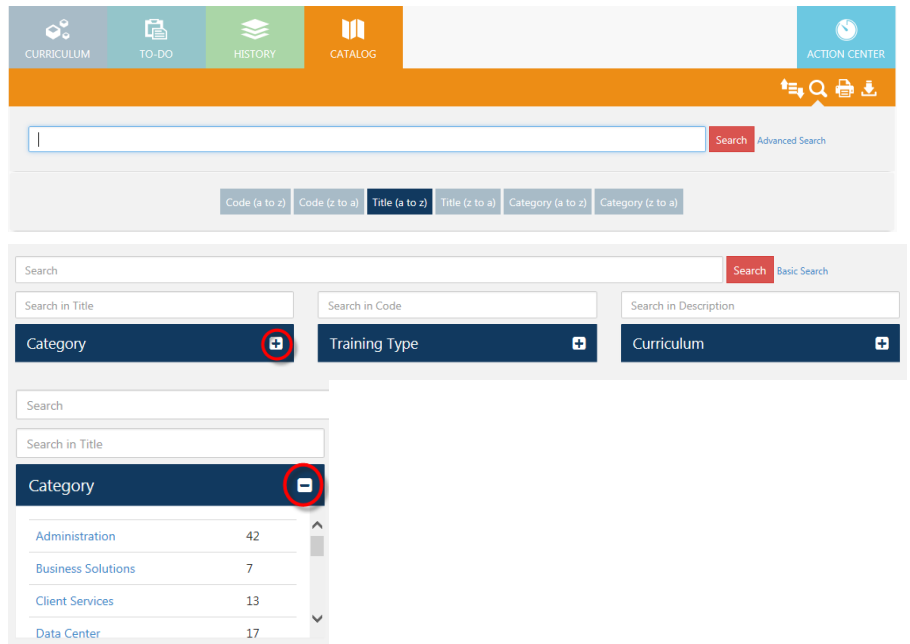
| | | | | CURRICULUM | TO-DO | HISTORY | CATALOG | ACTION CENTER | |
|--|---|------------------------|--------------------------------------|------------|-------|---------|---------|---------------|--|
| | Develop Platform Documentation | DPD1 (Ver 1.0) | Completed on: 03/28/2016 10:17:24 AM | Qualified | | | | | |
| | System Development Life Cycle (SDLC) | SDLC2 (Ver 1.0) | Completed on: 02/08/2016 11:09:08 AM | Qualified | | | | | |
| | User Acceptance Testing Server Process | UAT1 (Ver 5.0) | Completed on: 02/03/2016 12:04:17 PM | Qualified | | | | | |
| | Change Control | CC1 (Ver 21.0) | Completed on: 01/04/2016 01:08:53 PM | Qualified | | | | | |
| | Deviation Process | DEV1 (Ver 4.0) | Completed on: 12/17/2015 11:31:17 AM | Qualified | | | | | |
| | Corrective & Preventive Action | CAPA2 (Ver 3.0) | Completed on: 10/13/2015 10:13:28 AM | Qualified | | | | | |
| | Principles of Good Documentation | PHA74 (Ver 1.1) | Completed on: 09/30/2015 11:30:04 PM | Qualified | | | | | |
| | Doing the Right Thing for Customers and Business Partners (Mastery) | CORPETHICS03 (Ver 1.0) | Completed on: 09/30/2015 10:57:41 PM | Qualified | | | | | |
| | Approach to Computerized Systems Validation and Compliance | ISPE02 (Ver 3.0) | Completed on: 09/30/2015 10:28:46 PM | Qualified | | | | | |
| | Sarbanes-Oxley Act: An Overview | ETHICS07 (Ver 1.2) | Completed on: 09/30/2015 09:46:50 PM | Qualified | | | | | |
| | Sarbanes-Oxley Act: An Overview | ETHICS07 (Ver 1.3) | Completed on: 09/30/2015 09:46:50 PM | Qualified | | | | | |

Catalog

This view provides a list of all Training Items available in ComplianceWire.

The **Basic** search allows you to search for a Training Item by Keyword, Title, Course Code or Description

Using the **Advanced** search you can select a specific Category, Training Type, or Curriculum by the clicking on the + icon to expand the list.



