



User Guide

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1.0 Training

1.00 How to use your personal Training Dossier

This dossier shows all completed or open training assignments for the selected user, including all documents, tests and personal/group events.

- Click  [Dossier PDF](#) to download a PDF version of the user's entire dossier.
- Click  [Export Table](#) to download the filtered table.
- Click the [Just Show At-Risk / Non-Compliant Items](#) or [Show Full Dossier](#) links to quickly filter the table
- If you are viewing your own dossier, you will also see red links to execute training (Train Now, Take Test, Sign now)
- Current, Effective Document rows will include an Edit or Review link (depending on your access rights) and  icon to download the item
- Click the [Edit](#) link to edit the record (if you're an admin).
- Click the [PDF](#) link to create a PDF file of the single training record
- Click the [Certificate](#) link to create a PDF file of the training certificate of a single training record.
- Training Status for an item can be Compliant (green), At Risk (yellow—training due in next 30 days) or Red (training past due).
- Rows with completed training items show a green training icon and a [Certificate](#) link that downloads a PDF of the training certificate of completion.

1.01 Accessing Training Records by Group

If you have Super User access, you can view training records by groups. Choose Groups from the dropdown menu.

The screenshot shows a navigation bar with tabs: Dashboard, Documents, Training (highlighted in blue), and Issue/CAPA. Below the navigation bar, there are four categories: Trainee Records, Courses, Events, and Tests. The 'Trainee Records' category is expanded, showing a dropdown menu with options: Just Showing Myself, My Direct Reports, Whole Company, Groups, and Disabled Users. The 'Groups' option is currently selected. To the right of the dropdown, there are fields for Group Name and Group ID.

You can search and sort the table to find the group you are looking for. Please see the Searching for a Document section if you need instructions.

You can click on the hyperlink of any group that shows a "# Users" to see the individuals within the selected group, their training status, and other details. Or you can click the "Training Matrix" link to download an excel file showing all users in the group and their current training status on every group assigned item.

The screenshot shows a navigation bar with tabs: Dashboard, Documents, Training (highlighted in blue), Issue/CAPA, Audit, Forum, and Administration. Below the navigation bar, there are three categories: Trainee Records, Courses, Events, and Tests. The 'Trainee Records' category is expanded, showing a table titled 'Groups'. The table has columns: Action, Trainee / Group Name, Training Status, Assigned Courses, and Status. There are eight rows in the table, each representing a group: 'Alina group', 'Executive Team & Investors', 'Investigator GCP Training', 'Production', 'test', 'Quality Group 2', and 'Test Group'. The 'Production' row is highlighted with a red exclamation mark icon and '0 %' under 'Training Status'.

	Action	Trainee / Group Name	Training Status	Assigned Courses	Status
Courses	<input type="checkbox"/>				
Events					
Tests	<input type="checkbox"/> 1 Users Training Matrix <input type="checkbox"/> 5 Users Training Matrix <input type="checkbox"/> 2 Users Training Matrix <input type="checkbox"/> 13 Users Training Matrix <input type="checkbox"/> 2 Users Training Matrix <input type="checkbox"/> 4 Users Training Matrix <input type="checkbox"/> 1 Users Training Matrix	Alina group Executive Team & Investors Investigator GCP Training Production test Quality Group 2 Test Group	N/A N/A N/A 0 % N/A N/A N/A	0 0 0 3 0 0 0	

1.02 Accessing Your Direct Reports Training Status

If you are a supervisor, you can choose from a dropdown menu to show your direct reports and their training status. Click on the hyperlink under the Training Status column will show you a detailed list of assigned files the user has or needs to train on.

Events	Training	Issue/CAPA	Audit	Forum	Administration
My Direct Reports		Export Table			
Trainee Name		Training Status		Assigned Courses	
Bart Simpson		!	0 %	1	Elizabeth Lemon
Montgomery Burns		!	0 %	1	Elizabeth Lemon
Tami Taylor		!	0 %	1	Elizabeth Lemon
Matt Saracen		!	0 %	1	Elizabeth Lemon

1.03 Accessing Your User Training Dossier

All users will be able to access their own training dossier from the Training tab. There is a table with just the single user listed. It will show the user, their training status, the number of courses assigned, the user's supervisor, and the site which the user is assigned to.

Dashboard	Documents	Training	Issue/CAPA	Audit	Forum	Administration
Trainee Records		Just Showing Myself	Group Actions	Export Table		
Courses				Assigned Courses	Supervisor	Site
Events						
Tests	Dossier	Elizabeth Lemon	!	94 %	1	Ned Flanders
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Clicking on the Dossier link will bring you a list of all training items, training status, and other details. You can search for training items using the column headers – dropdown fields, searching within the header, and advanced filters. If you need assistance on searching within a table please see the Documents section. You can download a certificate of the training by clicking the “Certificate” hyperlink. If there are items which you need to train on, you can click on the “Train Now” hyperlink to complete your training. You can export the full dossier to PDF by choosing the “Dossier PDF” button. You can export the table to CSV or Excel file formats by click the “Export Table” button. You can also set the table to show only items that are at-risk/non-compliant, currently assigned, or all items by clicking the appropriate hyperlink in the light blue box.

Training Dossier

[Add Personal Event](#)[Dossier PDF](#)[Export Table](#)[Exit](#)

Personal Training History

[At Risk/Non-Compliant](#) [Currently Assigned Files](#) [Everything](#)

	Training Status	Training Item	Type	Training Date ▾	Due Date
Edit Certificate	Compliant	SOP 301 (v.04)	File Review	23-Feb-2016	
Edit Train Now	Non-Compliant	SOP 501 (v.01)	File Review		08-Feb-2016

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Or you can also access your dossier right from your home page by clicking on your Training Status icon:

[Showing All Activity Since Last Login](#) [Change Date Range](#)

Training Status



Issue/CAPA

0

Inbox

[Since Last Login](#)

Sub

2.0 Getting Started (New Users/Members)

2.00 What to do when you get locked out of your account

You will know your account has been locked out if you get an email saying specifically that you have been locked out. If you haven't gotten this email BUT you forgot your password, then simply follow the instructions for automatically resetting your password [in this helpdesk article](#).

If you got an email from the system saying your account has been locked, it is probably because you (or someone else) tried to log into your account with the wrong password too many times. This is a security precaution for your benefit.

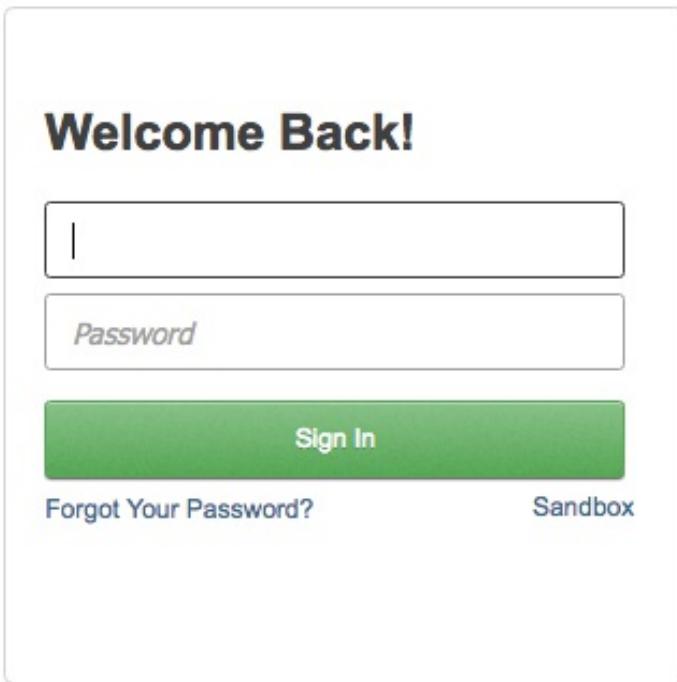
If this happens, you can contact your internal ZenDesk administrator to manually reset your account. Or you can email help@zenqms.com for the same.

When the manual reset is complete, you will receive an email with a link that takes you into the application to reset your password and security challenge question. Please note that this link expires 24 hours from when it was issued.

2.01 How to reset your password immediately (Forgot My Password)

If you have forgotten ZenQMS password you can easily request a password reset without assistance from your administrator or our helpdesk. The benefits are that this is immediate.

- From the login screen (app.zenqms.com) click the 'Forgot Your Password?' hyperlink.



- Enter your email address which associated with your ZenQMS account and confirm that you are

not a robot using the reCAPTCHA feature. Please note-- if you are in a country that restricts google services a different version of the CAPTCHA will appear. Once confirmed, click the green "Reset My Password" button

Password Recovery

Please enter the email address you use to log into ZenQMS immediately.

youremail@yourcompany.com



I'm not a robot



reCAPTCHA

[Privacy](#) - [Terms](#)

Reset My Password

- You should receive an email with a hyperlink to access to your ZenQMS account almost immediately. If you don't please check your spam folder for an email from noreply@zenqms.com.
- This link is active for 24 hours, so be sure to finish this process as soon as possible!
- Clicking this link will take you to a screen that will either ask you your security challenge question you input when you initially set up your account OR send you a 2-factor authentication code if that is active on your account. Below is the security challenge question scenario from the application.

Security Verification

Your account is protected with the security challenge question you set. Enter it below.

In which city were you born?

Verify My Identity

- If you answer incorrectly too many times your account will be locked out and will require your

administrator or our helpdesk to manually reset it.

2.02 Downloading a copy of the ZenQMS User Guide / Knowledgebase

ZenQMS users can request a full copy of this knowledgebase as a standalone User Guide by submitting a support request or sending the same to help@zenqms.com

You can also log into the current application and click the user guide download link in the Support / Getting Help page.

2.03 Changing a user name and other personal information

Users can change their own personal details (name, address, etc.) as follows:

- Log in to application
- Click Administration tab
- Click mySettings link on left side
- Change First and Last name (and other details)
- Click green SAVE button

2.04 Applying Custom Filters in Tables

The default table formats come with fairly powerful tools to filter/sort/customize the visible data. One feature that shouldn't escape your attention is the "Create Filter" link at the bottom left of most all tables. Clicking this link opens the Filter Builder window where you can create a custom logic for complex filters that include date ranges, keyword searches, rules and conditions.

Click This Link To Start

Customize | Bookmark | Map | Export to PDF | Export Table | Search whole keywords

Drag a column header here to group by that column

Filter Builder

And Site Name Begins with ABC

Audit ID Is greater than or equal to 350

Audit Type Equals Routine

Or

Obs. Is not blank

Obs. Equals <enter a value>

Equals

Does not equal

Is greater than

Is greater than or equal to

Is less than

Is less than or equal to

Is between

Is not between

Is blank

Is not blank

Is any of

Is none of

	Audit Date	Audit Type	Unresolved Obs.	# Obs.
01-Jan-2014	Routine	1	1	
02-Jan-2014		0	0	
		0	0	
		0	0	
15-Jan-2014	Routine	0	0	
10-Jan-2014	Routine	2	2	
08-Jan-2014	Routine	0	0	
01-Jan-2014	For Cause	1	1	
07-Jan-2014	Qualification	1	1	

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2.05 Exporting Tables to Excel / spreadsheet

The latest version introduces a simple way to export most any tables into a spreadsheet. The example below focuses on the Audit > Reports, but we should note that the same functionality appears in the Observations tables and Watchlist. It's pretty powerful, especially since the change comes with even more data fields in the table.

1. Navigate to Home > Audit > Reports.
2. Click the "Export Table" button at the top of the page and wait a moment. The browser will download a file in CSV format, which can be opened by MS Excel as a spreadsheet.
3. Click the 'Customize' button at the top and note that the Field Chooser window opens.
4. You can 'drag/drop' fields from the Field Chooser into your table header. Or you can remove columns the same way. Add a few new columns and close the field chooser.
5. Now filter the table using the simple filters at the top of a column
6. Now click the Export to Table button once more and notice that the resulting file adjusts to only export what is currently in your entire table.
7. If you navigate to Home > Dashboard > Watchlist, notice that the "Customize" button will bring up any custom fields that have been defined by your administrator and display the data assigned in that site's Snapshot page or the most recent value recorded in audits. This is very cool.

2.06 Configuration: Custom Fields & Labels

There are a few other items that can be configured in this section described below.

Custom Data/Metrics:

This page allows administrators to create custom fields are visible in a site's Qsheet or collected as part of each audit. The latter can be used in Analytics and the former can be used effectively in Watchlist. Fields can be of various formats – short text, long test, drop down, boolean, date. Examples may be Risk Ratings (short text), Key Facts (long text), Approved Vendor List (Boolean), next audit date (date format), etc. Try adding new fields of various types and navigating to Qsheet to see how they work. You will need to have at least a Basic subscription to add any custom fields.

- Click "Add New Field". Input boxes will appear in a new row for the new fields name and abbreviation (for column headings). You must also define a field type, including integers, decimals, Boolean (True/False), Text fields ('Short' is a ~20 characters, while 'Long' can be multi-line/paragraph.), Member Defined Dropdown, Date, Multi-Select and URL.
- Click 'Save' link.
- If you selected "Member Defined Dropdown" you will see a "List" link in the row's last column after saving. Click the 'List' link to add all the dropdown options that should appear in the dropdown for users to select from.

Labels

This page can be used to allow a system administrator to designate certain of his personal labels they created using the "Manage Labels" button that appears in Qsheet > Overview > Snapshot or Home > Dashboard > Watchlist as global labels available for the entire company to access/use but not edit.

2.07 Configuration: Managing Groups/Permissions

Users' access to various parts of the application is restricted based on rights/permissions explicitly granted to them by their Member Administrators. Member Administrators can access this section either by a) clicking the "Manage Groups" button in the Home > Administration > Member Account > Users page; or b) by navigating to the Home > Administration > Configuration > Groups/Permission. Either method will bring up a window that looks like the picture below:

- The "Select a Group" dropdown allows you select which already defined group you want to manage
- Add new groups using the "Create Group" link.
- After selecting an existing group, you can add users to the group with the second dropdown list that appears. On the left side of the page. Delete users in the list with the trash can icon

The screenshot shows the ZenQMS Administration interface. At the top, there's a navigation bar with tabs: Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, and Administration. Below the navigation bar, there's a sub-navigation bar with tabs: Set Up Guide, Custom Fields, Groups/Permissions, Workflow Templates, Labels, and Form Templates. The 'Groups/Permissions' tab is selected. On the left side, there are several sections: mySettings (Super User), Member Account (Select A User dropdown with options like Elizabeth Lemon, Michael Scott, Ned Flanders), Site Management, and Configuration. The main area is titled 'Access Permissions' and lists various rights for the selected user. The rights are organized into sections: User Restricted to Audits, Observations, Issues, CAPAs, etc. From Their Site, Can Access Watchlist, Audit Reports, Administrative Section, Member Administration/Configuration, Super Admin: Has full Edit/Admin access to any Document, Course, Event, Test, Audit or Issue/CAPA, Site Administration/Management, and Issues/CAPA. Most of these rights have checkboxes checked.

Permissions are granted to Groups and users must be added to a group to gain new rights. ZenQMS has a few predefined groups with designated rights that make sense by function but your administrator can easily edit/delete these or create new ones.

- User rights are cumulative, so users can be added to more than one group. This means if a user is assigned to multiple groups, the group with the highest level of permission takes precedence.
- Users that are added to no groups will have very limited access to the system, including Qsheet.
- Rights are granted by checking off key elements of the application in the table on the right side.
- All changes take effect immediately, though in most cases it helps to have a user log out and back in again.

Here is a summary of the existing Subscriptions/Permissions (explanatory notes included where needed):

- User Restricted to Audits, Observations, Issues, CAPAs, etc from their site
- Can Access Watchlist

AUDIT REPORTS

- Can Close Out Any Audit Report—Users can close out audit reports authored by any other user in his account.
- Can Edit Audits & See All Observations and Audit Reports: Users can author and manage audit reports but can NOT create new audit reports. Auditors should have this right.
- Can Access Any Audit Report in Qsheet or Audit > Reports Page: Users that need to quickly find audit reports. Auditors should have this right.
- Can Create New Audit Reports or Manage Recurring Audits: Users with this permission can create new reports from Qsheet > Snapshot with the "Add a New Recurring Audit" link or from

Qsheet > Reports page using the "Compose New Audit" button. If you maintain central planning and want to control who gets to create new audit reports, then you should not give this permission to Auditors.

ADMINISTRATIVE SECTION

- Member Administration/Configuration: A very sensitive role—these users have full control of all settings and groups/permissions for the member in the Administration > Member Account and Configuration sections. This role should have limited access.
- Super Admin Role: Has full Edit/Admin access to any Document, Course, Event, Test, Audit or Issue/CAPA: This is a special role that allows designated users to open and edit any audit in your account. This role should also be carefully managed.
- Site Administration/Management: Access to the Administration > Site Management tab, which allows a user to update/edit his member's Site Qsheet Profiles.

ISSUES/CAPAS

- Can See All Issues Or CAPAs
- Can Edit Any Issue Or CAPA

QSHEET

- Qsheet: Has Read/Write Access to Documents Section
- Qsheet: Can Access Consultants, Forum, & Documents
- Qsheet: Can Edit Qsheet/snapshot Private Data Fields

DOCUMENTS/TRAINING

- Can Add New Controlled Files
- Can Create/Manage Document Categories
- Can Create/Manage New Training Courses
- Can Create/Manage New Training Events
- Can See Training Records for Whole Company
- Can See Document Archive & Delete Past Due Items
- Can Add New Tests
- Can See & Edit All Tests
- Can Certify Destruction of a Controlled Copy

Create a new Group or Select an Existing Group

1. Navigate to the Home > Administration > Configuration > Groups/Permission page. If you don't see this, you don't have proper access.
2. Select or create a Group using the dropdown control. You will see a list of active users who are part of that group below and to the right a summary of the access rights assigned to that group.
3. Add users to the group using the "Select a User" dropdown box.
4. Delete users from a group.
5. Edit the group's Subscriptions/Access Permissions by checking the boxes that correspond with that group's roles/responsibilities.

****WARNING**** If you select the Member Administrator Role Be Careful not to eliminate your access to the Member Admin Pages sections**. Users who have had their settings changes should log out and log back in again before seeing the changes take full effect.

2.08 Configuration: Setting up your Member Account Backup

Thanks for using the backup service.

The way it works is:

- From the Member Account page within the Administration tab, you can enable the service and schedule a backup frequency (e.g. weekly, monthly, etc.)

Account Backup

This back up utility offers clients a means for creating a local backup of all account data beyond the robust disaster recovery protocols that ZenQMS deploys to ensure business continuity. Enabling this option will create a single zip file containing
1) PDFs of all your exported files (e.g., Documents, Issues, CAPAs, etc.); and
2) CSV files of all critical tables in the applications (e.g., Controlled Files table, etc.).
Note: enabling this option requires a service contract -- please discuss with your ZenQMS project manager.

Backup Frequency

Status	Scheduled Backups	Creation Date	File Name
Completed with errors	Annually	06-Sep-2016 11:06 UTC	Backup Phake Pharma, LLC 2016-09-06.zip
Completed	29-Jul-2016	06:02 UTC	Backup Phake Pharma, LLC 2016-07-29.zip
Completed	28-Apr-2016	06:41 UTC	Backup Phake Pharma, LLC 2016-04-28.zip

- The first backup is usually scheduled in the next available production queue.
- This process can take some time-- it's not instant. When the backup is created, an email is sent to the contact person in the account backup settings.
- When you log in after the email notification about a completed backup, your table will include a hyperlinked file name in last column. Clicking on it downloads the entire zip file. The zip file expands to a folder that is organized by item type. Table data is in excel files and all exported docs are in PDF.

Account Backup Save

This backup utility offers clients a means for creating a local backup of all account data beyond the robust disaster recovery protocols that ZenQMS deploys to ensure business continuity.

Enabling this option will create a single zip file containing

- 1) PDFs of all your exported files (e.g., Documents, Issues, CAPAs, etc.); and
- 2) CSV files of all critical tables in the applications (e.g., Controlled Files table, etc.).

Note: enabling this option requires a service contract -- please discuss with your ZenQMS project manager.