Course Credits

The Course Credit feature is designed to provide Learners credit for a Training Assignment completed outside of ComplianceWire. For example, if a Learner attends a seminar that covers the same content as a ComplianceWire assignment, a Course Credit could be given.

When the 'Course Credit Request & Approval' feature is enabled, a Learner can 'request' a Course Credit and the authorized 'credit approvers' can then be able to review the request and approve or reject it. Once the request is approved, a completion for the ComplianceWire Training Item is issued in the form of a Course Credit and the Training Item no longer appears in the Learner's To-Do List.

The features related to Course Credit are *not On* by default. When enabled, these features can be configured so that Course Credits can be – (a) 'requested' by Learners followed by an approval process, (b) simply 'granted' by the Administrator.

Additional configurable options are available when Course Credit features are enabled:


| Course Credit Features | Configuration |
|---|--|
| Course Credit Request (Learner) | When enabled, <u>ALL</u> Learners will be able to submit a request Credit for <u>ANY</u> Training Item and Type on their To-Do list. |
| Course Credit Grant | When enabled, Administrators (with appropriate security permissions) will be able to 'grant' Course Credit to a Learner for assignments on their To-Do List. |
| Credit Reasons | When requesting a reason must be selected. |
| Course Credit File Attachment (Required) | When requesting a file must be attached in support of the course completion if the Administrator has made this a requirement. |

Request Course Credit

When the Course Credit feature is enabled, the expanded view of an assignment on the Learner's To-Do list screen will include an option to 'Request Credit.'

Note: When turned *On* this feature is available to all Learners and for all Training Types.

To request Credit, complete the following steps:

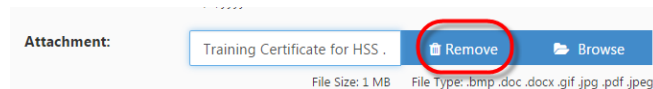
1. Search for the assignment in the To-Do list.
2. Click the expand icon  to view the details of the assignment.
3. Click **Request Credit**.

The Request Credit screen is displayed.

The *User* section displays the Learner's (Credit requester) credentials, the *Training* section displays the details of the Training Item for which Learner is requesting Credit, the *Assignment* section displays the Complete By date for the assignment that is currently on their to-do list.

4. Select a **Reason** for the Credit request from the drop-down list and then the actual **Completion Date** for the training that warrants a Credit being given for the current assignment.

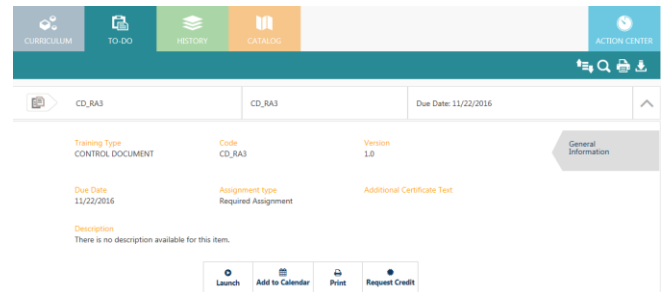
To attach a document or image in support of the external training completion, click **Browse** to select the file from the computer.



To delete the file selected, click **Remove**. To select a different file, select **Browse**.

Note: The file size limit and the acceptable file types are listed. A warning message is displayed when the File Size exceeds the System limit of 1 MB or an incompatible file type is selected.

5. Click **Submit** to complete the Credit Request or **Cancel** to return to the To-Do list without completing the request.



Request Credit

| USER | | |
|------------|------|--|
| User Id | nans | |
| Last Name | nans | |
| First Name | nans | |

| TRAINING | | |
|----------|------------------|--|
| Title | CD_RA3 | |
| Code | CD_RA3 | |
| Version | 1.0 | |
| Type | CONTROL DOCUMENT | |

| ASSIGNMENT | |
|-------------|------------|
| Complete By | 11/08/2016 |

Required fields are marked with a red asterisk (*)

Reason:*

Completion Date:*

Attachment: **Browse**

File Size: 1 MB File Type: .bmp .doc .docx .gif .jpg .pdf .jpeg

Comments:

A confirmation screen is displayed upon successful submission of the request as shown in the example below:

Request Credit - Confirmed

USER

User Id: nans

Last Name: nans

First Name: nans

TRAINING

Title: CD_RA3

Code: CD_RA3

Version: 1.0

Type: CONTROL DOCUMENT

ASSIGNMENT

Complete By: 11/08/2016

CREDIT

Reason: RA Credit1

Completion Date: 9/20/2016

Attachment: [Training Certificate for HSS .jpg](#)


Comments: Additional training completed

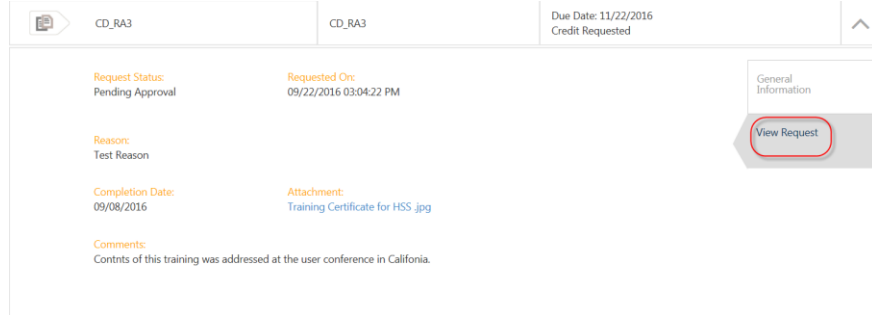
6. Select **Return** to go back to the To-Do list.

Notice the new Credit status for the Assignment in the To-Do list.

| <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="display: flex; gap: 10px;"> CURRICULUM TO-DO HISTORY CATALOG </div> <div style="text-align: right;"> ACTION CENTER</div> </div> | | | |
|--|------------------|-------------|--|
| | CD_RA3 | CD_RA3 | Due Date: 11/22/2016 Credit Requested |
| | CD_EDUQA_RA | CD_EDUQA_RA | Due Date: None |
| | cd-02 | cd-02 | Due Date: None |
| | cd-03 | cd-03 | Due Date: None |
| | Basic operations | CDA 1 | Due Date: None |

To view the details for the submitted Credit request, search for the assignment in the To-Do list.

Click the expand icon  and then select **View Request**.



When a Credit Request is submitted, the designated approver with valid email addresses will receive an email notification with instructions to login to ComplianceWire to process the request.

Learners with valid e-mail addresses will receive an email notification when the requested Credit is approved or rejected as shown in the example below:

From: ComplianceWire@Eduneering.com [<mailto:ComplianceWire@Eduneering.com>]

Sent: Friday, September 09, 2016 11:14 AM

To: Sam Miller

Subject: Request for Credit - Approved

Sam,

Your request for credit has been approved for the following item for which you had requested a credit.

| Training Title | Training Code | Training Version | Training Type | Approved By | Approved On |
|--------------------------|---------------------------|------------------|-----------------|-----------------------|-------------|
| Training Management Plan | UL-EDU-Training-Mgmt-Plan | 1.0 | UL-EDU DOCUMENT | Sinha, Leena (Isinha) | 9/8/2016 |

From: ComplianceWire@Eduneering.com [<mailto:ComplianceWire@Eduneering.com>]

Sent: Friday, September 09, 2016 11:14 AM

To: Sinha, Leena

Subject: Request for Credit - Rejected

Leena,

The request for credit for the following item has been rejected.

| Training Title | Training Code | Training Version | Training Type | Rejected By | Rejected On |
|-------------------|-------------------|------------------|---------------|-----------------------|-------------|
| Manager Only Form | Manager Only Form | 1.0 | Forms | Sinha, Leena (Isinha) | 9/7/2016 |

Monitor the Credit Status

In addition to receiving an email notification when a Credit is approved or rejected, Learners can monitor the status of the Credit on their To List as described below.