Disable Account Backup

Backup Frequency

Weekly ▼

Email Notification

Art Monk ▼ ▼

Request Immediate Backup

Status	Scheduled Backup Date ▼	Backup Completion Date	File Name
Completed with errors	06-Sep-2016 11:06 UTC	06-Sep-2016 12:33 UTC	Backup Phake Pharma, LLC 2016-09-06.zip
Completed	29-Jul-2016 06:02 UTC	29-Jul-2016 07:22 UTC	Backup Phake Pharma, LLC 2016-07-29.zip
Completed	28-Apr-2016 06:41 UTC	28-Apr-2016 08:01 UTC	Backup Phake Pharma, LLC 2016-04-28.zip

2.09 Configuration: Form Templates

Form Templates are important if you plan to use ZenQMS for creating your own audit reports. For instance, you may have one audit format for auditing API suppliers and another for drug product manufacturers. You can create as many templates as needed. Auditors can also add more than one template to a single report (e.g. a general template plus a specific questionnaire). Finally, templates are also used in the Audit Close Out process.

1. Navigate to the Home > Administration > Configuration menu and select the "Form Templates" tab. If you don't see this menu, you need to request system administrator privileges.
2. Select an existing template from the dropdown list or click the "Create New" button to create a new template that all your users can access.

The screenshot shows the ZEN-XMS software interface. At the top, there's a navigation bar with tabs: Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, and Administration. The Administration tab is selected. Below the navigation bar, there's a sub-navigation menu with tabs: Set Up Guide, Custom Fields, Groups/Permissions, Workflow Templates (which is highlighted in blue), Labels, and Form Templates. On the left side, there are several links: mySettings, Member Account, Site Management, and Configuration. The main content area is titled "Add Required Workflow Steps and Groups/Users Authorized to Approve Each Step and a Specific Reason Code". It contains a form with fields for "Step" (set to "Approval"), "Reason Code" (set to "I have reviewed and approve this document."), and a "Save Changes" button. There's also a checkbox for delegation ("Can this step be delegated by the receiver to another authorized user?") with options "Yes" (checked) and "No". Below this, there's a section for "Authorized Groups & Users" with a dropdown menu "Start Typing User or Group Name to Add". At the bottom left, there's a "Add Workflow Step" button.

3. Set the Template Type to "Audit Report Body" or "Audit Report Close Out" and add a name.
4. Use the "Load an Existing File" link to upload an existing template from MSWord.
5. Save your template when finished. Then click the "Exit Edit Mode" link.

2.10 Configuration: Workflows (Important)

Workflow Templates: Publishing Final Audit Reports internally and issuing them to an Auditee are driven by Part 11 compliant workflows that are defined by your system administrator. In order to ensure proper operation, you must define workflow steps for the following key workflows:

- "Audit Report: Publishing Final Audit Reports" – Completing this workflow results in issuance of a 'final' audit report. You must complete this step before being able to send it to the Auditee for response. Remember each Audit Category defined for your member has its own discrete approval workflow.
- "Audit Report: Send to Auditee" – Launching this workflow will make the audit report components you selected visible to the Auditee. When the Auditee "Approves" this workflow, they will immediately be able to start logging responses to audit findings.

Follow the Steps Below to Configure Workflows:

1. Navigate to the Home > Administration > Configuration menu and select the "Workflow Templates" tab. If you don't see this menu, you need to request system administrator privileges.
2. Select the "Audit Report: Publish Final Report" workflow from the dropdown control.
3. A second dropdown appears asking you to select an Audit Category. This will show you the currently defined workflow steps required for publishing an audit report of that category internally.
4. You can add workflow steps using the "Add Workflow Step" button. After adding a name, reason code and delegation option, you will see the new step added.

5. You can delete a workflow step by clicking the "Delete Step" button next to it. Note: Workflows require at least one step.

The screenshot shows the ZenQMS Administration interface. At the top, there's a navigation bar with tabs: Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, and Administration. The Administration tab is selected. Below the navigation bar, there's a sub-navigation menu with items: Set Up Guide, mySettings, Member Account, Site Management, Configuration, and a dropdown menu for Workflow Templates. The Workflow Templates menu is currently active. On the right side of the screen, there's a large form titled "Add Required Workflow Steps and Groups/Users Authorized to Approve Each Step and a Specific Reason Code". The form includes fields for "Step" (set to "Approval"), "Reason Code" ("I have reviewed and approve this document"), and "Save Changes" (a button). There's also a checkbox for delegation ("Can this step be delegated by the receiver to another authorized user?") with options "Yes" (checked) and "No". Below these, there's a section for "Authorized Groups & Users" with a dropdown menu ("Start Typing User or Group Name to Add"). At the bottom left of the form area, there's a button labeled "Add Workflow Step".

6. For any listed step, you can edit the name, reason code and delegation rights by making changes—just be sure to click "Save Changes" when finished.
7. Use the "Start Typing User or Group Name to Add" dropdown to add a group or individual user to a workflow. This is a one-click process. You can immediately delete any added rows using the garbage can icon. If you add a group to the workflow, a specific user from that group will need to be selected to complete the step. The user launching the audit will choose the specific user from the group before launching the workflow.
8. Repeat this process for all Audit Categories.
9. Repeat this process for the one "Send to Auditee" workflow.

2.11 Configuration: Defining Custom Observation Severities

Auditors can choose from 4 different severity levels when defining observations, with a default of Critical, Major, Minor and Comment. If you want to customize this further, follow these simple directions

1. Navigate to the Home > Administration > Member Account > General Preferences menu and scroll to the Audit Observations Severity Names section at the bottom of the page.
2. Click on the "Customize" link for any item you would like to customize and save your change.

Important Note: Changing severity names will change the names in all printed reports and tables. ZenQMS Analytics will still show the old severity names in this version, as will the Audit>Scoring page. And the ZenQMS Audit Scoring algorithm will remain unchanged as well—so a Critical Observation will still score very poorly even though you change its name.

Audit Observations Severity Names

You can define your own observation severity names below.

QAB Standard

Severity Names Custom Names

Critical	Customize
Major	Customize
Minor	Customize
Comment	Customize

2.12 Configuration: Defining Audit Categories

ZenQMS allows members to easily define different categories of audits to facilitate discrete workflow approvals for different groups (e.g. EHS vs Global Quality), enhanced audit planning and easier data segregation for analytical purposes.

1. Navigate to the Home > Administration > Member Account > General Preferences menu and scroll to the Audit Category section at the bottom of the page.

Audit Categories [Add Category](#)

The categories below are used by your auditors to manage discrete types of audits (e.g. QA GMP versus EHS). We have pre-loaded some examples items, but you are free to delete these and define your own. Please note: deleting a name below means it is no longer available for selection, but any published audits of this type will remain tagged with this category and prospective audits of this type will remain in draft form until manually deleted. Call QAB staff for help.

Active	Name	Interval Months
Yes	EHS Audits	36
Yes	Quality GxP	24
Yes	Sterility	36

-
2. Add new categories with the "Add Category" link. All you need is a name and a default audit interval (in months) that is used with recurring audits.
 3. Click the name of any existing Audit Categories to change its settings.
 4. The Yes/No field in the "Active" column allows you to easily manage which categories remain active for new audits.
 5. See Section 1.17 to define custom workflow for each audit category.

2.13 Configuration: Customizing Your Member Account

ZenQMS offers each member a simple way to customize several key aspects of the application through Custom Fields.

Users must have Member Administrator permissions to see the Configuration menu as seen below. If you don't see this menu, then contact your system administrator or ZenQMS Project Manager for help.

The screenshot shows the ZenQMS Administration interface. In the top right, there's a search bar with 'Jump to Qsheet: Start typing Site or Parent Name, Country or Site Q-ID' and a 'Add New Site' button. The top menu includes Home, Search, Support, and user info (Elizabeth Lemon, Maura Pharma, LLC | Sign-out). Below the menu, a navigation bar has tabs: Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, Administration, with Administration being the active tab. Under Administration, the 'Custom Fields' tab is selected. On the left, a sidebar lists 'Set Up Guide', 'mySettings', 'Member Account', 'Site Management', and 'Configuration' (which is highlighted with a red box). The main content area shows a table of custom fields:

Display Order	Abbreviation	Full Name	Placement	Type	Active	Required	
1	MEC	Maura Test 1	Document	Text (short)	Yes	No	Edit Delete
1	MEC2	Maura Test 2	Document	Date	Yes	No	Edit Delete
1	Name	Supplier Name	Issue	Text (short)	Yes	No	Edit Delete
3	Maura	Maura 1	Issue	Date	Yes	No	Edit Delete
4	Test	Test	Issue	Text (long)	Yes	No	Edit Delete
5	Vendor	Approved Vendor	Qsheet	Member Defined Dropdown	Yes	No	Edit Delete List

2.14 New Members: Managing "Qsheet Update Requests"

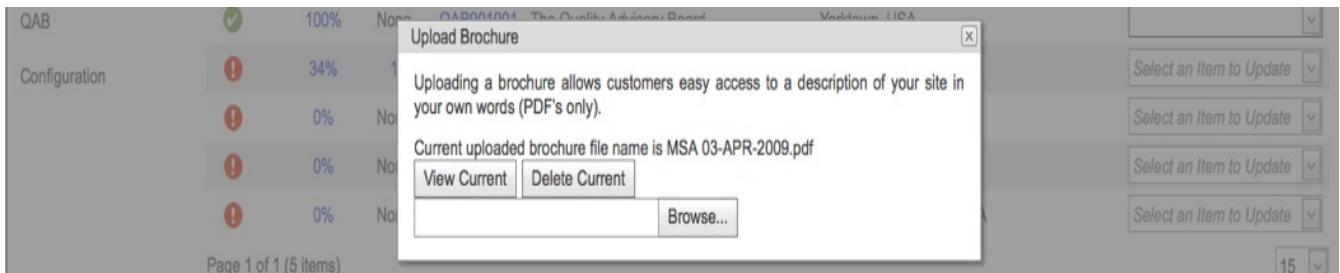
Any ZenQMS user is able to submit an information update for your consideration, and it has to be approved by you or ZenQMS staff. This is a great way to keep your site's information current.

1. Navigate to Home > Administration > Site Management. Check the Qsheet Update column—sites with a number in this column have pending requests that require your attention.
2. Click on a number to open the "Pending Site Updates" window.
3. Click the "Review" hyperlink in a row to download a PDF summary of the suggested change.
4. Click the "Approve" link if you agree with the change—or—click the "Reject" link if you don't. Either way a message will be sent back to the user who submitted the original request.
5. You can always reverse these changes or manage your profile directly using the Qsheet Profile options (see Section 1.10).

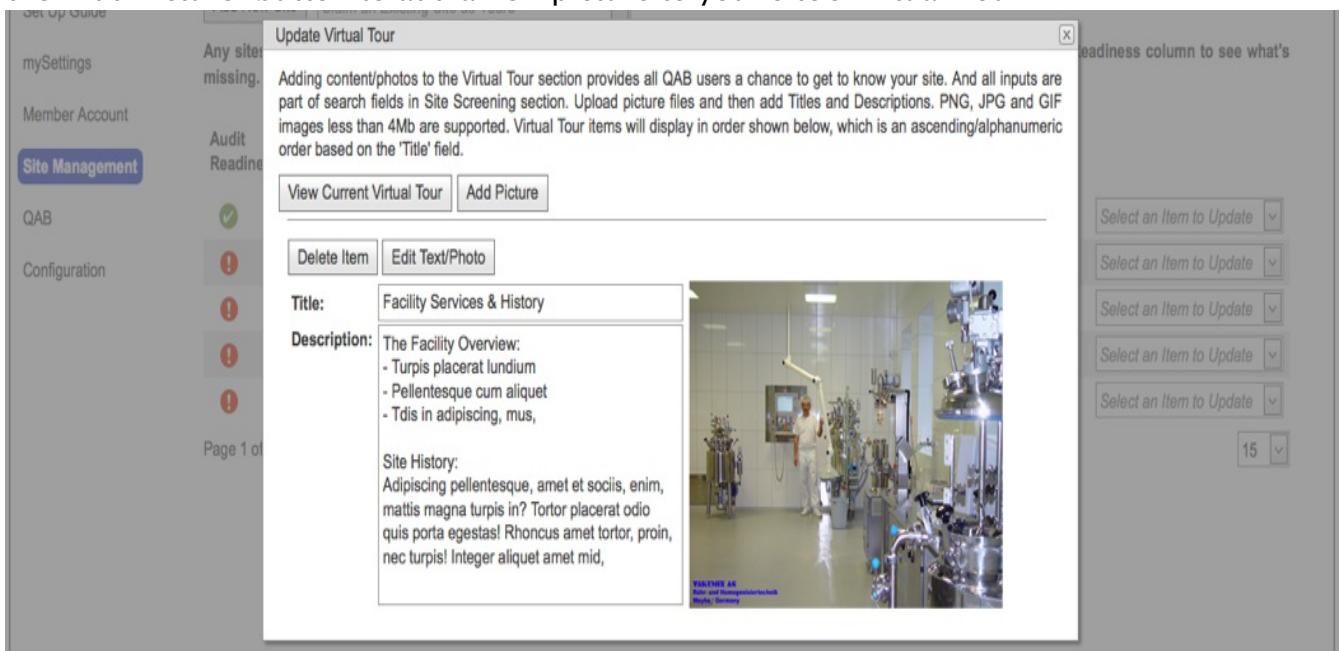
The screenshot shows a 'Pending Site Updates' dialog box. The title bar says 'Pending Site Updates'. Inside, there's a table with columns 'Date' and 'Submitted By'. One row shows '09-Sep-2013' and 'John Smith'. At the bottom right of the dialog are buttons for 'Review', 'Approve', and 'Reject'. The background shows a blurred view of the ZenQMS interface with a 'Configuration' section and a 'Qsheet' progress bar.

2.15 New Members: Adding Qsheet Brochure & Virtual Tour

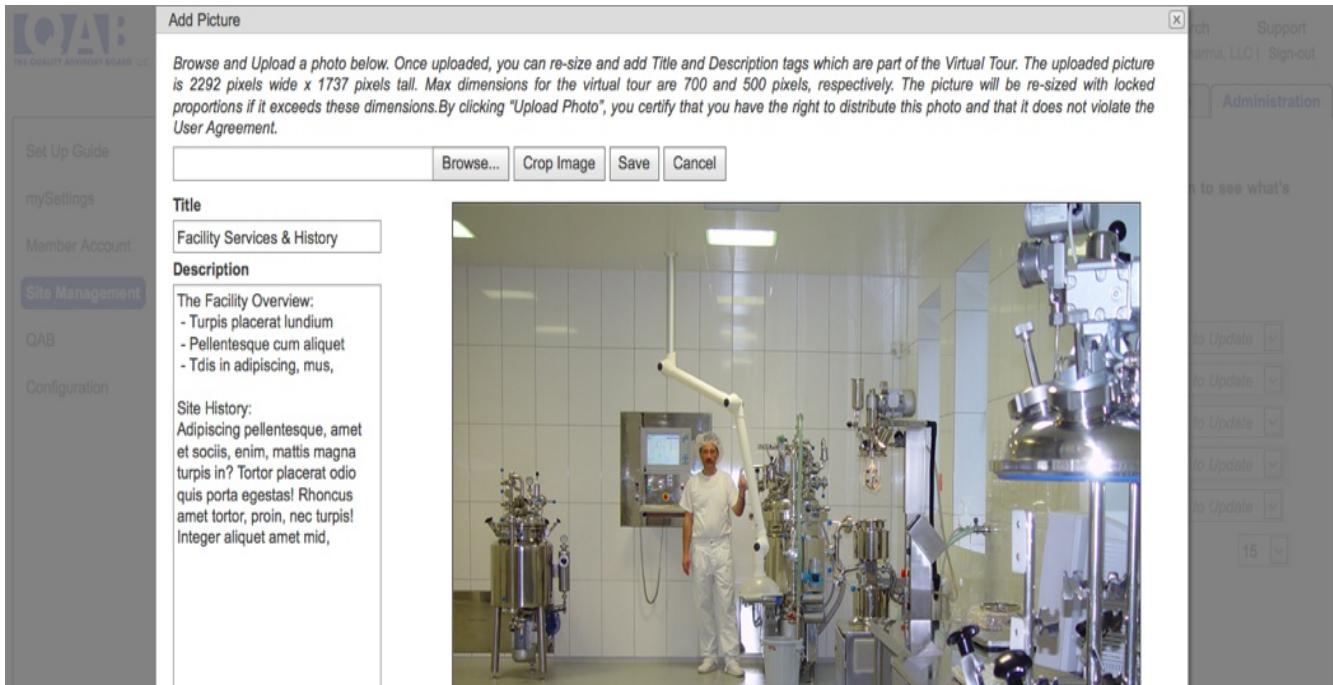
1. Navigate to Home > Administration > Site Management. You can manage brochures and Virtual Tour items by either a) Clicking on the Qsheet Profile percentage for the site and then selecting "Update Brochure" or "Update Virtual Tour" hyperlinks; or b) use the dropdown control in the site's row by selecting one of the same items from the dropdown list.
2. Upload a brochure for the site by clicking the "Browse" button in that section and uploading a PDF. You can use the "View Current" or "Delete Current" buttons to manage any existing uploads



3. Upload or edit Virtual Tour content by selecting "Update Virtual Tour" from the dropdown. Click the "Add Picture" button to add a new picture to your site's Virtual Tour.



4. Click the "View Current Virtual Tour" button to navigate directly to the selected site's Virtual Tour for a preview.
5. Scroll through and edit your existing content using the "Edit Text/Photo" button. This will open the "Add Picture" window.

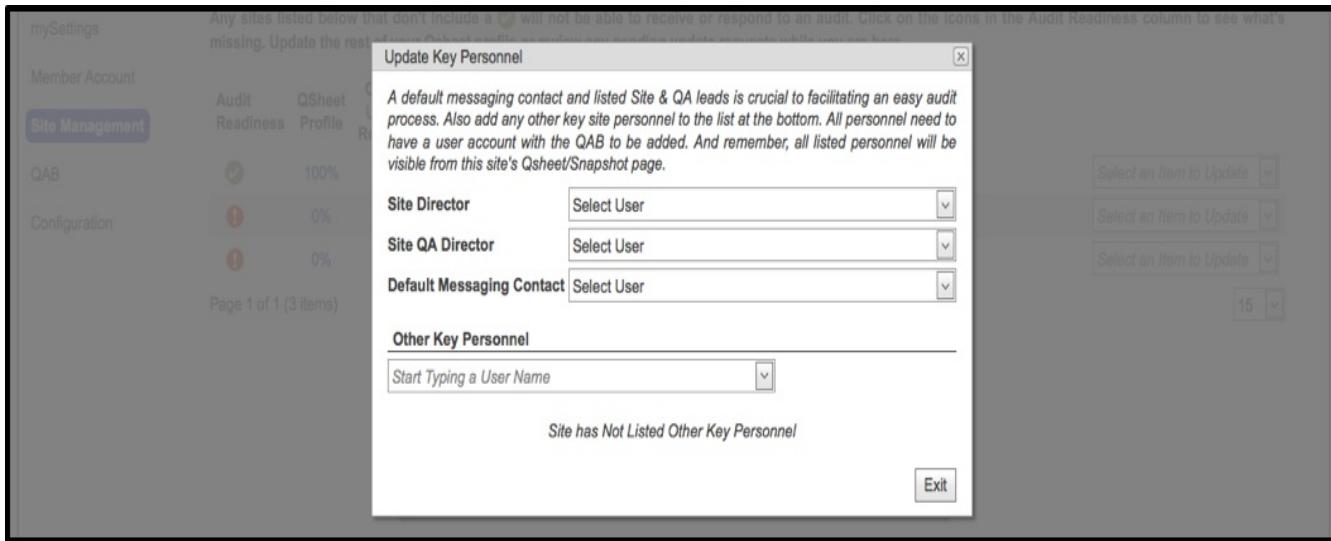


6. Click the Browse button in the new window to find/upload a picture. You can crop uploaded photos using the "Crop Image" button.
7. Add title and description. Remember that all this language is searchable later by clients looking for capabilities. Site overview pictures, maps, key team bios and or technology/services should be added here.
8. Close this window using the "X" in the top right corner.