| Credit Request Status | Description |
|-----------------------|---|
| Credit Requested | No action has been taken by the approver after a credit request was placed. |
| Credit Approved | Not displayed on Learner's to-do list. When a Credit request is approved, the assignment will no longer appear in the Learner's To-Do list. |
| Credit Rejected | The rejected Credit request will remain on their To-Do list with the "Credit Rejected" status. |

| Icon | Status | ID | Description | Due Date | Action |
|------|---------------------|-------------|-------------|-----------------------------------|--------|
| | 0 | 0 | | Due Date: 04/08/2016 - Overdue | ▼ |
| | ILC101 | ILC511 | | Due Date: 04/30/2016 - Overdue | ▼ |
| | ILC911 | ILC911 | | Due Date: None | ▼ |
| | 100% sop | 100% sop | | Due Date: None | ▼ |
| | Performance Testing | 051113 SOP | | Due Date: None | ▼ |
| | bshah | bshah1 | | Due Date: None | ▼ |
| | Test SOP | 1065 SOP | | Due Date: None | ▼ |
| | Athena-Quiz | Athena-Quiz | | Due Date: None | ▼ |
| | CD_RA3 | CD_RA3 | | Due Date: None Credit Rejected | ▼ |

To view the details of the rejected Credit, click the expand icon ▼ and then select View Request.

CD_RA3 | CD_RA3 | Due Date: None
Credit Rejected

Request Status: Credit Rejected

Rejected On: 09/22/2016 02:44:51 PM

Rejected By: Bidare, Nitin (nbidare)

Reason: Equivalent External Training

Completion Date: 09/07/2016

Attachment: Training Certificate for HSS .jpg

Comments: Completed this training at XYZ User Conference in September. Course content is the same.


Rejection Comments: External Course does not include the safety guidelines.



















[Request Credit](#)

The Learner can choose to Request Credit again by submitting a new request for Credit.

Learner's Credit History


After a Course Credit is Approved or Granted, the Training Item will be displayed in the Learner's history.


Note: The Certificate of Completion icon  will not be displayed for a Training Item that received *Credit* as shown in the example below.

| CURRICULUM | | TO-DO | | HISTORY | | CATALOG | | ACTION CENTER | |
|---|-----------|---------------------|--------------------------------------|-----------|---|---|--|---------------|--|
|  | CD_RA3 | CD_RA3 (Ver 1.0) | Completed on: 09/08/2016 12:00:00 AM | Qualified |   | | | | |
|  | TR2506 | TR2506 (Ver 1.0) | Completed on: 09/20/2016 02:53:08 PM | Qualified |    |  | | | |
|  | SOP_RA_RP | SOP_RA_RP (Ver 1.0) | Completed on: 09/19/2016 12:35:54 PM | Qualified |    |  | | | |
|  | TR2493 | TR2493 (Ver 1.0) | Completed on: 09/19/2016 12:19:05 PM | Qualified |    |  | | | |

Click on the Training Item line to view the Credit Information.

The screen displays three sections as shown in the example below: (1) User information (2) Training information (3) Credit information - Credit Reason, Result, Completion Date, Expiration Date, file attachment (if any), comments, who granted the Credit, and when (date/time).

History > Credit Information 




Review


USER

| | |
|------------|------|
| User ID | nans |
| Last Name | nans |
| First Name | nans |

TRAINING

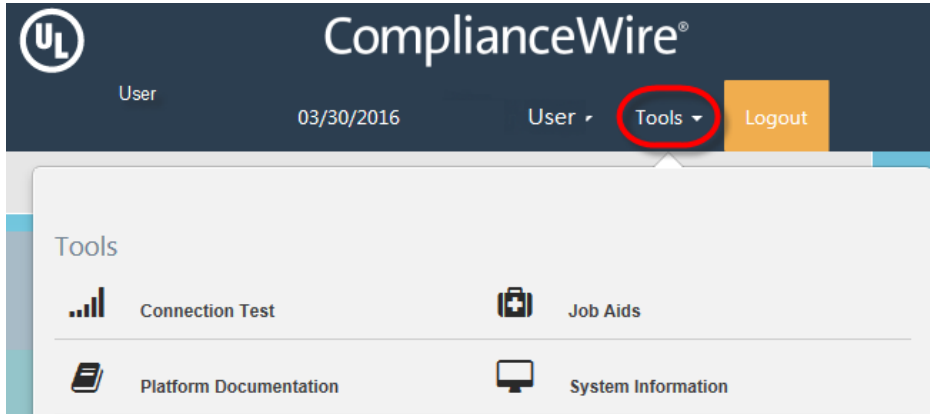
| | |
|---------|--|
| Title | CD_RA3 |
| Code | CD_RA3 |
| Version | 1.0 |
| Type |  CONTROL DOCUMENT |

CREDIT

| | |
|-----------------|---|
| Reason | Test Reason |
| Result |  Qualified |
| Completion Date | 09/08/2016 12:00:00 AM |
| Expiration Date | - NONE - |
| Attachment | Training Certificate for HSS .jpg |
| Comments | External Course Satisfactory |
| Granted By | Bidare, Nitin (nbidare) |
| Granted On | 09/22/2016 03:12:33 PM |

Tools Menu

The Tools Menu provides access to platform documents, job aids, the connection test and system info. You can also submit comments.



User Profile Menu

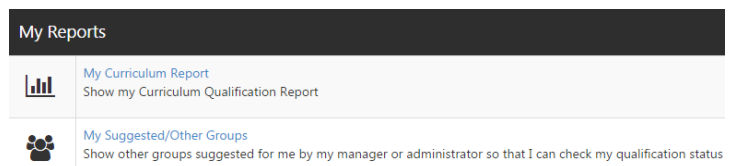
You have access to customize various settings under your user profile menu.



My Reports

Provides access to 2 report options:

- My Curriculum Report
- My Suggested/Other Groups



My Curriculum Report – lists the curriculums assigned to you with the status.

- **Qualified:** Training item has a current passing score and no current assignment
- **Partially Trained:** Training item has no current qualifying score, for one of these reasons:
 - Training item was not begun
 - Training item was begun/bookmarked but not completed
 - Training item has a failing score
- **Not Qualified:** Training item has a current qualifying score and a new assignment.

My Reports > My Curriculum Report Print Download

Your report contains 4 records.

| Curriculum Code | Curriculum Title | Status |
|------------------------------------|------------------------------------|-------------------|
| Annual Trainings for all employees | Annual Trainings for all employees | Partially trained |
| New Hire Employee | New Hire Employee | Qualified |
| New Jersey Employees | New Jersey Employees | Qualified |
| Product Management | Product Management | Qualified |

My Reports > My Curriculum Report > Annual Trainings for all... Print Download

Your report contains 16 records.

| Name of Curriculum / Training | Tokens | Status |
|---|--------|-------------------|
| Annual Trainings for all employees (Annual Trainings for all employees) | | Partially trained |
| Acceptable Use of Networking & Computing Resources (SECR6 Ver 10.0) | | Qualified |
| Comparison of 21 CFR Part 11 and Annex 11 of EU Guidelines to GMP (Annex11_Part11_WP Ver 5.0) | | Qualified |
| Complying with 21 CFR Part 11: Electronic Records & Signatures (CFR1 Ver 17.0) | | Qualified |
| Confidentiality, Intellectual Property Protection, and Information Security (LAV19 Ver 2.0) | | Qualified |
| Document Retention Policy (DRP1 Ver 2.0) | | Qualified |
| Good Documentation Practices (VALD1 Ver 15.0) | | Qualified |

Clicking on a specific curriculum will display the current status for each training item in the curriculum. The list may contain up to five levels of nested curriculums (curriculums within other curriculums). Sub curriculums are distinguished from their master by one level of right indentation

My Suggested/Other Groups – shows all the user groups in which you are a “suggested” or “recommended” member and view your qualification status against that group, without being assigned that entire curriculum or being an actual member of that group.

My Curriculum Report for Suggested Group : QA215

Curriculum List

Viewing 1 - 1 of 1 Records Print Download

| Name of Curriculum / Training | Status |
|-------------------------------|-------------------|
| user curriculum | Partially trained |

Curriculum Vitae (CV)

Your user information is displayed.

Note: This is an optional feature. If you do not see this feature under your user profile menu, then it may not be available for your instance of ComplianceWire.