2.16 New Members: Adding Key Personnel & Messaging Contact

It is absolutely critical for you to update key personnel for each site in order to interact with clients on audit reports.

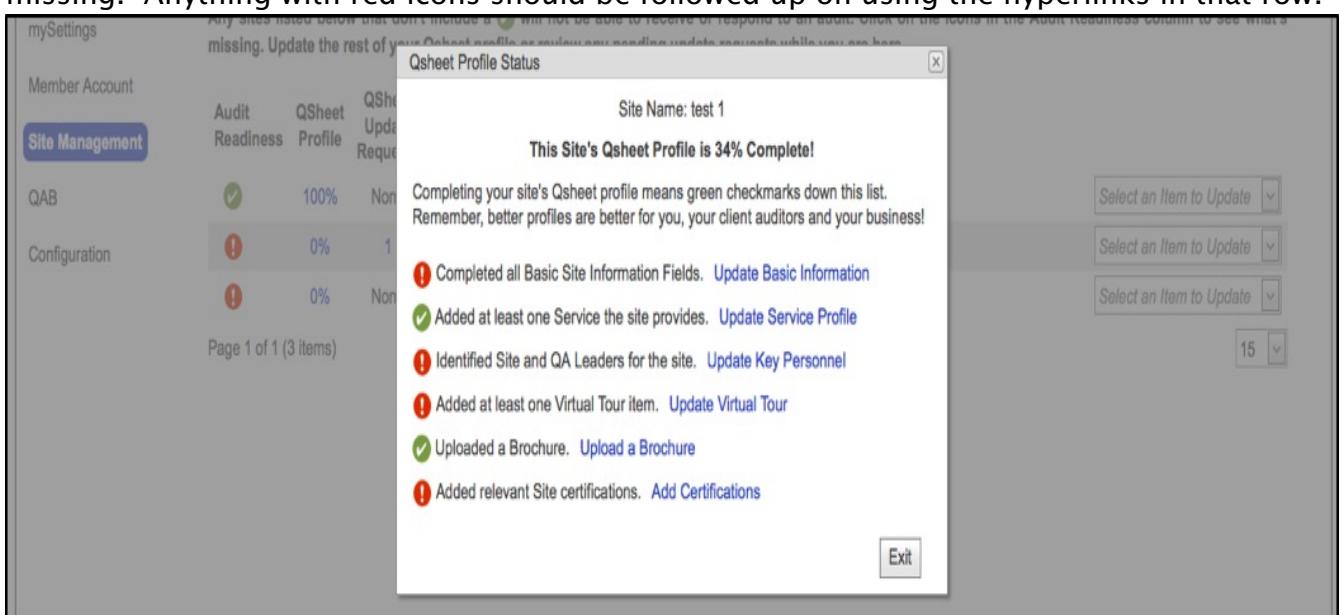
1. Navigate to Home > Administration > Site Management. Open the Update Key Personnel window either by a) Clicking on the Qsheet Profile percentage for the site and then selecting "Update Key Personnel" hyperlink; or b) use the dropdown control in the site's row by selecting "Update Key Personnel"
2. Use the dropdowns to select a Site Director, QA Director and Default messaging contact. The latter is most critical for receiving messages from clients. If there are other key personnel at the site, add them using the Add Key Personnel button at the bottom. Only active ZenQMS users will appear in these dropdowns.



2.17 New Members: Updating your Site Qsheet Profile

Every site in the database has a Qsheet profile—see Section 2 for more information. Keeping this profile information updated is critical but also easy to manage. When you log in to the Site Management page below, take note of the Qsheet Profile column. Any sites that don't indicate a "100%" status likely have some data missing in the site profile. Either click on this Qsheet Profile status percentage to see what is missing (look for green checks!) or make changes/updates manually using the dropdown in each site's row.

1. Navigate to Home > Administration > Site Management page. There are two ways to update information on a site:
 - Option 1: Click on the Qsheet Profile column value for a site that you are trying to update. The modal window that appears (see picture below) is a simple way to see what information is missing. Anything with red icons should be followed up on using the hyperlinks in that row.



- Option 2: Each row includes a dropdown control that says "Select an Item to Update". Click on the dropdown in the row you want to edit and select from one of actions listed.

Click dropdown to see list of actions in the row you'd like to edit

Select an Item to Update

- Update Basic Information
- Update Service Profile
- Update Key Personnel
- Update Certifications
- Update Virtual Tour
- Upload Brochure
- Merge this Site with Another of My Sites
- Remove this Site

2. Below is a summary of the update actions you can take:

- "Update Basic Information" edits the basic site data. The most important information is proper Site Name, Internal/External designation, phone, website, address and GPS coordinates. Remember, that GPS coordinates are required for accurate mapping—you can get this from google maps (see instructions using the blue question mark).

General

Click Data Fields to Update

Site Name	Test Site Northeast
Facility Type	Internal (only visible to your users)
Main Phone	
Fax Number	
Web Address	
Facility Size	0.0 <input type="checkbox"/> Meters ² <input checked="" type="checkbox"/> Feet ²
Total Employees	0
Mailing Address ?	

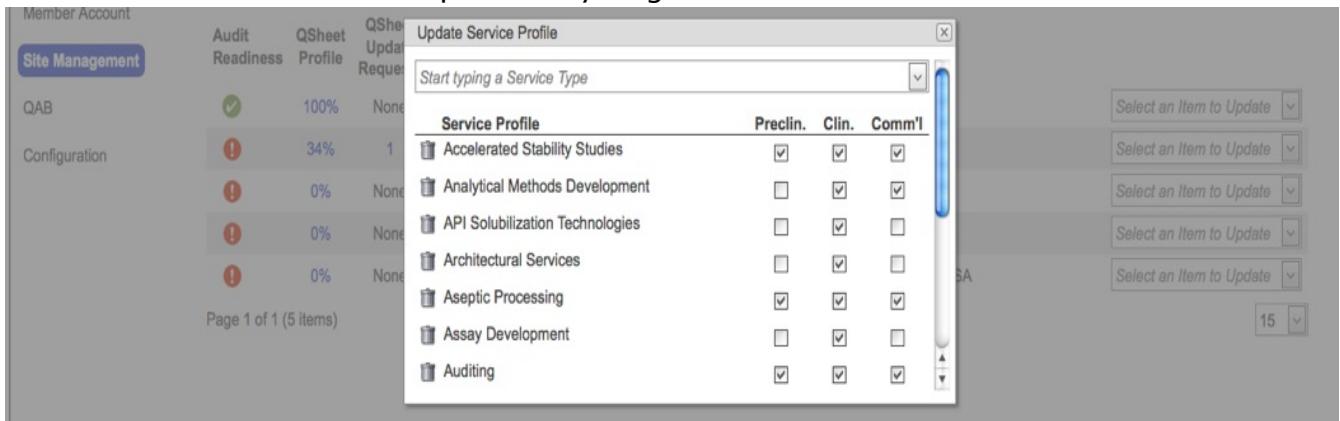
Map Location ?

Look up site's location (at least city, state-region, country)	
Town/City	Philadelphia
State/Region	Pennsylvania
Country	United States of America
Latitude	39.95240
Longitude	-75.16359

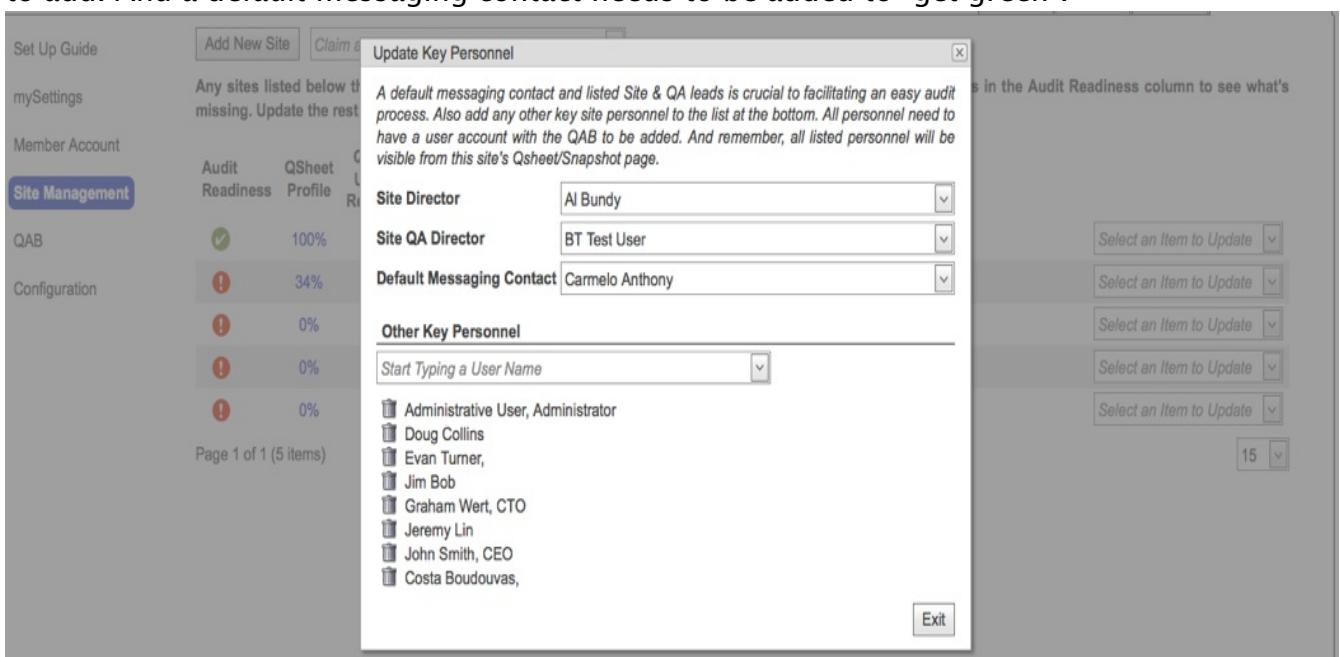
Save Exit/Cancel

- "Update Service Profile" to add Service Profile items to the site. Use the search box to find all

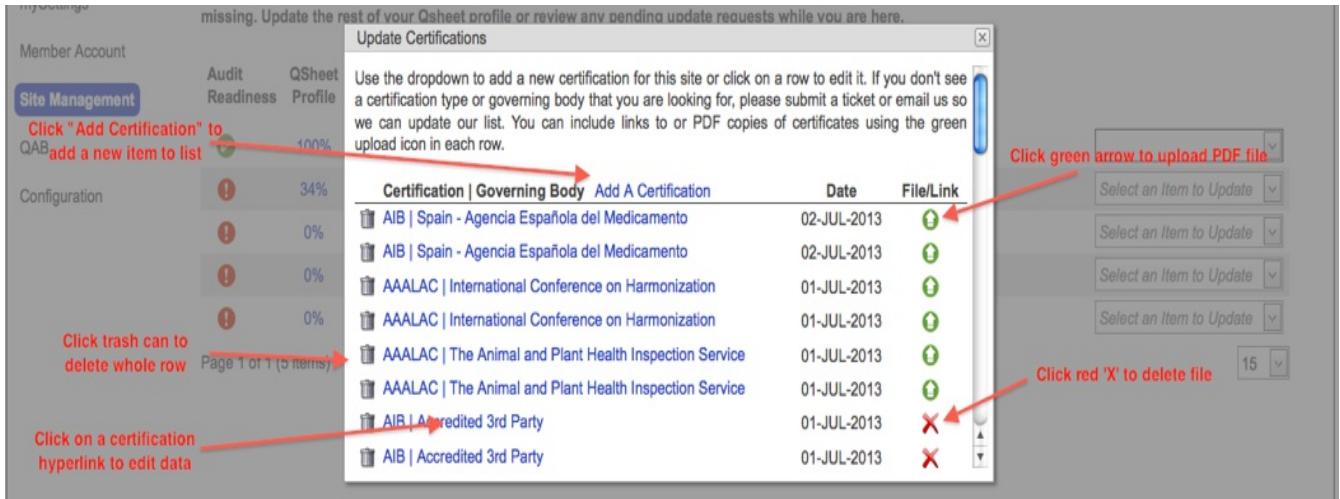
services that your site offers. You can select sites in the dropdown list using your mouse or the Enter/Return key. Service items should match your site's main purposes and can be used by ZenQMS members in analytics and in searching for sites with specific capabilities. Please let ZenQMS staff know if you think a service is missing—we can add them easily. Note each service item could be further specified by stage.



- "Update Key Personnel": There is more information in 1.11. Site and QA directors are important to add. And a default messaging contact needs to be added to "get green".



- "Upload Certifications" to add any key certifications that your site has earned. Add the Certification type first (e.g. cGMP or ISO9001), and then select a Governing Body (e.g. FDA). You could also add the date of the last visit. Once you save an item, you can also upload a PDF copy of the certificate for client reference. Alternatively, some members choose to upload a more thorough certification dossier/summary. Click the Save button when finished.



2.18 New Members: Adding New Sites, Merging Duplicates and Removing Sites

Most likely, ZenQMS staff or your client has already added your site to the database. But you should take a moment to add any other sites that may be audited by internal or external entities using these steps so that your complete network is in the system for your clients to find.

Sites that you designate "Internal (captive)" sites/entities will be visible only to your staff.

1. Navigate to Home > Administration > Site Management where you will see a list of all sites associated with your company.
2. Add New Site: Add a New Site to your MemberID using the "Add New Site" button. Note the default is for any new site to be designated an 'Internal' site, which means it is only visible to your staff—if you mean for the site to be visible to all ZenQMS members then check the 'No' option.

Add New Site

Enter all the information below and we will create the new site. We will also use the contact information you provide to reach out to the site to take ownership of its profile.

Site Name	<input type="text"/>
Map Location 	<input type="text"/> Look up site's location (at least city, state-region, country)
Town/City	<input type="text"/>
State/Region	<input type="text"/>
Country	<input type="text"/>
Latitude	<input type="text"/> 0.00000
Longitude	<input type="text"/> 0.00000
Is this an internal (captive) facility? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="button" value="Cancel/Exit"/> <input type="button" value="Create New Site"/>	

- Merge Duplicate Sites: You can merge duplicate sites by clicking the "Select an Item to Update" dropdown for the row the site appears. Then select "Merge this Site with Another of my Sites" to open the window shown below. Select from a list of your other sites that you want to merge into. The 'winning' site will inherit all audit reports, forum posts and documents stored for the site that is being merged; all contact information, services, and certifications will be lost.

The Quality Advisory Board Yorktown, USA

Merging Duplicate Sites

Select one of your remaining sites as the 'winner' of the merge, which will inherit all existing scorecards, attachments and forum posts of the duplicate site. Note: All information in the losing site's Qsheet 'Snapshot', Virtual Tour and Brochure pages WILL BE PERMANENTLY DELETED after the merge.

Start typing the name of the site or corporate parent

- Delete a Site: If a site has been assigned to your MemberID erroneously, then click the "Select an Item to Update" dropdown for the row the site appears in and select the "Remove This Site" option. After a confirmation window, the site will be removed from your MemberID.
- Claim an Existing Site: If there is a site in the database that should belong to your MemberID, find the site in the "Claim an Existing Site as Yours" drop down. After a confirmation window, ZenQMS staff will be notified to investigate and take action on your behalf.

2.19 New Members: Site Management (Overview)

Only users with proper permissions can enter the Site Management section to update a site's Qsheet profile. If you don't see the "Site Management" option (see below) on the left side menu when you navigate to Home > Administration section, then you need to get proper access from an existing system. System administrators automatically have access to this section.

This is a powerful page that lets users manage all aspects of a site's profile. You can easily add new sites/delete new sites and update all profile information, virtual tours and brochures. See snapshot below for a general orientation.

The screenshot shows the ZenQMS Site Management page. At the top, there are navigation links: Home, Search, Support, Elizabeth Lemon, Maura Pharma, LLC | Sign-out. Below that is a header with tabs: Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, Administration (which is selected). A search bar says "Jump to Qsheet. Start typing Site or Parent Name, Country or Site Q-ID". Buttons for "Add New Site" and "Claim an Existing Site as Yours" are visible. The main content area has sections for Set Up Guide, mySettings, Member Account, and Site Management. Under Site Management, there is a table with columns: Audit Readiness, QSheet Profile, QSheet Update Requests, Site Q-ID, and Site Location. The table contains four rows:

	Audit Readiness	QSheet Profile	QSheet Update Requests	Site Q-ID	Site Location
1	51%	None	MAU001001	Maura Pharma	College Station, Texas, United States of America
2	17%	None	MAU001002	Test Site Northeast	Philadelphia, Pennsylvania, United States of America
3	51%	None	MAU001003	Supplier Complaint Tests	Conshohocken, Pennsylvania, United States of America
4	0%	None	MAU001004	Test Site Texas	College Station, Texas, United States of America

Red annotations with arrows point to specific elements:

- An arrow points to the first row with the text: "Click red icon to see why site is not Audit Ready".
- An arrow points to the "Audit Readiness" column with the text: "Click here to go to this Site's Qsheet".
- An arrow points to the "Action" dropdown for the first site with the text: "Click the dropdown to take an action for a site".
- An arrow points to the page number "Page 1 of 1 (4 items)" with the text: "Click number to see what part of site's profile is missing".

2.20 New Members: Managing Your Subscription

Select the right subscription for your company in this section.

1. Navigate to Home > Administration > Member Account > Subscriptions
2. Click the "Update Billing Information" link to add the name, email address and billing reference that you want monthly invoice receipts being sent to. Save your information.
3. Click the "Update Card" button to enter your credit card information. Once a valid credit card is in place you will be able to select a pay subscription for monthly charging (default) or add prepaid credit to the account from which ZenQMS will draw monthly subscription costs for the Premium subscriptions. No credit card is required for a Collaborator account.
4. Select the right subscription using the radio buttons at the bottom.

ZEN QMS

Jump to Qsheet: Start typing Site or Parent Name, Country or Site Q-ID
[Return to General Preferences](#) [Add New Site](#)

Home Search Support
 Elizabeth Lemon, Maura Pharma, LLC | Sign-out

Dashboard Documents Training Issue/CAPA Audit Forum Administration

Set Up Guide General Preferences Users Subscriptions ZenQMS Access History

mySettings Billing Information

Member Account Name Update Billing Information

Site Management Phone

Configuration Email AddYourOwnBillingEmail@theqab.com We will send invoices/receipts here

Memo This text will appear on your invoice

No Credit Card information entered. Update Card

Current prepaid credit for this account is USD\$0 Add Credit

Credit card billing makes it easy for us to maintain simple/transparent pricing model. We accept all major credit cards- if you have any problems please contact us at: billing@zenqms.com

Prefer to pay in one lump sum instead of monthly? We will bill your credit card every 30 days. You can also pay in one lump sum using your credit card and the "Add Credit" hyperlink. Monthly charges are pulled from prepaid credit first, though an invoice will still be logged for your records. We can also take advance lump sums as bank checks or transfers with some notice. In any event, all members with a Basic or Premium account still need to provide a valid credit card. A billing contact is also recommended.

What happens when I upgrade/downgrade? Upgrading/downgrading will result in two transactions: 1) a pro rata refund to prepaid credit for the subscription you were on before the transaction; and 2) an invoice/charge for the new subscription in a new 30-day period.

Monthly Subscription Cost Monthly Cost USD\$

Choose a subscription: <input type="radio"/> Collaborator (Free) <input checked="" type="radio"/> Pro (Premium)	\$250
Additional \$100 for every 100 items in your account	\$0
Total # of Audits	7
Total # of Issues	21
Total # of CAPAs	26
Total # of Documents	18
Total # of Training Events	3
Total # of Qsheet Attachments	0
Total # of Virtual Tour Photos	0
Total # of Site Brochures	0
Total Items in Your Account	75
Monthly Premium Support	\$0

Total monthly charge **\$250**

Free Trials and Limited Subscriptions If the bottom of the screen at left says "The charges above do not apply while you are enjoying your Free Trial", you will not be charged any amount and can freely select any subscription you want. When your trial is over you can remain in the selected subscription provided you have loaded a valid credit card for Basic/Premium subscriptions. Remember, Limited Memberships are FREE for life, so downgrade instead of leaving us!

Thanks for your support!