CVs typically contain a summary of the educational and academic backgrounds, as well as employment history, publications, presentations, awards, honors, affiliations, and other details.

Return – closes the Curriculum Vitae screen.

Pending CV – CVs that are uploaded, but not yet approved are in ‘Pending’ status.

Curriculum Vitae Print

| | |
|--------------------------|--|
| Status | Pending |
| First Name | User |
| Middle Name | |
| Last Name | nans |
| User Id | nans |
| Current Status | Enabled |
| Home Organization | Org Level 10 |
| E-Mail | |
| Compliance Status | In Compliance (Last Modified Date: 4/6/2016 11:30:00 AM) |
| Employment History | Add |
| Education | Add |
| Development and Training | Add |
| Activities | Add |
| Committees | Add |

Upload CV – allows you to add a CV as a PDF file instead of copying and pasting the content into the Curriculum Vitae Builder.

Print CV – click on the print icon (top right corner of the Curriculum Vitae screen).

Change Password

Password rules are described and you can enter their Current and new password to complete the change.

Note: You may be asked to complete your Curriculum Vitae as a training item. Launch the training and complete the sections.

Date / Time Format

You can manage the input and display format settings, as well as the time display settings.

Drop down option menus provide the choices available.

International standards for date formats apply.

Forgotten Password Question

You can manage a series of questions that will be used to verify your credentials if you forget your password.

- Questions that have answers are marked with a check in the Answer column.
- You can edit the answers for questions previously entered or answer additional questions.
- Clicking on the question or on the edit icon will open the edit screen.

Forgotten Password Question
You must select and answer at least 3 questions to enable this feature. These questions will be used in the future in the event that you forget your password.

| Question | Answer | | |
|--|--------|---|--|
| What is your favorite color? | ⊗ | ✎ | |
| What make was your first car? | ⊗ | ✎ | |
| What is your all-time favorite sports team? | ⊗ | ✎ | |
| What is your father's middle name? | | ✎ | |
| What was your high school mascot? | | ✎ | |
| What was the name of your first school? | | ✎ | |
| Where did you first meet your spouse? | | ✎ | |
| What is your mother's maiden name? | | ✎ | |
| Who is your favorite actor, musician, or artist? | | ✎ | |
| What was your favorite place to visit as a child? | | ✎ | |
| What is the first and last name of your first boyfriend or girlfriend? | | ✎ | |
| Which phone number do you remember most from your childhood? | | ✎ | |

Language Setting

The ComplianceWire languages configured will be available from the drop down option menu.

Once the language is chosen, click **Save Language Change**.

All languages will now appear as translated along with the language name in English for ease of selection.

In this example, English is the preferred language.

The option from the drop down menu for Italian displays as:

Italiano / Italian

Preferences

Click below to change your preferences

Language Settings

Select your preferred language to be used in the system

English

Save Language Change

Note: Only licensed languages are displayed in the drop down option menu. Once the preference is saved, ComplianceWire is displayed in the language selected.

Preferred View

You can set a preference to see the **To-Do List** or **Curriculum** View as the default landing page here.

Set Default View: When you switch from one view to another, the system will remember the last setting when you next login to ComplianceWire.

Action Center Settings:

- You will have an option to override the Company Preference that determines if the Action Center should appear in a collapsed or expanded state upon login.
- Additionally, you can set the following Action Center options:
 - Click on the star to select a “favorite” dashboard. This selection will be the default dashboard that will appear on the Action Center when expanded upon login.
 - Change the order in which the dashboard types (Training, Status and My Team) are displayed using the drag and drop feature.

Preferences

Click below to change your preferences

Language Settings

Date/Time Format

Preferred View

Select Default View

Curriculum

To-Do

Action Center Settings

Select the way in which you like the action center to appear when you are logged in.

Expand

Collapse

The following adjustments can be made:

- Drag and drop the dashboard types below to adjust the order in which they appear on the Action Center.
- Use the “On” and “Off” toggles to add or remove certain dashboards from the Action Center.
- Click on the star to select a favorite dashboard. This will be the default dashboard that would appear on the Action Center when it is expanded upon login.

| | | |
|----------------------|---|-----|
| ☆ Status Dashboard | <input checked="" type="radio"/> On <input type="radio"/> Off | ↑ ↓ |
| ☆ Training Dashboard | <input checked="" type="radio"/> On <input type="radio"/> Off | ↑ ↓ |
| ★ My Team Dashboard | <input checked="" type="radio"/> On <input type="radio"/> Off | ↑ ↓ |

Save

Completing a Learning Activity

You may be required to complete a Learning Activity or Quiz at the end of the course.

Select **Click to Start**, answer each question, and then click **Continue**.

An eSignature may be required. Enter your User ID and Password. Then click **Electronically Sign**.

Email Reminders

New Assignments – You will receive a confirmation email after the item is assigned based on your Company's choice.

Reminders – You will receive periodic reminder emails prior to the assignment Due Date.

Overdue Items – You and your manager (optionally) will receive an email after a Due Date has passed for an assignment.

Instructor Led Course (ILC)

The instructor for an ILC you have been assigned to may request you to electronically register (to eliminate the need for paper check-in).

Click on **Class Information**, select the **Class Code** and then click **Register for Class**.

Class Information

Class Code 5521672

Class Start Time 04/08/2016 09:00:00 AM

Class End Time 04/08/2016 05:00:00 PM

[Register for Class](#)

Print/Add to Calendar

You can print the training item information by clicking the **Print** icon.

You can also add an ILC to your personal calendar (such as Microsoft Outlook) by clicking the **Add to Calendar** icon.

In Download dialog box select, Open, Save, and Cancel.

A hyperlink to ComplianceWire is provided. Clicking on the link takes you to the Login screen.

Clicking "**Save and Close**" saves the reminder to your calendar. You will receive a reminder when the assignment is due.

Note: If an ILC is cancelled, it will remain on your calendar and must be manually removed.

Add to Calendar

The Add to Calendar function enables you to receive a reminder when your assignment is due. It is compatible with most calendar programs, such as Microsoft Outlook. Clicking the "Add to Calendar" button below will open an appointment window with your assignment details. In Microsoft Outlook, click "Save and Close" to save the reminder to your calendar.

[Add to Calendar](#)

Frequently Asked Questions

I forgot my password, what do I do?

You may request your password by email or answer the security questions.

Can I Login from home or away from my desk?

Yes, you can login from your computer anywhere you have internet access.

What happens when I exit a Training Item before completion?

Your progress in a training item is automatically “bookmarked.” If you need to interrupt your training session and continue later, click Exit.


The course remains on your To-Do List and you can re-launch it at a later date. You will continue the course from where you left off – or review sections you have already completed.

How do I reset my password?

To change your password at any time, click the Support tab, then select **Change Password**.

How do I print the Certificate of Completion for a Training Item?

To print your Certificate of Completion after successfully completing a Training Item:

1. Click History.
2. Click the Certificate icon  for the training completed. The Certificate screen displays.
3. Click the Print button.

Can I review a completed Training Item?

Yes. The 'History' tab lists all the Training Items you have completed. Click on a training to review. You can may also print your Certificate of Completion from this screen.

Where can I find completed training items?

The Catalog enables you to search for specific words or phrases within a Training Item. This contains all training materials available to you. Click the Catalog button; then click the applicable type link to view the training items by type.

What do I have to score on my quiz to pass?

You will complete a quiz at the end of each topic in order to proceed to the next topic. You can retake a quiz as many times as needed to advance to the next topic.

At the end of the course, you must successfully complete a quiz to receive credit for the Training Item based on the proficiency level set. Additionally, you may have to sign off by typing “I acknowledge” at the prompt.