Review Your Billing History

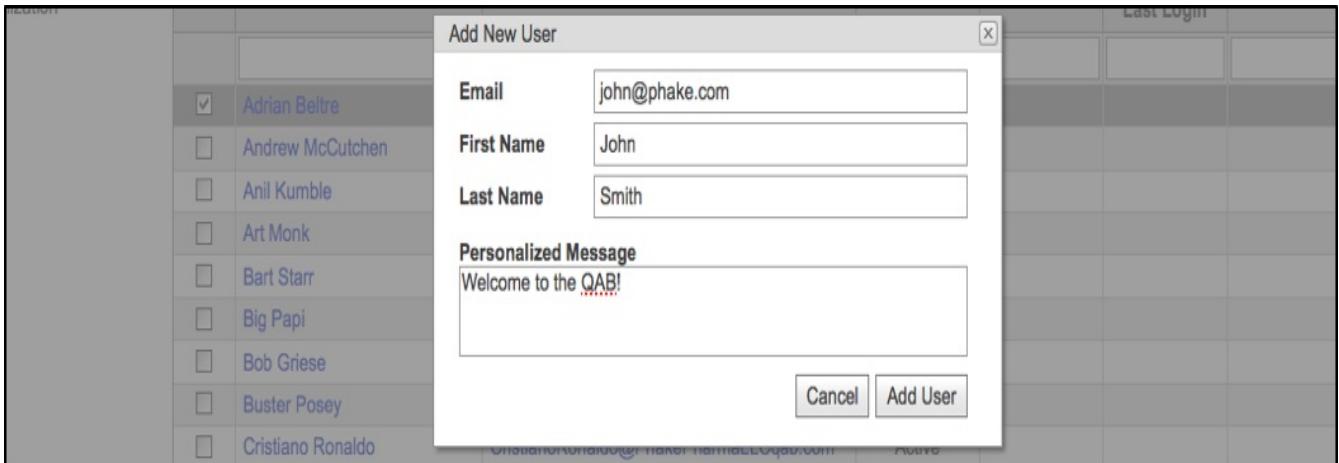
The charges above do not apply while you are enjoying your Free Trial

2.21 New Members: Managing Users

** Required Member Administrator Permissions **

Navigate to Home > Administration > Member Account > Users to execute all of these activities. Use this section to add/disable users, reset passwords, manage user permissions or assign supervisors.

1. Adding a Single New User: You will see a list of all users. Add a single user at a time by clicking the "Add New User" button and following the instructions (see below). The user will instantly be sent an invite and appear as active in the application.



- Adding Multiple Users from an Upload Sheet: You can also add multiple users at one time using an excel template that only requires First Name, Last Name and Email Address. You can download the template and then upload it. A confirmation window will let you know if there were any failures in the upload. And all new users will instantly appear in the table.

The screenshot shows a modal dialog titled "Upload Multiple Users". It contains instructions: "Click here to download the Excel template for uploading multiple users. Please make entries in the template, save the file, and upload it below. Email, First Name and Last Name fields are required." Below this is a file upload input field with a "Browse..." button. At the bottom is a "Send Immediate Invites?" checkbox followed by "Yes" (checked) and "No".

Please note the option for "Send Immediate Invites?". This is an option to defer the immediate email invitation that goes out to new users. This means that the users can be 'silently' added to your account for set up and configuration purposes and you can manually send invites out to one or all of them later when you are ready using the Send Invite button.

- Disable User(s) & Activate User(s): Disabling users means that they can no longer log in. You cannot delete a user in ZenQMS. You will see an instant confirmation, the user will get a notification that they are disabled and their status will change to "Disabled" in the table. Click the "Activate User(s)" button to reverse this action. Note—any user who fails the log in process too many times will be "Locked out" and require an authorized person to "Activate" their account.

4. Reset Passwords: You can reset a password for a user by selecting the affected user(s) and clicking the "Reset Password" button at the top. This will send a password reset email to the affected user(s) with a link to log in and will require the user to set a new password and security challenge question on log in.
5. Send Invite: You have the ability to add multiple users to the system without immediately inviting them to access the application. First use the "Upload Multiple Users" feature and make sure to choose "No" for the question of "Send Immediate Invites". Next select those users from the table and click the "Send Invite" button when you are ready to provide access to those users.
6. Manage Groups: This button is a short cut to the controls for managing groups and user permissions in ZenQMS. Review the article "Customization: Groups/Permissions" for more details on this.
7. Assign Supervisor: Select the users from the table that you'd like to assign a Supervisor to and click the "Assign Supervisor" button. Choose the appropriate user from the dropdown field to set the Supervisor role. You would also use this same process to remove an existing supervisor assignment by clicking the "Clear Existing Assignment" hyperlink.

2.22 New Members: Managing Member Profile & Settings

A 'Member' is the direct or ultimate corporate parent of one or more sites. There is a great deal of flexibility here. If you have a corporate parent or holding company with multiple sites and subsidiaries (or multiple groups within the same company) that want to share a single account and share information, then you would put the ultimate parent/holding company information here and use the Auditee Site Names to differentiate. Or you could create multiple individual accounts for each entity.

1. Navigate to Home > Administration > Member Account > General Preferences (the default selection)
2. Update your company's general corporate information at the top of the page.
3. Click the "Save" button when you are finished (the app will remind you)
4. Review the instructions on this page for managing settings for ZENQMS Support Access, Email Domain Restrictions, Password Restrictions, Logo, Scorecard Publishing and Custom Member Tags/Categories.

** Requires Member Admin Access **

2.23 New Members: System Administrator Access

Only a user with System Administrator permissions can access the Member Account settings, including basic settings, user management, and subscription management. If you don't see the "Member Account" option (see below) on the left side menu when you navigate to Home > Administration section, then you need to get proper access from an existing system administrator or from ZenQMS support staff (help@zenqms.com)

The screenshot shows the ZenQMS Administration interface. At the top, there's a navigation bar with links for Home, Search, Support, Add New Site, and Sign-out. Below the navigation is a menu bar with Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, and Administration. The Administration tab is selected. Under Administration, there's a sub-menu with Set Up Guide, General Preferences, Users, Subscriptions, and ZenQMS Access History. The General Preferences tab is selected. On the left, there are sections for mySettings, Member Account (which is highlighted with a red arrow), Site Management, and Configuration. The Member Account section contains fields for Company Name (Maura Pharma, LLC), Member Type (Biotech), Public/Private (Public checked, Private checked), Web URL, and Total employees (0). A 'Save' button is present.

Also, if you have Member Administrator privileges your means that your navigating to Home > Administration > Set Up Guide page will show you two sections for setting up your member account and sites. See picture below. If you don't see these sections please confirm that you have the right permissions.

The screenshot shows the ZenQMS Set Up Guide page. At the top, there's a navigation bar with links for Home, Search, Support, Add New Site, and Sign-out. Below the navigation is a menu bar with Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, and Administration. The Administration tab is selected. Under Administration, there's a sub-menu with Set Up Guide, General Preferences, Users, Subscriptions, and ZenQMS Access History. The General Preferences tab is selected. On the left, there are sections for mySettings, Member Account, Site Management, and Configuration. The Member Account section is highlighted with a red box and contains a warning icon (!) and the text: "Some Member Information items are blank. Update". Below it, another section has a warning icon (!) and the text: "One or more of your sites has an incomplete Qsheet profile. Check Qsheet Status". To the right, there's a large box titled "A Cheat Sheet for Everyone!" which contains a green checkmark icon and the text: "The guide below identifies areas that need your attention to complete your set up. The goal (as always!) is to see green checks like this one (checkmark) for all sections." It also includes a general overview for users, auditors, system administrators, and site managers, followed by a list of useful links.

2.24 New Users: Practicing in a demo or "sandbox" account

All users can log in to a safe demo or "sandbox" environment for practice. Or just for fun! It is identical to production in all other respects.

You can access sandbox as follows:

- Go to sandbox.zenqms.com
- Click the Sandbox link from the main log in screen

Please note-- Sandbox and 'Production' (which is at app.zenqms.com) are completely separate instances of the software and database. This means that your login credentials won't update each other from one instance to the other. And data won't be the same. It is strictly for practice and testing.

If you don't have a log in to the Sandbox, please email help@zenqms.com

2.25 New Users: Configure Personal Settings

If this is your initial log in, you will receive an invitation email from "noreply@zenqms.com" with a link in it. The link expires within 24 hours, after which time you will have to request another from the log in page using the "Forgot Your Password?" link.

You will be re-directed to the Administration > mySettings > Password page and required to set a new password if this is your initial log in.

Now take a moment and click through the remaining subtabs within mySettings to configure your account.

1. Personal Information: Fill in the details of your personal information and press "Save" when finished. Be sure to indicate if you are a Consultant.
2. Password: If you'd like to change your password at any time, follow the password guidelines and steps under this page.
3. Security: Update your security challenge question and enable two-factor authentication. Two-factor authentication will require users to enter a security code which they will receive via SMS text message whenever logging in from a new device or in a password recovery scenario. To enable two-factor authentication, click the "enable" button, enter your cellular telephone number, and save.
4. Preferences: Configure your visibility within ZenQMS to others, choose the form of measurement for data to be displayed within the system and set your language preference.
5. Picture/CV: Upload a picture and CV and enter summary background information. This background information is probably most helpful for consultants, auditors and other front-line quality colleagues in large organizations.
6. Permissions: Show the permission levels and groups the user is assigned to but does not allow for any changes or edits in these settings.

2.26 New Users: Accessing ZenQMS & Using the "Set Up Guide"

All you need to access ZenQMS is a valid email address and a web browser. Your system administrator can add you as a user or reset your account if you have forgotten your password or been logged out.

- Go to www.zenqms.com
- Click the "Log In" button in top right of screen
- Log in using your email address and temporary or permanent password

Users who want a simple guide to getting their user profile, company account or site profiles set up properly should navigate to Home > Administration > Set Up Guide (see screen shot). It's a passive

page that lets you know what you have to do. If you have a green check mark in all sections, you are all set. Red icons indicate items that may require your attention. Follow the links to get to the page that can help solve the problem.

There are three sections of this page for setting up user profiles, company accounts or site profiles, but users will only see items that are appropriate to their access/permission level.

The screenshot shows a user interface for managing user profiles and account settings. At the top, there's a navigation bar with links for Home, Search, Support, and a sign-out option. Below the navigation is a search bar labeled "Jump to Qsheet: Start typing Site or Parent Name, Country or Site Q-ID" and a "Add New Site" button. The main content area has tabs for Dashboard, Documents, Training, Issue/CAPA, Audit, Forum, and Administration. On the left, there's a sidebar with links for Set Up Guide, mySettings, Member Account, Site Management, Configuration, and a "User Profile" section which is highlighted with a red box. The "User Profile" section contains three items with red exclamation marks: "Some Personal Information items are blank. Update", "Perhaps you forgot to upload a photo, CV or CV Summary? Update", and "Fill out your auditor profile with Regional Focus & Audit Specialties. Update". To the right of the sidebar, there's a large text area titled "A Cheat Sheet for Everyone!" which provides general instructions and links to useful resources.

3.0 Documents

3.00 Permission to view documents in Controlled Files

Users only see items in their Documents>Controlled Files page that:

1. They have been assigned for training
2. They are authors of; or
3. They are 'category users' for.

The third item is probably the only one that needs explanation. Basically click on Member Category button Controlled Files page and click on the "Users with Editor/Access Rights" link. Any users in the resulting table will see ALL documents in that category. Users designated with other rights will have additional permissions as stated. This option is helpful if its a category of documents that ALL users should see.

3.01 How to view a document issued as Controlled Copy (using .PDC viewer)

Documents issued as controlled copies are 'locked down' to expire and only be printed one time. We do this using digital rights management protocols which rely on a proprietary file format (.pdc) and

that can only be accessed by the Safeguard Viewer. Here's what you need to do:

- Go to mySettings > Preferences page

Personal Information Password Security **Preferences** Picture/CV Permissions

Save

Users who can see my profile and send messages to me Internal & External

Make your name visible as Client/Auditor/Participant? Yes No

Display measurement data using: Square Meters Square Feet

Select your language preference: English

Controlled Copy Issuance

Application you need to install to view controlled copies

License key required to view controlled copies

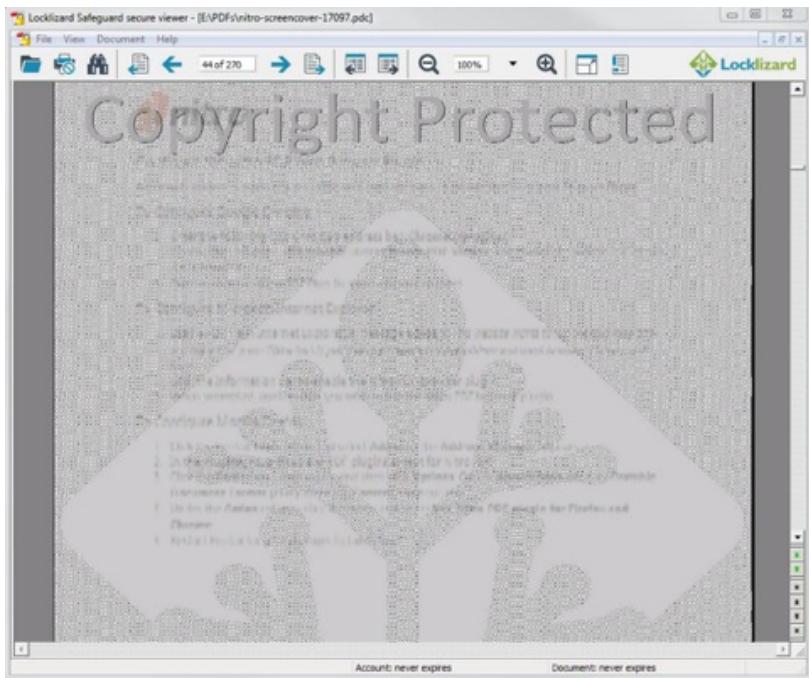
- Click on the “Application you need to install to view controlled copies” link to download the The Safeguard Viewer application.
- Now click the “License key required to view controlled copies” link to add the required license key specific to your account.
- You will now be able to view controlled copies issued from your account.

If you try to view a protected PDF file before you have registered, the following dialog box (or similar) is displayed.



The publisher may only have licensed you to view a document for a specific number of times.

The publisher may have imposed additional screen grabber limitations. If this is the case, when viewing a document with these limitations, Windows will temporarily change the color scheme to Windows Basic. When the document is closed the Windows color scheme will return to your previous settings. A screen mask may also be applied when mouse focus is removed from the viewer window as shown in the diagram below.



You may or may not be able to print a document (the print icon therefore may or may not be enabled) and/or printing may be limited to a number of copies.



If printing is disabled the print icon will be shown as .

When you print a document a watermark image or text may be displayed on the printed document.

Details of when your account expires (if ever) and when the document you are viewing expires (if ever) are displayed at the bottom of the viewer window in the status bar.

3.02 Certifying Destruction of a Controlled Copy

You can document and certify the destruction of an issued controlled copy of a document in ZenQMS using your username and password as an electronic signature,

Within the Controlled Copies subtab of the Document Management/Review screen:

- Select the issued copy from the table by clicking the check mark box on the left-hand side.
- Click the blue "Certify Destruction" button.
- Enter your username and password to electronically sign and complete the documentation of the destruction of the controlled copy.
- The status should now be updated in the table.

Document Management/Review

Controlled Copy Test 2

Version 3 - Effective

Save Export to PDF Review/Retire Document Exit 

Details Training Workflows / Signatures Controlled Copies

Certify Destruction **Issue New Controlled Copy** Export Table

	Copy ID	Requested By	Document Version	Issue Date (UTC)	Recipient	Page Range	Status	Details
	7099-01	Jamie Nar	03	01-Jun-2016 03:13:10	Jamie Nar	All	Destruction Certified by: Jamie Nar	Details
	7099-02	Peter Smith	03	01-Jun-2016 03:14:56	Al Bundy	All	Issued	Production Room
	7099-03	Jamie Nar	03	01-Jun-2016 03:21:49	Jamie Nar	1-3	Issued	Batch Number# 123
	7099-04	Jamie Nar	03	02-Jun-2016 12:56:17	Jamie Nar	5-5	Destruction Certified by: Jamie Nar	Batch # 123
	7099-05	Jamie Nar	03	03-Jun-2016 01:19:40	Jamie Nar	5-5	Issued	Batch# 123
	7099-06	Jamie Nar	03	03-Jun-2016 03:18:32	Jamie Nar	All	Destruction Certified by:	Batch 123

3.03 Issuing a Controlled Copy of a Document

With the proper permissions granted, a user may issue a controlled copy and document the event within ZenQMS using the “Controlled Copies” feature and their electronic signature.

Document Management/Review

Controlled Copy Test 1

Version 1 - Effective

Save Export to PDF Review/Retire Document Exit 

Details Training Workflows / Signatures Controlled Copies

Certify Destruction **Issue New Controlled Copy** Export Table

	Copy ID	Requested By	Document Version	Issue Date (UTC)	Recipient	Page Range	Status	Details
	22431-01	Elizabeth Lemon	01	15-Jun-2016 08:04:29	Michael Scott	All	Destruction Certified by: Elizabeth Lemon	test
	22431-02	Elizabeth Lemon	01	16-Jun-2016 06:49:00	Ned Flanders	1-1	Destruction Certified by: Elizabeth Lemon	jkhgjhfhgdghfg
	22431-03	Elizabeth Lemon	01	16-Jun-2016 08:04:04	Ron Swanson	1-1	Issued	fsfdsfds

Page 1 of 1 (3 items)  [1]  Page size: 15 

Within the Document Management/Review Screen, click the “Controlled Copies” subtab. Here you will see a table that will contain all of the controlled copies issued and specific details of the issued document including a unique Copy ID, the user who requested the issued copy, the issue date, the recipient, pages included, current status (if it is issued or destroyed and by whom), and the details of issued copy.

To issue a new controlled copy:

- Click the blue “Issue New Controlled Copy” button.
- Select from the dropdown menu a ZenQMS user to whom you are issuing this controlled copy.
- Select your page range.
- Enter in key details in the short text box.
- Click the green ‘Generate Preview’ button to see an updated preview of the controlled copy before downloading the file. Please note the unique Copy ID will be located in the Header at the top right hand corner in red along with your key details entered. Once it is downloaded the “XX” at the end of the Copy ID will contain the number corresponding the number of times the document has been issued. For example, if this is the second controlled copy issued, the Copy ID will end in -02.
- Click the blue “Download Controlled Copy” button when you are ready to download the final version of the document into a PDF format.

Controlled Copy Issuance

Lucille Bluth	Key details (max 50 characters):*														
Page range: <input type="radio"/> All		Your details here													
<input checked="" type="radio"/> From <input type="text" value="1"/> to <input type="text" value="1"/>		Download Controlled Copy	Cancel												
Page: <input type="text" value="1"/> of 1 - + Automatic Zoom															
<table border="1"> <tr> <td></td> <td colspan="3"> Category: Controlled Copy Title: Controlled Copy Test 1 </td> </tr> <tr> <td>Version 01</td> <td>State Effective</td> <td>Effective Date 15-JUN-2016</td> <td>Document ID 22431</td> </tr> <tr> <td>Maura Test 1 test</td> <td>Maura Test 2 29-JUN-2016</td> <td colspan="2"></td> </tr> </table> <p>Printed by maura+demo@zenqms.com from test.zenqms.com on 16-Jun-2016 at 8:39:10 PM UTC • Page 1 of 6 Copy 22431-XX Your details here</p> <p>[Type here]</p> <p style="text-align: center;">Uncontrolled BLUTH</p>					Category: Controlled Copy Title: Controlled Copy Test 1			Version 01	State Effective	Effective Date 15-JUN-2016	Document ID 22431	Maura Test 1 test	Maura Test 2 29-JUN-2016		
	Category: Controlled Copy Title: Controlled Copy Test 1														
Version 01	State Effective	Effective Date 15-JUN-2016	Document ID 22431												
Maura Test 1 test	Maura Test 2 29-JUN-2016														

You can also issue a controlled copy by clicking on the download icon in the Documents table and then select “Issue Controlled Copy” hyperlink.

3.04 Managing Document Categories

** Users need to be Super Administrators or have the permission "Can Create/Manage Document Categories" to be able to create and manage document categories.