Glossary

This document contains a general glossary of terms, acronyms, and abbreviations used in ComplianceWire.

| | |
|-------------------------------|--|
| CBT (Computer based training) | Refers to an electronic media used for education. |
| Certifications | <p>The procedure and action of determining, verifying, and attesting to the qualifications of personnel in accordance with applicable requirements.</p> <p>The purpose of certification is twofold. The first is to validate knowledge in a particular course of study (curriculum). The second is to pass a "certification" exam.</p> <ul style="list-style-type: none"> • Qualified has the appropriate knowledge. • Certified has passed an exam to verify proficiency. |
| 21 CFR Part 11 SOP. | Details how the system addresses the technical requirements of 21 CFR Part 11. Complying with: Electronic Records & Signatures |
| Class | Specific offering of an Instructor Based Training. It takes place at a specific time and location. There may be several classes for each course. |
| ComplianceWire | A learning management system of UL. The LMS is the software that operates and tracks training activity of customers. LMS is not course content. |
| Control Document | <p>A particular type of training. Used to present such documents as SOPs, functional specifications, mechanical drawings, etc.</p> <p>Any document that provides an evidentiary trail that a process has been followed. Control Documents can be forms, lists, checklists etc. Control Documents must be signed and approved.</p> |
| Credit | A type of completion that is given when a Learner has taken training outside of ComplianceWire that is equivalent to the training that is currently assigned to them in ComplianceWire. When a completion is given in the form of a credit, all requirements of the training assignment on their To-Do List must be met. |
| Credit History | Information associated with a course Credit request: Training Courses, request status (approved or rejected), the person who last modified the status and the date/time stamp. |
| Credit Reason | A purpose associated with requesting or granting course Credit for an assignment. |

| | |
|------------------------|---|
| Curriculum | Course of study. Related training items grouped according to subject matter (e.g., department, position, task, product, job function, skill, etc.). |
| Curriculum Vitae (CV) | A Curriculum Vitae (CV) provides a detailed synopsis of your background and skills. Typically, a CV includes a summary of your educational and academic backgrounds, as well as employment history, publications, presentations, awards, honors, affiliations, and other details. |
| Digital Signature | 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 of the signer and the integrity of the data can be verified. |
| Drop-Down | Displays a list of items from which users can select an option when they click the accompanying down arrow. Users can scroll through the list to view choices. |
| EDT | Eastern Daylight Time (EDT), when observing daylight saving time (spring/summer) is 4 hours behind Coordinated Universal Time (UTC-04:00). |
| Electronic Signature | 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. |
| Equivalency | Issued when a Learner completes a ComplianceWire Training Assignment that is considered 'equivalent' to other ComplianceWire Training Assignments. |
| EST | Eastern Standard Time (EST) when observing standard time (autumn/winter) are 5 hours behind Coordinated Universal Time (UTC-05:00). |
| ET | The Eastern Time Zone (ET) is a time zone encompassing 17 U.S. states in the eastern part of the contiguous United States, parts of eastern Canada, the state of Quintana Roo in Mexico, Panama in Central America and the Caribbean Islands. |
| Form | A specific training item type in ComplianceWire that can be assigned to a singular user or group of users. Forms contain text boxes and various question types that can be configured to collect and track various training related information. |
| Granting Credit | When the Grant Credit feature is enabled, an Administrator with appropriate permissions will be able to 'grant' Course Credit to a Learner for assignments on their To-Do List without a <i>formal</i> Request/Approval process. |
| Historical Completions | Issued when a Learner has completed a ComplianceWire Training Assignment in the past. |

| | |
|-------------------------|---|
| Instructor Led Training | The terms Instructor Led Training and Instructor Based Training are often used interchangeably. Used to track external (outside the system) training. |
| Platform | <p>Process, operation, function, or activity. It is defines as a collection of subsystems operating together as UL learning management system.</p> <p>The terms platform and system are often used interchangeably. Both terms refer to UL learning management.</p> |
| Quiz | Attached to a control document. A short test (with questions and possible answers) used to examine knowledge of the control document. |
| Requesting Credit | When the Course Credit feature is enabled, an additional option is presented in the expanded view of Training Items on the Learners To-Do list to request credit for training taken outside of ComplianceWire. |
| System Administrator | An individual responsible for administering user accounts, setting system parameters and defining permissions within the software environment. |
| System Requirement | A requirement that specifies a function that the system must be capable of performing. |
| Time Zone Offset | The definition for time zones can be written in short form as UTC±n (or GMT±n), where n is the offset in hours. |
| To-Do List | A list that shows your current training requirements. When your administrator assigns tasks to you, they appear in your To-Do List. |
| User ID | Assigned to each user within a company. It is used to login to the system. No two User IDs can be the same. |