From the Documents tab, click on the “Manage Categories” button. If it is inactive for you, you do not have the permission.

Adding a New Category

Click “New Category” at the top to see the window below.

The screenshot shows the 'Manage Document Categories' window. At the top, there are buttons for 'Exit', 'New Category', and 'Save'. Below this, a table lists various category settings:

DocumentCategory	Delete this Category	Select a Category
Category Name	SOP	
Date Created	05-Dec-2014	
Created By	John Riggins	
Archive Rule For Deletion	Flag Files for Deletion Immediately after Retirement	
Automatically create training records for authors/workflow participants?	No	
Default User Retraining Interval	Never	
Default Review Interval	How Often Documents in This Category be Reviewed	
Default Training Grace Period (days)	0	
Document Security	Users Can Download an Unrestricted PDF	
PDF Watermark	Type a Watermark	
PDF User/Time Stamp	Yes -- In Header	
PDF Header with Document Data	Insert header into attached file	
We recommend a 2.5" margin to accommodate the header	No custom field selected	

To the right of the table is a 'Instructions' section containing the following text:

Category settings are critical in terms of allowing access, setting defaults, enforcing approval requirements and archive rules. Click to create a new category or select an existing category from the .

- Document Categories Section:
 - Archive Rule for Deletion: this setting affects all archived documents from this category.
 - Set default values for the following items for all NEW documents, all of which can be changes at the document level: Automatic Training Records, Retraining Interval, Review Interval and Document Security.
 - PDF Watermark: You can add a watermark that appears on all converted PDFs when a user downloads the file. The watermark appears below the user name and time stamp. Watermark Changes are reflected immediately on all documents in the category.
 - You can see how many documents are in this category by clicking the number next to
 - You can see the users who have editor/access rights by clicking on the number next to
- Workflow for Publishing/Retiring Section
 - By default, authors of documents will have to complete the workflow approval!

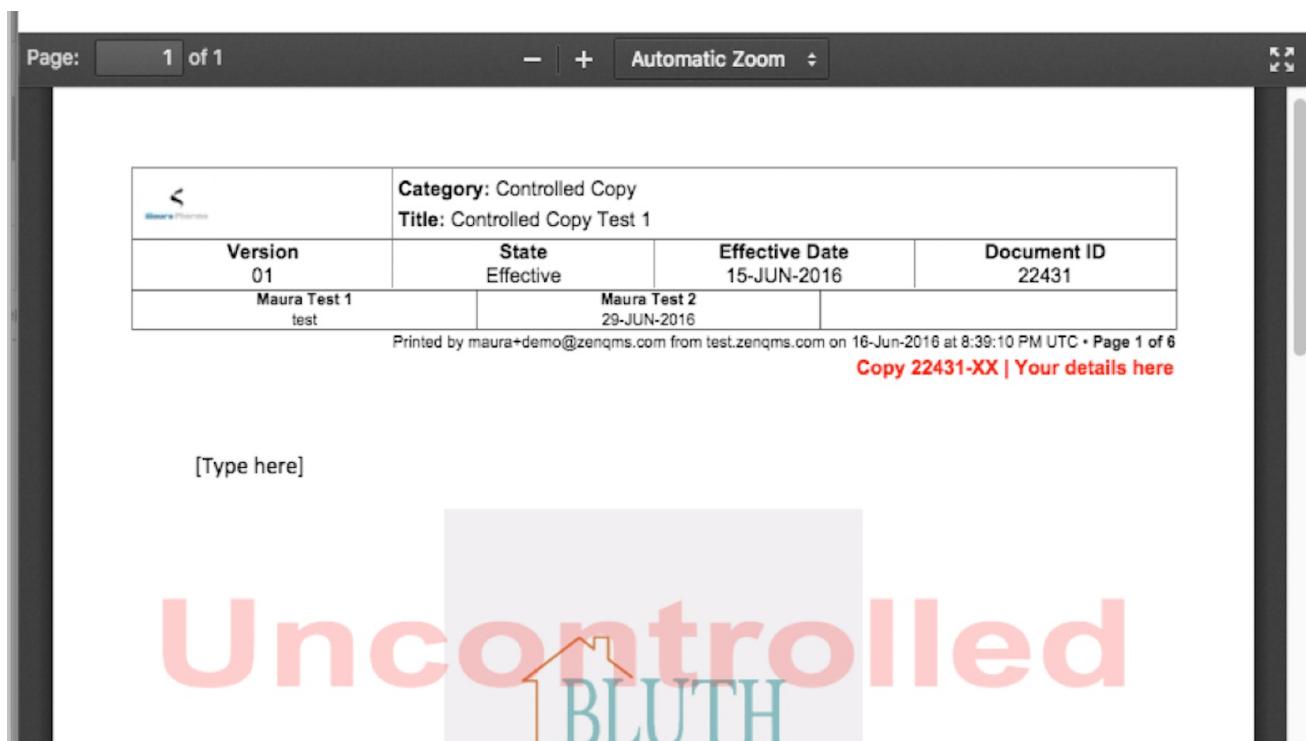
After you enter a name for your category you can update the Category Settings. Most of the settings are here as default settings for newly created documents and can be changed at the document level. Others are important toggles for functionality like document headers. If you need a more detailed explanation of these settings, please see the adding a document section.

- Archive Rule for Deletion: You will need to choose an archive rule for deletion. This determines if and when a document within this category can be permanently deleted from the system after it has been retired and is in the archive. All documents within the category will have this rule applied. You can choose for files never to be deleted or a time period between one and thirty years after the document is retired.
- Automatically create training records for workflow participants: Default setting, but can be changed at the document level as well.
- Default User Retraining Interval: Default setting, but can be changed at the document level as well.
- Default Review Interval: Default setting, but can be changed at the document level as well.
- Default Training Grace Period (days): This # of days will be added to the assignment date to

calculate training due date for newly assigned users. Note that a user's actual training due date = max [(assignment date + grace period days) or (Effective Date)]

- Document Security: Default setting, but can be changed at the document level as well.
- PDF Watermark: Text will appear in large red watermark font across all pages of the converted PDF. If you'd like to have a different PDF Watermark than "Uncontrolled", make sure to update that field. If you would like to not have a watermark, delete "Uncontrolled" from the text box.
- PDF User/Time Stamp: There are 3 options here. The header option inserts a detailed time stamp in the header and include user name, application environment, date/time in UTC format and unambiguous page numbers including any ZenQMS pages included at the end of the document include it as a watermark with less information. The watermark option includes the user ID and time stamp as a watermark.
- PDF Header with Document Data: This feature allows you to include dynamically generated header that will include your company logo, document title, document category, version number, state, effective date, and ZenQMS document ID. You also can add up to three custom fields from the Document Details section. If you are choosing to add this header to the documents within this category, please note that we recommend a 2.5" margin at the top of the document for the header to be inserted above your content.

Below is an example of a converted PDF that includes a full header with custom fields and userstamp AND a watermark.



Managing Category Users and Permissions

Click the hyperlink next to "Users with Editor/Access Rights". You will be able to add users or groups of users to the table here. Any user in the table automatically will have read only rights to ALL documents in the category. There are also three columns for managing other permissions for the document category.

- Category Editor: This permission means the user has full EDIT rights to all documents in this category.
- Can Add Files: This permission means if the user has the permission to add files, this category will appear in the dropdown for adding or editing document category.
- Controlled Copy: This permission is required for any user (including editors, super admins, etc.) if you want to be able to issue controlled copies of a document set with that security setting.

Manage Category Users

SOP

Select a User or Group to Add Group Actions Export Table Exit

User List

	<input type="checkbox"/>	Name	Category Editor	Can Add Files	Controlled Copy	Added By
	<input type="checkbox"/>		<input type="checkbox"/> <input type="button" value="X"/> <input type="button" value="▼"/>	<input type="checkbox"/> <input type="button" value="X"/> <input type="button" value="▼"/>	<input type="checkbox"/> <input type="button" value="X"/> <input type="button" value="▼"/>	
<ul style="list-style-type: none"> ▪ Individuals <input type="checkbox"/> <input type="button" value="X"/> Art Monk Yes No No John Riggins <input type="checkbox"/> <input type="button" value="X"/> John Riggins Yes Yes Yes John Riggins 						
<ul style="list-style-type: none"> ▪ <input type="checkbox"/> <input type="button" value="X"/> Executive Team & Investors Andrew McCutchen No No No John Riggins Art Monk No No No John Riggins Bob Griese No No No John Riggins Buster Posey No No No John Riggins Lionel Messi No No No John Riggins 						
<ul style="list-style-type: none"> ▪ <input type="checkbox"/> <input type="button" value="X"/> Production Andrew McCutchen No No No John Riggins Bart Starr No No No John Riggins Bob Griese No No No John Riggins Buster Posey No No No John Riggins Cristiano Ronaldo No No No John Riggins 						
Page 1 of 2 (23 items) <input type="button" value="<"/> [1] <input type="button" value="2"/> <input type="button" value=">"/>				Page size: 15 <input type="button" value="▼"/>		

Managing Document Approval Workflows

If you need to add specific workflow steps and collect signatures for the document to become effective/approved, you will enter them under the Workflow for Publishing/Retiring section. Remember all authors of the document will always need to sign to make the document effective. You can add as many steps as needed.

- Click the “Add Step” button and fill in the details
- Name your step
- Choose a reason code from the dropdown list
- Determine if the step can be delegated to another user
- Choose either an individual or group of users from the dropdown list. All those selected will appear as authorized users for that signature step.

- Press save when you are finished.

Users with Editor/Access Rights

15

Workflow for Publishing/Retiring (optional)		Add Required Workflow Step
Sign in Order?	Yes	<input type="button" value="▼"/>
Step 1 Delete this Step		
Step Name	<input type="text" value="Type a Name"/>	
Reason Code	<input type="text" value="I have reviewed and approve this document."/> <input type="button" value="▼"/>	
Can Step be Delegated?	<input type="text" value="No"/> <input type="button" value="▼"/>	
Workflow Step Users	<input type="text" value="Start Typing a Group or User Name to Add"/> <input type="button" value="▼"/> <i>No authorized groups or users selected.</i>	

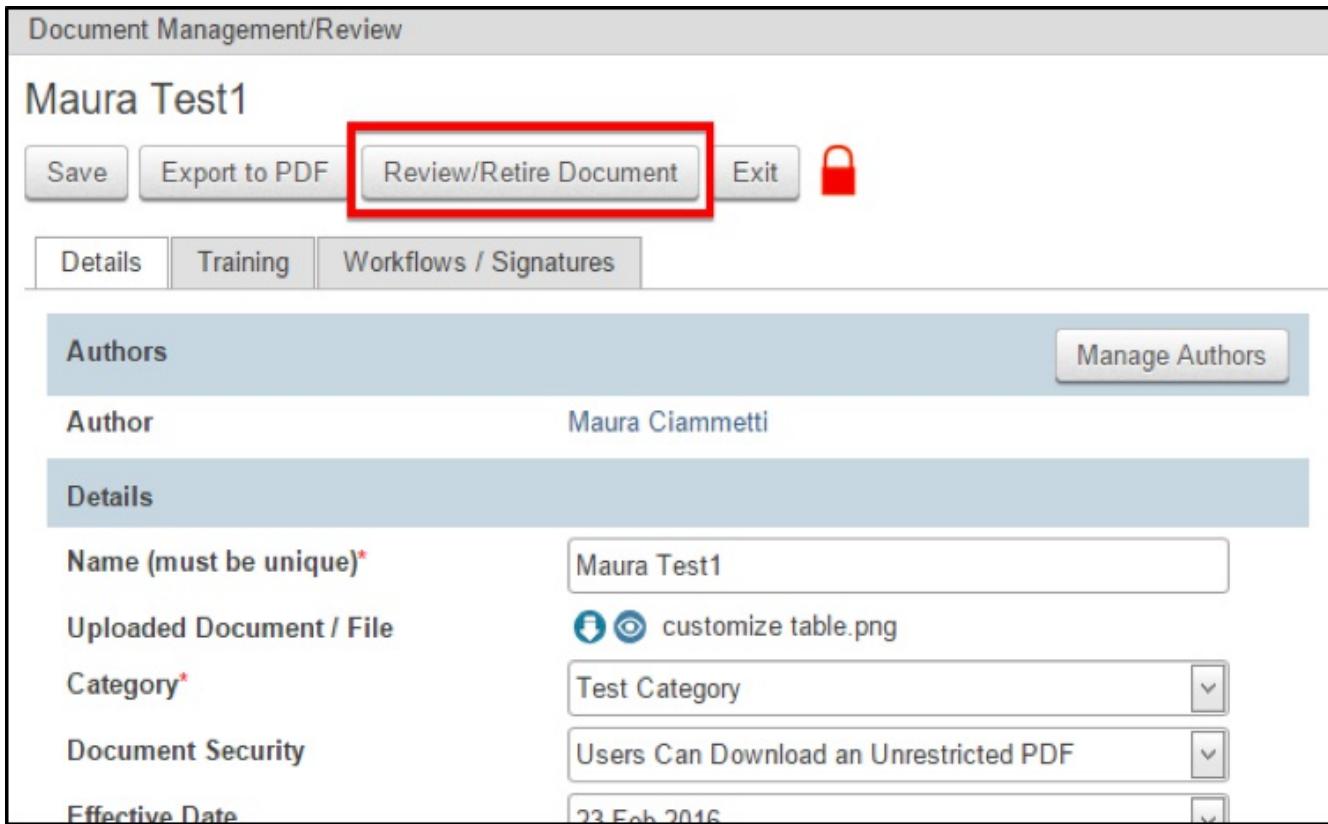
Managing Existing Categories

If you need to update an existing category, choose your category from the dropdown menu at the top of the screen and update your settings as needed. Press save when you are finished.

Manage Document Categories	
Exit	New Category
Save	
DocumentCategory	Delete this Category
Category Name	<input type="text" value="SOP"/> <input type="button" value="▼"/>
Date Created	05-Dec-2014
Created By	John Riggins
Archive Rule For Deletion	<input type="text" value="Flag Files for"/> <input type="button" value="▼"/>
Automatically create training records for authors/workflow participants?	<input type="text" value="No"/> <input type="button" value="▼"/>
Default User Retraining Interval	<input type="text" value="Never"/> <input type="button" value="▼"/>
Default Review Interval	<input type="text" value="How Often Documents in This Category be Reviewed"/> <input type="button" value="▼"/>

3.05 Reviewing/Retiring a Document

If you are a Super User or an author, you may need to review or retire an effective document within the system. From the Documents tab, use the table to quickly search for the document you need to update or retire. Once you find what you're looking for, click "Edit".



The screenshot shows the 'Document Management/Review' interface for a document titled 'Maura Test1'. At the top, there are buttons for 'Save', 'Export to PDF', 'Review/Retire Document' (which is highlighted with a red box), and 'Exit'. To the right of the 'Review/Retire Document' button is a red padlock icon. Below these buttons are three tabs: 'Details', 'Training', and 'Workflows / Signatures'. The 'Details' tab is selected. In the main content area, there is a section titled 'Authors' with a 'Manage Authors' button. Under 'Details', there are several fields: 'Name (must be unique)*' containing 'Maura Test1'; 'Uploaded Document / File' showing 'customize table.png'; 'Category*' set to 'Test Category'; 'Document Security' set to 'Users Can Download an Unrestricted PDF'; and 'Effective Date' set to '22 Feb 2016'.

From the document review window, click Review/Retire Document towards the top of the screen. From here, you have 3 options:

- Mark the item as current, with comments and an electronic signature–this will keep the current version as the effective version
- Indicate the item must be updated–and include a comment as to why–this will allow you to create a new version
- Mark the item as obsolete, which also requires a comment as to why–this will allow you to permanently retire a document (please note, ALL retired documents are available in the Archive section of the documents module)

To update the document, enter a comment in the box provided with the reason the document is being updated. Once you've entered your comment, click "Item Must Be Updated". Enter your credentials to authorize the change.

QA SOP

Actions You Can Take

Logs your review and comments with signature.

Logs review and creates new draft version.

Logs review and launches retirement workflow.

Comments (required)

New version available.



The system will notify you that the previously effective version has been flagged for retirement, and that a new draft version has been created. Click Ok.

To access past versions of the document, click the hyperlink that says “Click HERE to see the past x versions of this document”, and then click on the line item that says “Draft”.

Automatically create training records
for authors/workflow participants?

No

User Retraining Interval

Never

Document Review Interval

Never

Document Description

QA Training SOP

Version Comments

version 2

[Click HERE to see the 3 past version\(s\) of this document](#)

Document Versions		
QA SOP		
File Name / Version	State	Retirement Date
QA SOP (v.03)	Draft	
QA SOP (v.02)	Flagged For Retirement	
QA SOP (v.01)	Retired	01-Jan-2016

Page 1 of 1 (3 items) [\[<\]](#) [\[1\]](#) [\[>\]](#) Page size: [10](#) [\[▼\]](#)

First, we need to upload the new version. Click the “Upload Document/File” button, and choose the document you want to upload. Next, choose the effective date for the new version. Any settings from the previous version will have been carried over, however they can be edited here. Review the information such as a user retraining interval, document review interval, etc. You will also need to enter version comments here. Once you’ve made all necessary changes, click the “Launch Approval Workflow” button. Then, click the green “Launch Workflow” button. Once the document has been approved, it will appear in the table as the latest version. Retired versions of the document can be found in the Archive table.

3.06 Assigning a Document for Training

If you are a user who has permissions to assign documents for training, head to the Documents table and locate the document you want to assign for training. See the section on searching for a document if you need assistance. Once you’ve located the document, click “Edit”.

Add New Document	Batch Upload	Manage Categories	Customize	Export Table	Search whole keywords
Drag a column header here to group by that column					
	Document Name	Date Created	Effective Date	State	Category
Edit	QA	29-Dec-2015	01-Jan-2016	Effective	SOP
Edit	QA SOP				
Edit	QA Template	29-Dec-2015	29-Dec-2015	Effective	QA Documentation

Page 1 of 1 (2 items) [\[<\]](#) [\[1\]](#) [\[>\]](#)

[State] Equals 'Effective' And Contains([Document Name], 'QA')

Click the “Training” subtab. The first light blue box on the screen will list how many users are assigned to the document directly or through a course. Click the “manage” button to see the list of users or add users to train on the document. You can type in the box to add individuals or groups to train on this document. Once an individual or group has been added to the training, you are done! Trainees will be automatically notified to log in to the system to complete their training. Users or groups of users will be organized within this table by how they were assigned to the document (either directly to the document or as part of a course).

Document Management/Review

PeanutTest

Save Export to PDF Review/Retire Document Exit

Details Training Workflows / Signatures

9 User(s) assigned to this document directly or through a course.

Training Challenge Questions (optional)

Trainees must answer at least 100% to complete training.

Question	Type	Answer	Pass %
choice Choices: • 1 • 2 • 3	Choice	1	46%
adev / fals	T/F	FALSE	77%

Manage Assigned Trainees

PeanutTest

Version 1 - Effective

Select a User or Group to Add Group Actions Export Table Exit

Trainee / Group Name Show all users with training compliance at risk or past due

	<input type="checkbox"/>	Training Status	Trainee	Supervisor	Courses	Training Date	Due Date
<input checked="" type="checkbox"/>		Users/Groups Assigned Directly to This Document					
Individuals							
<input type="checkbox"/>		Non-Compliant	Administrative User	Alin Cobarzan			29-Jan-2016
<input type="checkbox"/>		Compliant	Alina +1 Test	Alina Cobarzan		28-Jan-2016	
<input type="checkbox"/>		Non-Compliant	Alina +10 Test				25-Jan-2016
<input type="checkbox"/>		Non-Compliant	Alina+4 Test				29-Jan-2016
<input type="checkbox"/>		Compliant	Marius+123 Test	Administrative User		11-Jan-2016	
<input type="checkbox"/> TestareAlina							
<input type="checkbox"/>		Compliant	Alina Test	Alina Cobarzan		21-Jan-2016	
<input checked="" type="checkbox"/>		Users/Groups Assigned to this Document as Part of a Course					
Individuals							
<input type="checkbox"/>		Non-Compliant	Alin Cobarzan	Peter Smith	PeanutCourse		11-Jan-2016
<input type="checkbox"/>		Compliant	Alina +1 Test	Alina Cobarzan	PeanutCourse	28-Jan-2016	
<input type="checkbox"/>		Non-Compliant	Alina +100 Test		Test ZENO-954		28-Jan-2016
<input type="checkbox"/>		Compliant	Alina Cobarzan		Test ZENO-954	11-Jan-2016	

3.07 Approving a Document

If a document has been assigned to you for approval, you will be notified via your daily summary email. From the Dashboard, click on “Items waiting for your review/signature” in the Workflows/e-signatures tile. Click on the item that you want to approve from the Workflow Action Items box.



You can choose to Download a PDF version of the document or you can click “Review/Edit in ZenQMS” to review or edit the document within the system.

If you want to approve the document, click Sign/Approve. In the next screen, enter your login credentials. If you want to reject the document, click Reject. In the next screen enter your login credentials.

A screenshot of the 'Workflow Action Item' page. At the top, the document name 'Unique Name for SOP (v.01)' is shown. Below it, a 'Workflow Details' section contains information about the workflow type ('DOCUMENT APPROVAL / Author Approval') and purpose ('Formal approval is required to make a controlled document 'Effective''.). Under 'Review Documents', there are two buttons: 'Download PDF' and 'Review/Edit in ZenQMS', both of which are highlighted with a red box. In the 'Actions You Can Take' section, there are two buttons: 'Sign/Approve' and 'Reject', both of which are also highlighted with a red box. To the right of each button is a brief description of its function.

If the document has been approved and no other signatures are needed, it will now appear as an effective document in the documents tab and can be assigned out for training.

3.08 Reviewing Previous Revisions of a Document

Any Author of a document can review all revisions of a document and compare the differences between the files. Within the draft document, click the hyperlink within the blue details box listing the number

of revisions available.

The screenshot shows a software application window titled "Document Management/Review". The main title bar says "Giulia Test" and the top right corner says "Version 1 - Draft". Below the title bar are several buttons: Save, Export to PDF, Delete, Launch Approval Workflow (highlighted in green), Launch Draft Review, and Exit. There is also a lock icon. A red arrow points to the "2 Revisions" link in the "Details" section of the main content area. The left sidebar has tabs for Details, Training, and Workflows / Signatures. The main content area has a "Authors" section with a "Manage Authors" button. The "Details" section contains fields for Name (must be unique), Uploaded Document / File, Category, Document Security, Effective Date, Automatically create training records for authors/workflow participants?, User Retraining Interval, Document Review Interval, and Document Description. To the right of the main content area is a large text box containing placeholder text: "Lorem ipsum dolor sit amet, consectetur adipiscing elit. Duis varius euismod eros et imperdiet. Etiam porta velit non lacinia semper. Vestibulum nec purus volutpat, ullamcorper justo nec, rhoncus turpis. Nam sit amet malesuada ex, nec pulvinar leo. Nullam euismod lorem ut turpis eleifend, sit amet auctor felis mollis. Vestibulum ante ipsum primis in faucibus orci luctus et ultrices posuere cubilia Curae; Suspendisse nulla lectus, lacinia quis lacus id, dignissim commodo odio." Below this text is a scroll bar.

From the list of document revisions, select the checkboxes of the items you'd like to compare. Click the blue “Compare Documents” button to download a Word document and review within Microsoft Office.

Giulia Test

Document Management/Review

Giulia Test

Version 1 - Draft

Save Export to F...

Details Training

Authors

Author

Details

Name (must be unique)

Uploaded Document

Category

Document Security

Effective Date

Automatically create for authors/workflow

User Retraining

Document Review

Document Description

Document Revision History

Compare Selected Documents Upload Revision Exit

ZenQMS Document Review.docx Standard Operating Procedure Template - Single Page.doc

giulia umile giulia umile

25-Jan-2016 07:45:22 25-Jan-2016 07:41:06

Current Version Revert to this Version

Page 1 of 1 (2 items) [4]

Page size: 10

Giulia Test Comparison (1).doc [Compatibility Mode] - Word

File Home Insert Design Layout References Mailings Review View Tell me what you want to do Giulia Umile Share

ABC ABC 123 Spelling & Thesaurus Word Count Smart Lookup Translate Language Insights Language

New Comment Delete Previous Next Show Comments Track Changes All Markup Show Markup Reviewing Pane Accept Reject Previous Changes Compare Block Authors Restrict Protect

Riverside City Seal

Xxxxxx Department
Xxxxxx Division/Function

SOP #
Revision #
Implementation Date

Page # 1 of xx Last Reviewed/Update Date

SOP Owner Approval

Edit Standard Operating Procedure

1. Purpose
Describe the process for <official name of SOP>. [edit](#)
Describe relevant background information.

2. Scope
Identify the intended audience and /or activities where the SOP may be relevant.
[Edit](#)

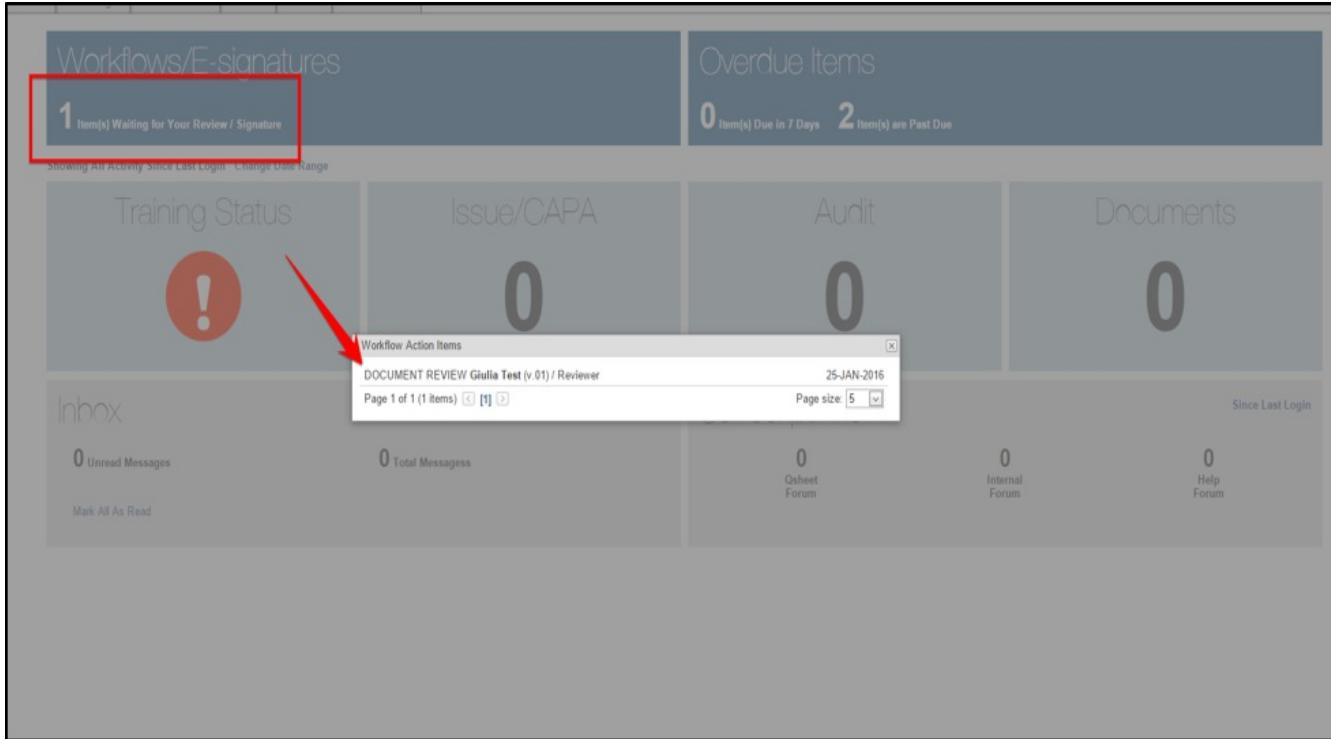
3. Prerequisites
[Edit](#) Outline information required before proceeding with the listed procedure; for example, worksheets, documents, IFAS reports, etc.

4. Responsibilities

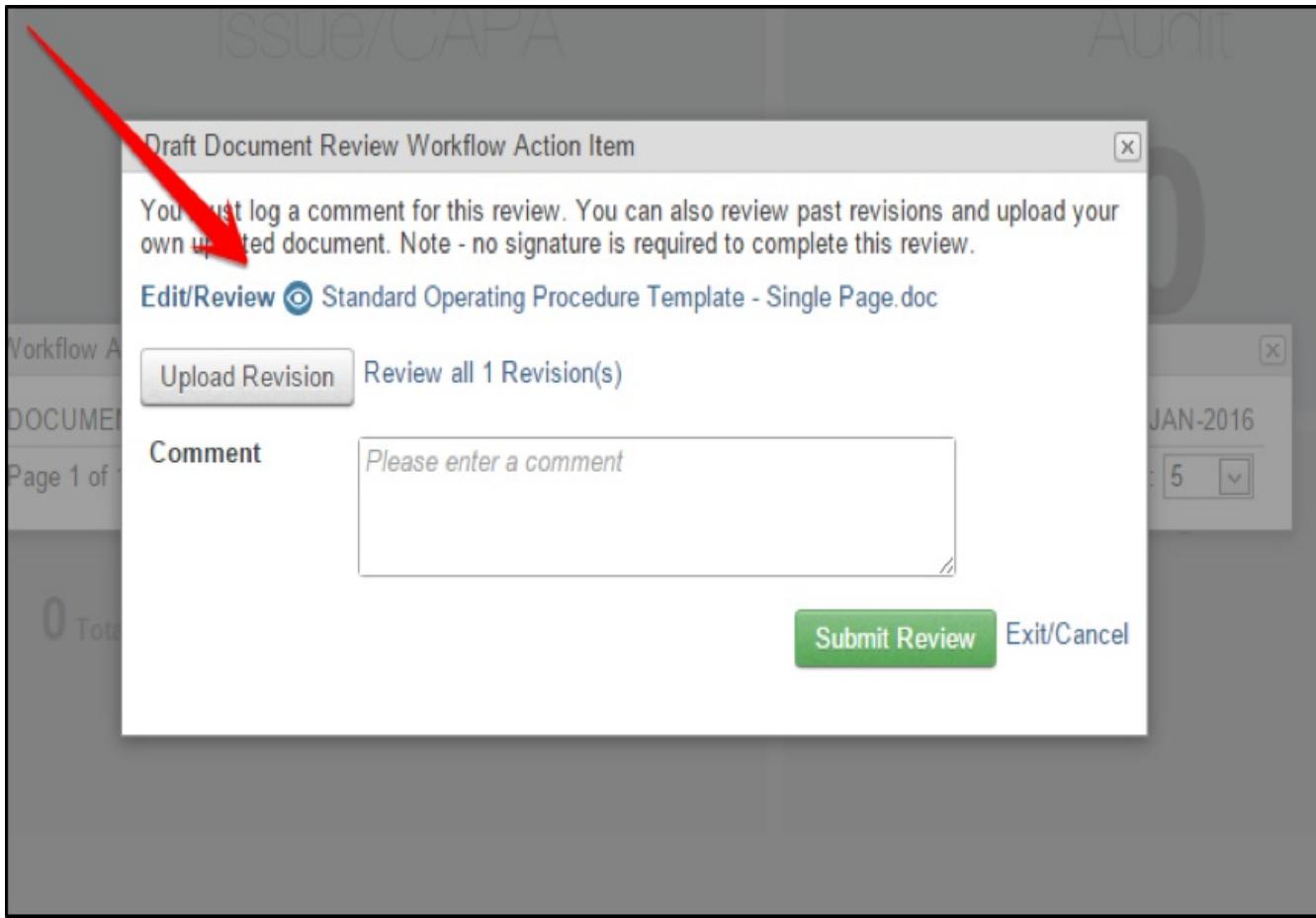
Page 1 of 1 144 words

3.09 Reviewing a Draft Document

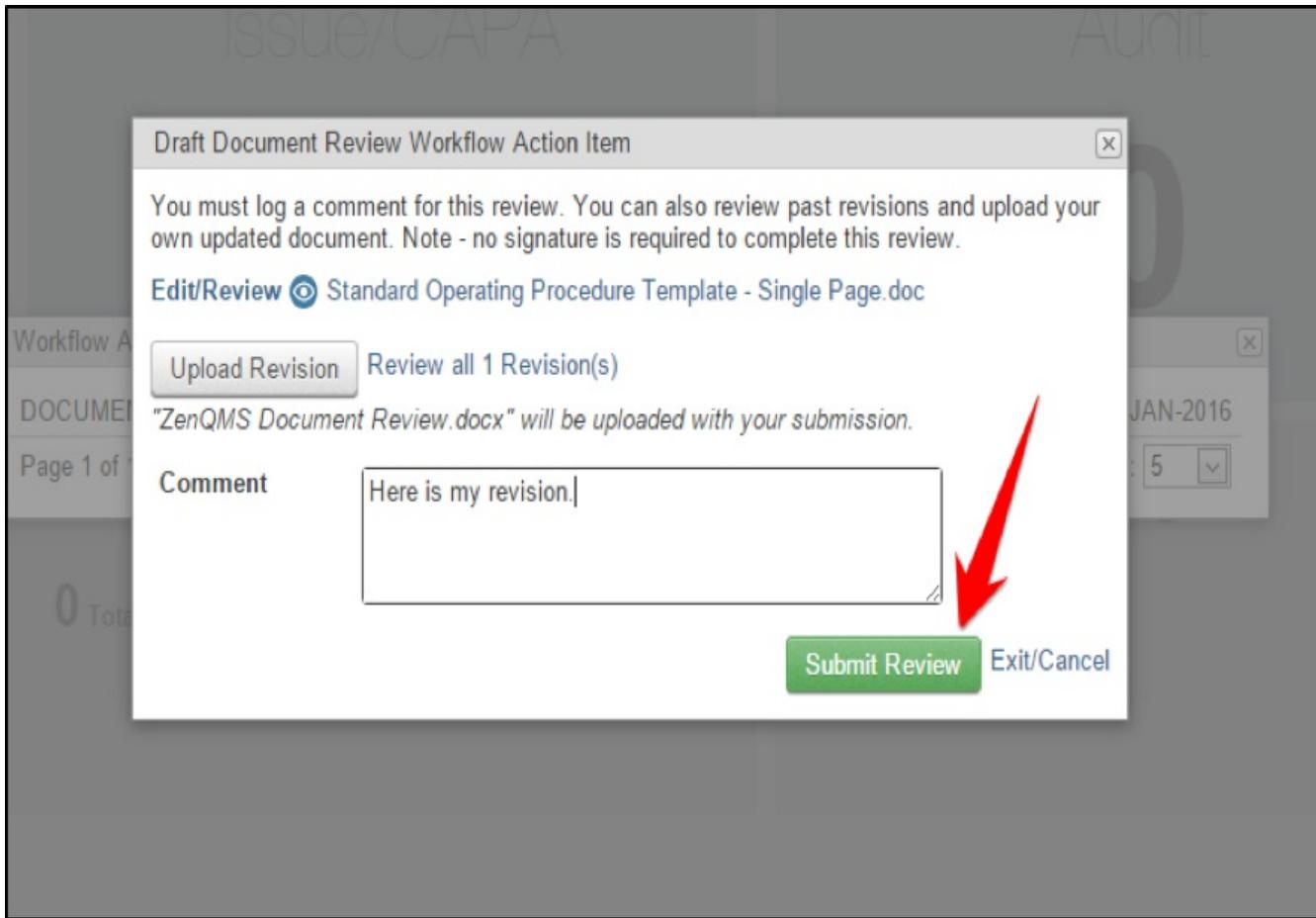
If a draft of a document has been assigned to a user for review it will appear as “Document Review” under the Workflows/E-Signatures tile on the Dashboard. Click on the item from the list that you’d like to review.



In the Draft Review screen, click on the file name (hyperlink) to download the version that was sent to you.



Make your edits to the downloaded document, save the file, and click the Upload Revision button. You can also enter comments for the Author. Press the green “Submit Review” button when finished.



3.10 Adding a New Document

Click the blue “Add New File Button” and name the document and select the document category. Please keep in mind, file names must be unique. Once you’ve entered the information, click “Create”.

The screenshot shows the Qsheet interface with a modal dialog titled "Add Document". The dialog contains fields for "Name*" and "Category*", both of which are highlighted with red boxes. A green "Create" button is also highlighted with a red box. The background shows a table with columns for Document Name, Version, Category, and State.

Enter the details for the document. If applicable, you can manage the authors of the document by clicking the “Manage Authors” button. You may choose up to 3 authors.

To upload the file, click the “Upload Revision” button. Browse to the location of the document you want to upload. The file upload has no size limit. You may also upload any type of file you would like.

The screenshot shows the "Document Management/Review" screen for a document named "Unique Name for Doc". It includes buttons for "Save", "Export to PDF", "Delete", "Launch Approval Workflow" (highlighted with a red box), "Launch Draft Review" (highlighted with a red box), and "Exit". Below these are tabs for "Details", "Training", and "Workflows / Signatures". The "Details" tab is active. Under the "Authors" section, there is an "Author" field containing "Maura Ciammetti" and a "Manage Authors" button (highlighted with a red box). Under the "Details" section, there is a "Name (must be unique)*" field containing "Unique Name for Doc" and an "Upload Revision" button (highlighted with a red box).

Under the Document Security field select one of the following options:

- Users Can Download Original File – all users assigned to this document or with permission to view the document will be able to download a copy of the original document. Please note all Super Users and Authors will always have access to the original file.
- Users Can Download an Unrestricted PDF – all users assigned to this document or with permission to view the document will be able to download a PDF version.
- Users Can Only View Document – all users assigned to this document or with permission to view the document will only be able to access a read only version within the system. They will not be able to right click, save, or print the document.
- Authorized Users Can Issue Controlled Copies – authorized users will be able to issue a controlled copy of the document. If users are assigned to or given access to this document but not given the authorization to issue a controlled copy they will only be able to view the document within the system. Lastly, the document category security setting must be set to “Authorized Users Can Issue Controlled Copies” for the individual document to allow this feature to accessed.

Select the effective date of the document. If all signatures are collected approving the document before the effective date, the document will remain in an approved state until the effective date arrives. At that time it will convert to an effective state.

Choose if you'd like to have training records automatically created for authors and workflow participants who will sign and approve the document.

Next choose how often you'd like assigned users to retrain on the document. You may choose that you never want users to retrain or a time period between 3 months and 60 months. Users assigned to train on this document will automatically be notified to retrain at the specified interval.

Document Review Interval works the same way as the User Retraining Interval. The author(s) of the document will be notified at this interval of time to review the document. Choose an interval of time from the dropdown list.

The Document Description and Version Comments boxes are both standard text boxes into which you can type directly or copy and paste. Add a description of the document uploaded and commentary on the version of the document. Remember this is searchable text and will appear in the table if the respective column is included.

Document Management/Review

Unique Name for Doc

Save Export to PDF Delete **Launch Approval Workflow** **Launch Draft Review** Exit 

Details Training Workflows / Signatures

Author	Maura Ciammetti
Details 1 Revisions Upload Revision	
Name (must be unique)*	Unique Name for Doc
Uploaded Document / File	   SOP Form.pdf
Category*	Test Category
Document Security	Users Can Download an Unrestricted PDF
Effective Date	29-Feb-2016
Automatically create training records for authors/workflow participants?	No
User Retraining Interval	Never
Document Review Interval	Every 12 Months
Document Description*	Standard SOP
Version Comments*	Version 1

If they've been added, you can also enter additional information in the custom fields. If you would like to create a bi-directional link to another item in the software you can click the Add Link button to choose a category and search for the specific item to link. This can be another document, issue, CAPA, event, audit, etc.

Document Management/Review

Unique Name for Doc

Version 1 - Draft

Save Export to PDF Delete Launch Approval Workflow Launch Draft Review Exit You Have Unsaved Work On This Page

Details Training Workflows / Signatures

Version Comments* Version 1

Custom Fields

Document Custom* Document URL* Document Multi-Select* DocDropdown

Select a Date Type a Value Test Link a c
 b Select a Value

Links Add Link

There are no links to this item.

Comments Add Comment

If you'd like to add a Training Challenge Question for users to answer before being able to complete their training, click the Training subtab then click the Add Question button. You will choose either multiple choice or true/false question type and enter your details. You may add as many questions as you'd like. You can set a minimum pass rate if you'd like by clicking the blue hyperlink that "Trainees must answer at least 100% to complete training" and update the percentage.

Document Management/Review

Unique Name for Doc

Save Export to PDF Delete Launch Approval Workflow Launch Draft Review Exit

Details Training Workflows / Signatures

0 User(s) assigned to this document directly or through a course. Manage

Training Challenge Questions (optional)

Add Question

No Training Questions.

Comments Add Comment

Document Management/Review

Unique Name for Doc

Save Export to PDF Delete **Launch Approval Workflow** Launch Draft Review Exit

Details Training Workflows / Signatures

0 User(s) assigned to this document directly or through a course.

Training Challenge Questions (optional)

Trainees must answer at least 100% to complete training.

Question	Type	Answer	Pass %
2+2=4	T/F	TRUE	N/A

Once all of that is done, you have one of two options – launch approval workflow or launch draft review.

If the document is the final version you will launch the approval workflow to get the document signed and bring the document from Draft status to an approved or effective document. Click the button that says “Launch Approval Workflow”. Your preset workflow settings will appear on the next screen. You can add additional steps if necessary by clicking “Add Another Workflow Step” at the bottom of this screen. By default all Authors will need to sign the document. The predefined workflow settings are determined by the category to which you are adding the document. To send the document out for Approval, click the green “Launch Workflow” button. As the author you will enter your username and password to sign immediately. Workflow users will be notified to come into the system to review and sign.

Document Workflow

Unique Name for SOP

Version 1 - Draft

Launch Workflow Exit

This workflows below are required. Add any additional steps you require and click the 'Launch Workflow' button.

Author Approval
Elizabeth Lemon

Required Workflow Steps for this Category
No Steps Defined.

Additional Steps Added (optional)
Add Another Workflow Step

If the document draft needs to be approved before bringing it to an effective or approved state within the software, you will click the “Launch Draft Review” button. Select from the list of names who you would like to review this draft. You can select multiple people, however it will progress in a linear fashion from the first name to the last. Click the green “Launch Workflow” button when you are

finished adding the names in the proper order. At anytime you can click on the “Workflows/Signatures” subtab within a document to see where the document is within the approval process and who needs to review and sign next.

3.11 Searching for a Document

When you are in the documents module you will see a table that contains all of the documents to which the user has access. Using the keyword search bar at the top, enter one or more words within the box and press enter. This will search all metadata associated with the documents and the attached file, given that the document is a searchable extension like Microsoft Word.

The screenshot shows a top navigation bar with buttons for "Add New Document", "Batch Upload", "Manage Categories", "Customize", "Export Table", and a search bar containing "Search whole keywords". Below this is a table with columns: Document Name, Date Created, State, Category, Version, and Training Sta. A tooltip "Drag a column header here to group by that column" is visible above the table. The table data is as follows:

	Document Name	Date Created	State	Category	Version	Training Sta
Edit	Action Plans	29-Dec-2015	Draft	Change Control	1	N/A
Edit	Change Control Doc 1	29-Dec-2015	Flagged For Retirement	Change Control	1	! 25%
Edit	Change Control Doc 1	25-Jan-2016	Draft	Change Control	2	N/A
Edit	Demo Doc 1	04-Jan-2016	Flagged For Retirement	Forms	1	! 25%
Edit	Demo Doc 1	04-Jan-2016	Draft	Forms	2	N/A
Edit	Form 123	29-Dec-2015	Effective	Forms	2	N/A
Edit	Onboarding Form	29-Dec-2015	Effective	Forms	1	! 25%
Edit	Pharma Phorm	29-Dec-2015	Effective	Forms	1	! 25%
Edit	Production SOP	29-Dec-2015	Effective	SOP	1	N/A

You can also use the columns displayed in the table to search for documents. Within column headers you can keyword search as well. By clicking on a column header, you can sort the table by that column in ascending or descending order.

Please note there are nine different document states:

- Draft: All documents start here. Only authors and users with special permission can see these documents.
- Draft Review: Documents with an active draft review workflow.
- Reviewed: Designates documents that have completed part or all of a draft review workflow.
- Awaiting Approval: Final Approval workflow is active.
- Rejected: Temporary state triggered by a workflow rejection.
- Approved: Document completed approval workflow.
- Effective: Document effective date has been reached.
- Flagged for Retirement: After a review has been completed, document has a new draft in process.
- Retired: document is retired and only visible to authors and users with archive access.

We can also apply filters within a column heading. For example, to filter by Effective Date. Let's say we want to see all documents with an effective date that was AFTER Jan 1, 2016. Set the filter to “equal to or greater than” and enter the date as 01–Jan–2016 and press Enter. Your results will automatically be

shown in the table.

A screenshot of a web-based document management system. At the top, there's a header with buttons for 'Add New Document', 'Batch Upload', 'Manage Categories', 'Customize' (which is highlighted with a red box), 'Export Table', and a search bar. Below the header is a table with columns: Document Name, Date Created, Effective Date, State, and Category. The 'Effective Date' column has a dropdown arrow icon. A red box highlights a dropdown menu that appears when the arrow is clicked. The menu contains the following options: Equals, Doesn't equal, Is less than, Is less than or equal to, Is greater than, and Is greater than or equal to. The 'Is greater than or equal to' option is checked. The table data includes rows for various documents like 'Action Plans', 'Change Control Doc 1', and 'Pharma Phorm'.

	Document Name	Date Created	Effective Date	State	Category
Edit	Action Plans	29-Dec-2015			
Edit	Change Control Doc 1	29-Dec-2015	29-Dec-2015		
Edit	Change Control Doc 1	25-Jan-2016			
Edit	Demo Doc 1	04-Jan-2016	04-Jan-2016		
Edit	Demo Doc 1	04-Jan-2016			
Edit	Form 123	29-Dec-2015	29-Dec-2015		
Edit	Onboarding Form	29-Dec-2015	29-Dec-2015		
Edit	Pharma Phorm	29-Dec-2015	29-Jan-2016		

Once you've located the document you are searching for, you can press "Edit" to edit the document, click the blue arrow to download a PDF copy of the document, or the eye icon to view the document within the system.

You can customize the columns within the table by clicking the Customize button and dragging and drop either a column from the table to the list of options or an option from the list to the table.

A screenshot of a web-based document management system. At the top, there's a header with buttons for 'Add New Document', 'Batch Upload', 'Manage Categories', 'Customize' (which is highlighted with a red box), 'Export Table', and a search bar. Below the header is a table with columns: Document Name, Date Created, Effective Date, State, and Category. The 'Effective Date' column has a dropdown arrow icon. A red box highlights the 'Customize' button. To the left of the table, there's a 'Field Chooser' sidebar with a list of fields: # Users, Authors, Custom: MEC, Custom: MEC2, Date Approved, Days to Approval, Training Plan, and Training SOP. A red arrow points from the 'Custom: MEC2' option in the field chooser to the 'Effective Date' column in the table. The table data includes rows for various documents like 'Demo Doc 1', 'Training Plan', and 'Training SOP'. At the bottom of the page, there's a footer with pagination information and a search filter: 'Page 1 of 1 (10 items)' and '[Effective Date] Is greater than or equal to '01-Jan-2016''. A red checkmark is next to the search filter.

	Document Name	Date Created	Effective Date	State	Category
Edit	Demo Doc 1	04-Jan-2016	04-Jan-2016	Flagged For Retirement	Forms
		29-Dec-2015	01-Jan-2016	Effective	Forms
		29-Dec-2015	01-Jan-2016	Effective	SOP
		25-Jan-2016	25-Jan-2016	Flagged For Retirement	SOP
		21-Jan-2016	27-Jan-2016	Flagged For Retirement	Change Co
		05-Jan-2016	28-Jan-2016	Flagged For Retirement	Forms
		25-Jan-2016	29-Jan-2016	Flagged For Retirement	SOP
		27-Jan-2016	28-Jan-2016	Flagged For Retirement	SOP
Edit	Training Plan	05-Jan-2016	22-Jan-2016	Effective	Change Co
Edit	Training SOP	29-Dec-2015	01-Jan-2016	Effective	SOP

You can export your view of the table at any time to CSV or Excel file format. Choose the Export Table button and then choose the file format you want to choose. A download of the file will automatically begin.

	Document Name	Date Created	Effective Date	Flags
Edit	Demo Doc 1	04-Jan-2016	04-Jan-2016	Flag
Edit	Pharma Phorm	29-Dec-2015	29-Jan-2016	
Edit	QA SOP	29-Dec-2015	01-Jan-2016	
Edit	Sop Test 123	25-Jan-2016	25-Jan-2016	Flag
Edit	Test Doc 123	21-Jan-2016	27-Jan-2016	Flag

4.0 Technical Issues & Considerations

4.00 Technical requirements

Our requirements are fairly simple, but we started this section to help diagnose problems that may arise

- Browser: We support most any modern, standards compliant web browsers, including Chrome, Firefox, Safari and IE11+. Security and speed are the major constraints with older browsers.
- Virtual Private Network "VPN": You are probably used to logging in to your company's system applications through. Accessing ZenQMS does NOT require this. You will experience faster response times without the VPN, and will probably be able to access WIFI hotspots not previously accessible. Remember all ZenQMS interactions are encoded already. So unless your corporate policy requires it, we would recommend access without the VPN.
- Screen Resolution: If you have a screen that is small and/or more square than rectangular, you may have trouble viewing our entire application screen without adjusting your resolution. This is usually manageable, except when viewing small windows (e.g. spell check, or citation assignments). So if something appears 'cut off' or things look missing, try either adjusting your screen resolution [1) Open Display Settings by clicking the Start button Picture of the Start button, clicking Control Panel, clicking Appearance and Personalization, clicking Personalization, and then clicking Display Settings; and 2) Under Resolution, move the slider to the resolution you want (1280x800 is ideal), and then click Apply] or simply 'zooming out' using your browser controls (usually in the "View/Zoom" menu or CTRL-Minus Sign to zoom out).

4.01 Explanation of UTC Time Stamps (Coordinated Universal Time)

ZenQMS uses "UTC" time stamps in the application, also known as "Coordinated Universal Time".

In order to avoid any ambiguity on actual time, especially for clients that are operating across multiple zones. There are also problems created when users don't properly set their time zone OR we have seen

issues when servers bounce through virtual private networks that are in a different zone.

As such, the best practice is to rely on "Coordinated Universal Time" which is abbreviated as "UTC". So all time stamps across the app are unambiguous, including in the audit trail.

You can read more about it here:

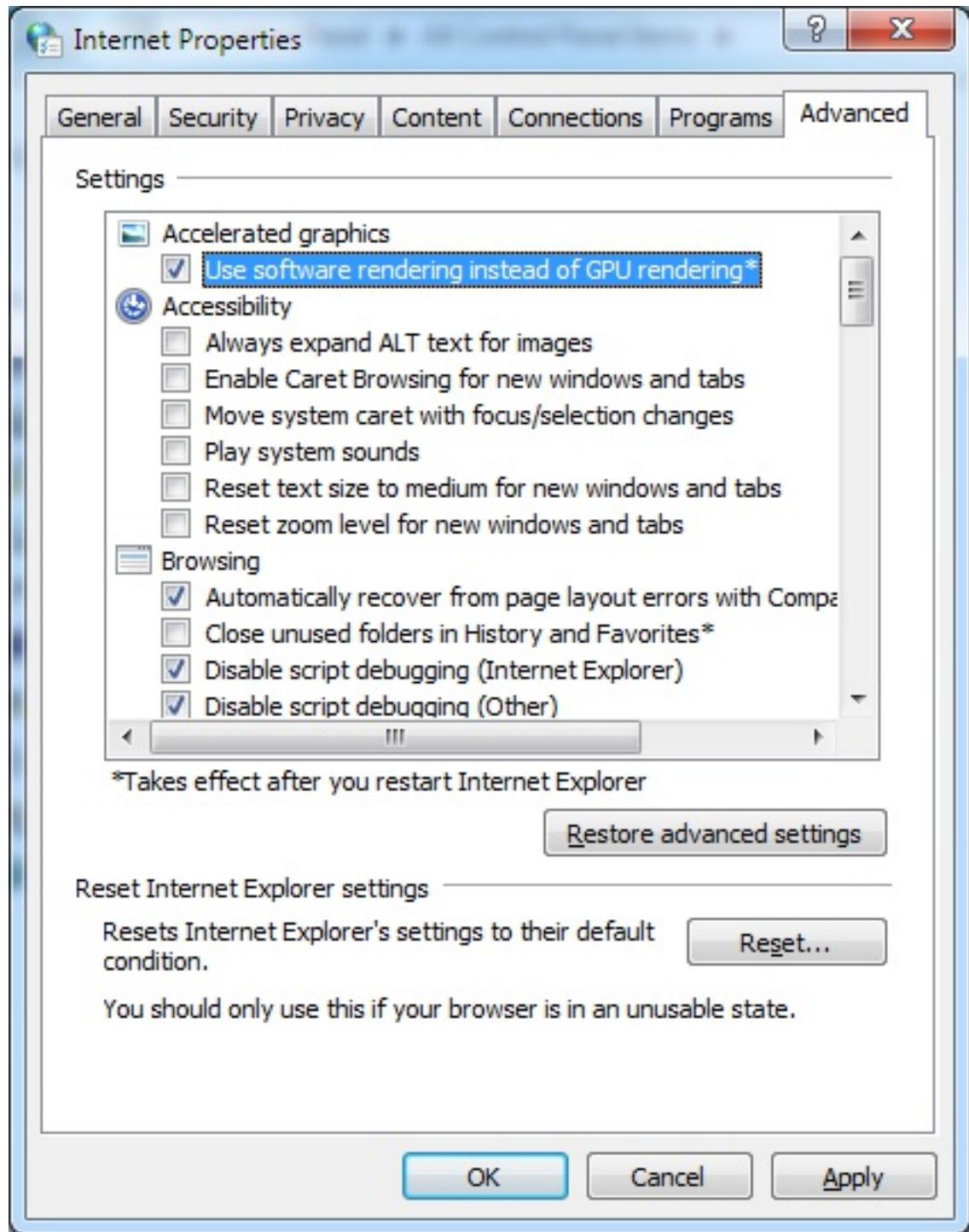
https://en.wikipedia.org/wiki/Coordinated_Universal_Time

4.02 Images not rendering in PDF Viewer due to IE Settings

See: <https://support.microsoft.com/en-us/kb/2528233>

To disable hardware acceleration, follow these steps:

1. Click Start, and then click Internet Explorer.
2. Click the Tools icon in the upper-right corner, and then click Internet Options.
3. Click the Advanced tab, and then under Accelerated graphics, select the Use software rendering instead of GPU rendering check box.



4. Click Apply, and then click OK.
5. Close Internet Explorer and then restart it so that the change takes effect.

To enable hardware acceleration again, follow the previous steps, but in step 3, clear the Use software rendering instead of GPU rendering check box.

5.0 Migration Process

5.00 Uploading your files using a Dropbox File Request

If you requested/approved Dropbox as vehicle for transferring the documents to migrated:

1. Your ZenQMS representative will send you a Dropbox File Request via email. It will contain a link that opens a page that looks like this:



[Sign in ▾](#)

PB Panos Boudouvas is requesting

ZenQMS_Avara Files for Migration

Only Panos Boudouvas will see these files unless they choose to share them.

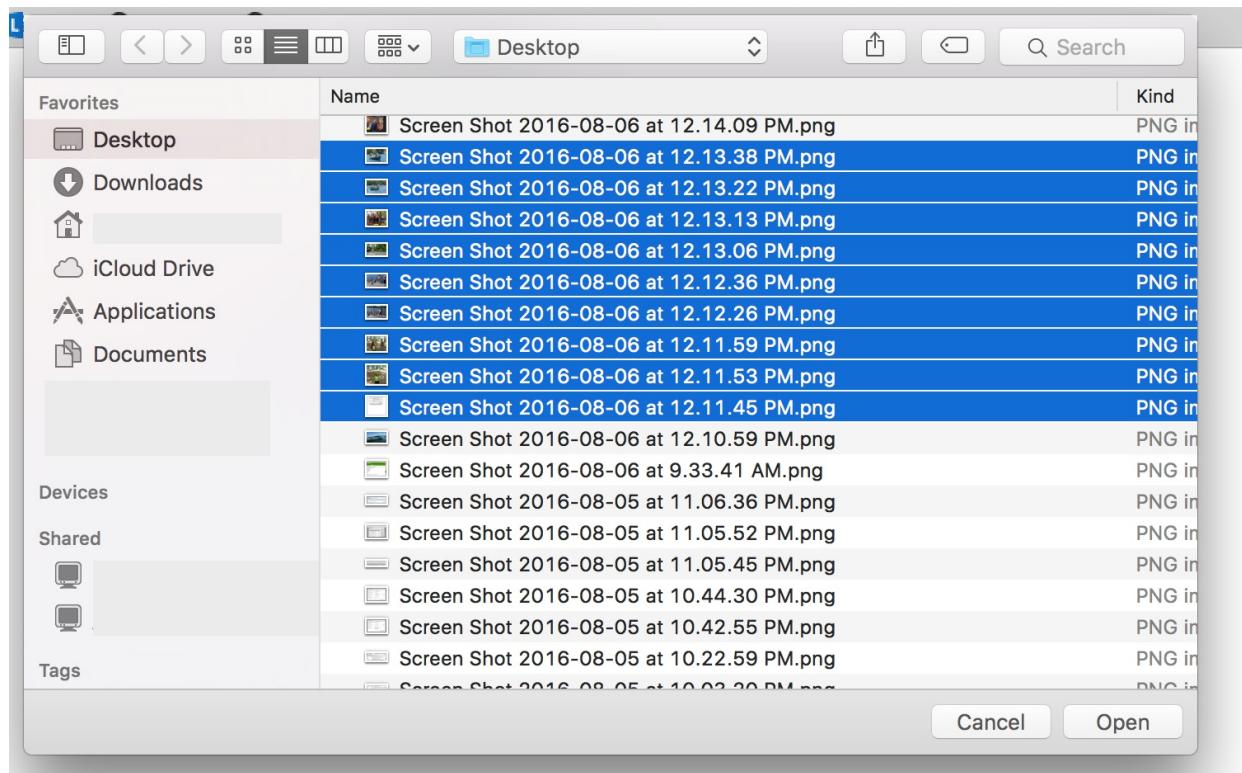
Choose files

How does this work?

Privacy & terms

English (United States) ▾

2. Click the "Choose Files" button and you should see a file upload viewer that looks like below. You can select one or more files using the shift and/or command/Ctrl keys. You cannot select folder(s), but you can select all the files inside of a folder.



6.0 Qsheet & Watchlist

6.00 Watchlist Labels: Using Labels Across the Application

Users are able to assign multiple labels to each site using the "Manage Labels" button that appears in Dashboard> Watchlist, Search > Sites, and Qsheet > Snapshot. Labels provide a very flexible way for users to create custom lists of sites around various product supply chains, or risk categories. The labels in turn can be used for analytical purposes- here are two examples:

- Watchlist: Show me all sites tagged with a "Product XYZ Supply Chain" tag, which is a key product. Use Watchlist to sort/filter for any suppliers who are overdue for an audit and/or have a high-risk rating.
- Analytics: You can use labels to organize standard DASHBOARD analytics (e.g. show me box plot of Audit Score organized by Label). You can also filter using labels (e.g. show me the summary analytics for just those sites tagged with a "Product XYZ Supply Chain" tag).

To assign a label follow these steps:

1. Navigate to Search > Sites
2. Select one or more sites using the first check box column.
3. Click the "Manage Labels" button
4. Create a new label called "Test Label"
5. Now go to Home > Dashboard > Watchlist
6. Use the "Show All Labels" dropdown control to select your new label.
7. To test this feature in Home > Audit > Analytics, you must first log some audits in the system.

6.01 Watchlist: Key Watchlist Features

Watchlist is a powerful tool, particularly as you add audits or as a user takes advantage of the labeling feature. You can try it now even with limited data, but contemplate the broader value as you interact with your entire supply chain.

*Note: if your company has not logged any audits in the system yet, then follow Section 5.02 on using Labels to quickly add some sites to your table. At the very list, add a label to the two DASHBOARD Sites in the database. Or contact ZenQMS for a live demonstration.

1. Navigate to Home > Dashboard > Watchlist
2. Select one or more sites from the list using the check box column.
3. Click the "Map" button to see all the selected sites on an interactive map. Click a pushpin. Exit the map when finished.
4. Click the "Customize" button to add/delete columns by dragging/dropping them in place
5. Type "DASHBOARD" into the textbox on top of the "Site Name" column and pause– you will see that it will filter through all sites.
6. Select the two DASHBOARD sites and then click the "Send Message" button to send a message to the default messaging contact.

Note: this last sequence (Steps 5 & 6) is incredibly powerful. The best example is the Tsunami catastrophe in Japan—imagine being able to quickly identify which sites are in Japan near the danger zone, put them on a map and/or contact them. All with just a click of the mouse.

6.02 Updating a Site's Qsheet Profile using "Update Site Info" button

A site's corporate owners maintain its Qsheet profile information unless they are not registered or active with ZenQMS, in which case ZenQMS staff directly manage profiles and updates. But any ZenQMS user can submit a profile update for any Qsheet using the Update Site Info button. If the site's corporate owner has an active ZenQMS account, the site's default messaging contact will be notified of your update request and can accept/reject it. ZenQMS staff review and manage all requests for sites that are not active members and process them accordingly on a regular schedule.

1. Navigate to a site's Qsheet using the Jump to Qsheet control. You will be taken to the selected site's Qsheet > Overview > Snapshot page.
2. Click on the "Update Site Info" button at the top of the profile.

Phake Pharma / Site 3 Report this site as a duplicate

Q-ID: ZZZ001003 | Albany, New York, United States

[Overview](#)
[Issue/CAPA](#)
[Reports](#)
[Consultants](#)
[Forum](#)
[Documents](#)
[Snapshot](#)
[Update Site Info](#)
[Log a New Issue](#)
[Send Message](#)
[Manage Labels](#)
[Existing Labels](#)
[Virtual Tour](#)

This Qsheet was last updated on 15-MAY-2013.

There are 11 completed audit reports for this site.

[Brochure](#)

There are 1 draft audit reports and 0 awaiting Auditee approvals.

There are 0 pending Qsheet updates awaiting Auditee approval.

[Create New Report](#)
[Who Can See This Site in ZenQMS?](#)
[Only Visible to My Company](#)

3. In the window that opens, you will see a form that has all the current information for the selected site. You can make any changes you see fit, including a comments section. Then click the "Submit" button at bottom right of the window (note you may have to scroll down to the bottom)
4. Your request will be immediately submitted for review by either the site's owners and the ZenQMS Staff and processed accordingly. Note, your submission will be stored until it is acted upon—so if you click the "Update Site Info" button again before your update request has been approved/rejected, the window will note that you have a pending request in the system and the window fields will reflect your existing request.

Important Note: If you need an update to be processed immediately -or- have noticed a request has not been acted upon within a few days, please log a support ticket noting the site name or Site Q-ID and we will remedy the situation immediately.

6.03 Qsheet Overview: Snapshot

1. Use the "Jump to Qsheet" control to find "Phake Pharma / Site 1". Select this site to see its Qsheet.
2. You will be taken to the site's Qsheet > Snapshot section, which displays most of the 'public' information on a site.
3. Notice the header at the top of the page in example below. It includes the sites name, the sites Q-ID (a unique identifier for every site in the database), its city/state/country and phone number.

The header also includes a red/yellow/green icon indicating a site's status in terms of ZenQMS registration (see right side of header picture below). Active sites that have been registered and are ready to receive/respond to audits should show a GREEN icon (). Hovering over this icon with your pointer will tell you more information about the site's status.

The screenshot shows the QAB Test Site dashboard. At the top left is the QAB logo. Next to it is the PHAKE Pharma LLC logo. In the center, there's a dropdown menu labeled "Jump to a QSheet" and a link "Return to Dashboard". On the right side, there are links for "Home", "QSheet", "Search", and a user profile for "John Riggins, Phake Pharma LLC". Below the header, a banner displays the site information: "QAB Test Site | The Quality Advisory Board, LLC (QAB)(2) | Q-ID: QAB001002 | Kansas City, Missouri, United States | Phone: 222.222.2222". A large red arrow points from the bottom right towards the top right corner of the screen.

4. The "General" section on the left-hand side is 'public' information on the site. Clicking on blue hyperlinks will open up more information about that item. Try it now.
5. Links in the certification table will download a PDF copy of whatever certificate or supporting documentation the site has uploaded for that item. Try it now.
6. Click on the "Map It" link to see an interactive map of the site, including satellite imagery. Pin locations will only be accurate to the City/State/Country level until a site has updated its GPS coordinates—either submit an Update Info request in Qsheet or see Sections 1.08 – 1.13 regarding managing Qsheet profiles if the site belongs to you.
7. The right side of the Snapshot page includes a section for 'private' fields that your administrator has configured. Your team can create whatever custom fields it needs to manage suppliers. Examples include fields to manage approved vendor lists, audit frequency, risk ratings, key notes, logistics, etc. Some important note regarding these custom fields
 1. Any user from your account will be able to see this page and these fields.
 2. Only users with the "QSheet: Can Edit Qsheet/Snapshot Private Data Fields" permission are able to see the "Edit" links to make changes to these fields.
 3. You can add these fields for all sites in Watchlist for download/ analysis later. Below is an example:

My Company's Data/Metrics		Private
Scorecard		
Private Audit Acore		History
Audit Number		History
QSheet		
Approved Vendor	<input type="text" value="No"/>	Edit
CTPAT Approved	<input type="text" value="No"/>	Edit
Next Audit Date		Edit
Risk Rating (RYG)	<input type="text" value="Green"/>	Edit
Key Facts		
Cate Kelly is our primary contact @ 610.555.1212		
This vendor is NOT approved for Category X Product Development work.		
Auditors should use the LAX terminal for easiest access...		

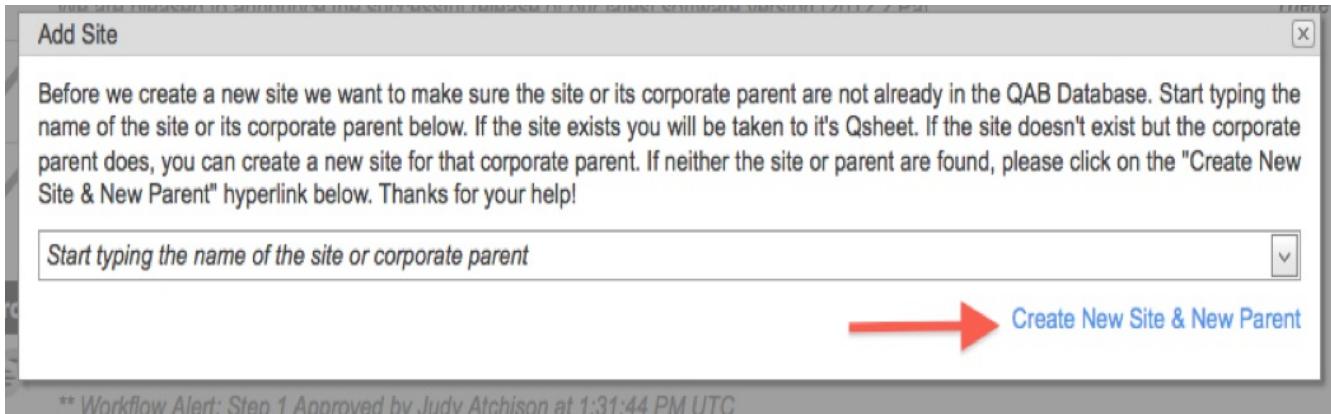
8. Click on the "Virtual Tour" menu item on the left side of the page to review any pictures/content that the site owners have uploaded—the example below is a screen shot from the ZENQMS Test Site virtual tour. Sites can add maps, directions, and pictures/descriptions of key services/selling points or even key management/scientist BIOS. Remember that all this content is keyword searchable in the Search > Sites page and can also be used in analytics, so finding sites with particular capabilities is simple for sites with virtual tours.

<p>Available Views</p> <p>This is NOT Panos.</p> <p>Maddyn</p> <p>Panos' Kids</p> <p>Rowan</p>	<p>VAKUMEX AG Rühr- und Homogenisiertechnik Weyhe / Germany</p>
<p>Description/Features</p> <ul style="list-style-type: none"> - This is an example of Virtual Tour - All this data is fully searchable - Try to search for "demo" later 	

9. Click on the "Brochure" menu link on the left hand side of the page to download a copy of the brochure the site has uploaded. Properly created PDF brochures are also keyword searchable in the Search > Sites page.
10. Click on the REPORTS tab to find all past audit reports your company has access to for this site.
11. Click on CONSULTANTS tab to see what consultants have audited a site in the past. You can click on a consultant name to see their profile and contact information.
12. Click on FORUM/ATTACHMENTS tab to see any comments that your colleagues from around the world have logged about this site. Remember that this section is private to your company's users. Notice the "Subscribe" button—clicking it will automatically flag any new posts made on this site in your Dashboard, which is a great way to stay on top of your key sites.
13. Within the Forum/Attachments section, click on ATTACHMENTS menu item on the left side to download critical documents linked to this site and stored here (e.g. Quality Agreements or Risk Assessments).

6.04 Creating a New Site for a NEW Member (e.g. Corporate Parent)

If the site and its corporate parent are not in the database, you can click the "Create New Site & New Parent" link at the bottom right of the initial version of the "Add Site" modal window. Then you can enter all the information for the site and its corporate parent in one motion. From there the directions are the same as 2.2, but with a requirement to also add information for the Corporate Parent.



6.05 Adding a New Site to an Existing Member

1. If you can't find the site you are looking for, then you can easily create it by clicking the "Add New Site" hyperlink below the "Jump to Qsheet" control.
2. To avoid duplicates, a window will open that helps you verify that the site's corporate parent is not already in the database. For instance, you may be looking for a ZenQMS site called "ZenQMS Site XYZ", and while that facility is not in the database, its corporate parent is in the database. Selecting the row that has a blank in the Site Name column but has a value for "ZenQMS" will create the new site and add it to ZenQMS' site network. See the example below:

Add Site		
<p>Before we create a new site we want to make sure the site or its corporate parent are not already in the QAB Database. Start typing the name of the site or its corporate parent below. If the site exists you will be taken to its Qsheet. If the site doesn't exist but the corporate parent does, you can create a new site for that corporate parent. If neither the site or parent are found, please click on the "Create New Site & New Parent" hyperlink below. Thanks for your help!</p>		
Site Name	Parent Name	Location
	The Quality Advisory Board, LLC (QAB)	Wayne, Pennsylvania, United States
QAB HQ - For GMP Audits	The Quality Advisory Board, LLC (QAB)	Wayne, Pennsylvania, United States
QAB Test Site	The Quality Advisory Board, LLC (QAB)	Kansas City, Missouri, United States

3. The "Add Site" window opens to collect the most basic information required to immediately create a new site for this existing member (see below). In order to prevent duplicates (to maintain database integrity and to help get a complete site profile) the following actions happen once you create the site: i) an email will be sent to the contact person you enter notifying them that their site has been added to their network in the ZenQMS database; and ii) ZenQMS staff will reach out to the site owner to verify the information.
4. If you decide that the site in fact does not belong to the Corporate Parent you initially selected, click on the "This is Not Right, Create New Parent" link at the bottom right and enter information about the appropriate corporate parent.

Overview Reports

Add Site X

Enter all the information below and we will create the new site. We will also use the contact information you provide to reach out to the site to take ownership of its profile.

Site Name	ABC Site Name
Location	London Tennessee United States
Is this an internal (captive) facility? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Contact Name at the Site	John
Phone Number	+1.372-555-1212
Email Address	jdoe@abcsitename.com

Corporate Parent Name
Many sites are single entity sites, in which case the Corporate Parent and Site Name are the same. For multi-site companies, however, Site Names frequently differ from the corporate parent, and we like to keep track of the entire network of sites underneath a corporate parent.

You selected the following Corporate Parent: The Quality Advisory Board, LLC (QAB)

[This Is Not Right, Create New Parent](#)

[Submit](#) [Cancel/Exit](#)

6.06 Searching for an Existing Site

To find a site in the database, use the "Jump to Qsheet" control, which is at the top of every page in the application. The only exception here is that a site designated as "Internal" (e.g. a captive manufacturing facility) is only visible to users that belong to that site's Member.

1. Click the "Jump to Qsheet Control" at the top of all pages (see example below)

Jump to Qsheet: Start typing Site or Parent Name, Country or Site Q-ID

Return to Reports

Add New Site

2. Start typing the name of the site. If you enter two partial fragments separated by a space, the filter will only return sites that have all fragments. In the example below, the user searched for "Zoet" and "EU" and returned all sites in the database that have BOTH fragments. You can search for word fragments in the name of the site, the name of its corporate parent (e.g. Member Name), it's Site Q-ID or it's country location.

Site Name	Site Q-ID	Parent Name	Country Name
Zoetis (EU) / Catania, Italy	ZOE001121	Zoetis, Inc.	Italy
Zoetis (EU) / Louvain la Neuve Belgium	ZOE001031	Zoetis, Inc.	Belgium
Zoetis (EU) / Medolla, Italy	ZOE001212	Zoetis, Inc.	Italy
Zoetis (EU) / Olot, Spain	ZOE001097	Zoetis, Inc.	Spain

3. You can select a row with a mouse click or by using the Up/Down Arrow and Enter keys. Doing so will immediately take you to that site's Qsheet.

7.0 Auditee: Receiving / Responding to an Audit

7.00 Managing Your Assigned Observations

Auditors and Auditees can assign responsibility for one or more observations to any active DASHBOARD user in their account (on either the Auditor or Auditee side). Users are immediately notified of the assignment and all assignments appear in that users Home > Dashboard > myObservations page, which has all the same functionality as the Audit > Observations page.

Any observations that are past due will also appear in the user's dashboard in the "My Overdue Items" tile.

7.01 Accessing Audit Reports

1. Authorized users can access ALL audit reports from your account in all stages by navigating to Home > Audit > Reports.
2. Users with the same permission can also access audit reports from any site's Qsheet>Reports page.
3. All users have a table that works the same way at Home > Dashboard > myReports which only lists reports that a user has been an auditor/author of.
4. These three pages work almost exactly the same. Key functions include:
 - o "Map" button will map the locations of every selected audit report auditee
 - o "Customize" button allows you to add/remove columns
 - o "Export to PDF" downloads selected audit reports as PDFs
 - o "Export Table" exports the all data from the current filter (including all rows no displayed) into a CSV file that can easily be opened in Excel.
 - o Key word search box allows you to look for any whole key words anywhere in the audit report text, observation text, and attachments.
 - o Site Names in the tables are hyperlinked to the site's Qsheet
 - o "EDIT" hyperlinks in a row appear if you have edit privileges to an audit report. Clicking on it takes you to that audit report
 - o "PDF" downloads a PDF copy of the selected audit report.

- "State" values indicate where the audit report is in its lifecycle. Clicking on these links at different times allows authorized users to schedule/assign an audit, launch the Send to Auditee workflow or close out an audit report.

The screenshot shows a software interface for managing audit observations. At the top, there's a navigation bar with links like Home, Search, Support, and a user profile. Below the navigation is a search bar and a 'Add New Site' button. The main area has tabs for Dashboard, Documents, and Qsheet Link (which is highlighted with a red box). Other tabs include Issue/CAPA, Audit, Forum, and Administration. A sub-navigation bar below the tabs includes links for Customize, Bookmark, Map, Export to PDF, Export Table, and a search bar for whole keywords. On the left, there are sidebar categories: Dashboard, Watch List, myReports, Bookmarks, myObservations, myIssues, and myCAPAs. The main content area displays a table of audit observations with columns for Site Name, State, Audit ID, Audit Date, Audit Type, Category, and # Obs. One row in the table is highlighted with a red box and labeled 'Action Link'. A red box also highlights the 'Quick Link to Observations' link in the top right corner of the page.

	Site Name	State	Audit ID	Audit Date	Audit Type	Category	# Obs.
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Report	16089	25-Jan-2016	Routine	Quality GxP	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Rep		25-Jan-2016	Qualification	Quality GxP	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Report	16089	21-Jan-2016	Routine	General Compliance	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Report	16063	19-Jan-2016	Routine	Quality GxP	1
<input type="checkbox"/> Edit PDF	Maura Pharma	Execution	15892	18-Jan-2016	Due Diligence	Quality GxP	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Scheduled	15974	13-Jan-2016			0
<input type="checkbox"/> Edit PDF	Supplier Complaint Tests	Awaiting Approval	16123	12-Jan-2016	Qualification	General Compliance	0

7.02 Auditee: Responding & Managing Audit Findings

2. There are three ways to find the observations for the audit you just got from your client:
 - If you just completed the workflow from the client, look in your inbox for the message that includes a quicklink to the observations.
 - You can always Navigate to the Home > Audit > Observations page to get to the same place. The default view of the table is all observations that your audit staff issued in audits of external or internal Auditees. Change the dropdown selection at the top of the screen to "Client Audits of our Sites" to see all observations from audits of your sites that were either entered/shared by your clients or entered by you. INTERNAL AUDITS: since this audit is an audit executed by your internal auditors, you will find your observations by selecting "Audits We Performed".
 - Navigate to Audit > Reports page, find the audit report and click the hyperlink in the # Obs. column.
3. Click on the "Review" hyperlink to open a window that looks like the one below. For audits that were done by a client, your actions are limited to providing a response, rejecting the observation outright or adding a comment.

Observation Review

Observation ID#: 15844-01 | Unresolved

Observation Details

Site Name / ID: Maura Pharma / MAU001001
 Observation Headline: Review Compliance measures
 Severity: Minor / New Observation
 System: Quality System
 Category: Registration Compliance > Annual Reporting
 Action Due Date: 07-Feb-2016
 Auditor Assignee: Ned Flanders
 Auditee Assignee: Select User
 ZenQMS Scoring Algorithm: This Observation Will Be Scored

Detailed Observation
 Observation here

GxP Citations
 No GxP Citations.

Observation Response - DRAFT

Submit Final to Auditor

This window's works differently depending on a user's permissions and whether they are from the Auditor or Auditee. So if you can't do some of the actions listed below make sure that you are correctly listed as the Auditor Assignee or Auditee Assignee user. Once an observation has been "RESOLVED", it will remain locked for editing by most all users unless the Auditor Assignee unlocks it.

Instructions for Auditors

- Set 'Auditor Assignee' to yourself and click the **Save** button to be able to edit this observation.
- Change the 'Action Due Date' if needed.
- Review the 'Observation Response'. Auditor Assignees can edit the DRAFT response directly until the Audit has been Sent to the Auditee. When that happens, Auditors will only see the FINAL version of the Auditee's response.
- Click the **Resolve This Observation** button to set status to "Resolved". You can always reverse this by clicking the "Click to Reset Status to 'Unresolved'" link.

You can upload files at any time. If the Auditee has linked an Issue investigation or related CAPAs to this Observation, you will not see them here unless they have explicitly added you as an External Notification.

- Click the "Edit" link to open a text editor for your formal response. When you click "Save", your response will be committed, a notification will be sent to your auditor and your action will be logged in the audit trail and comments section. Note: You can edit the response as many times as you need to.
- Click the "Upload Attachments" link to upload any relevant documents.
- Click the "Reject This Observation" link if you will not undertake any action regarding the finding.
- You must now wait for the Auditor to resolve the finding or request further clarifications/CAPA.
- Note that all actions are logged in the audit trail and comments section.
- You are now finished with this observation!

Some other items for your consideration:

- Clicking the "Reject this Observation" if the Auditor refuses to resolve an observation after reviewing a response you meant as final. Please note that only the Auditor can reverse this status.
- Click on a column heading to sort the table by that column. You can change column order by dragging/dropping the column. Or click the "Customize" button to add/remove columns.
- Select a few observations using the check boxes in left column and click the "Export to PDF" button to download a PDF of the selected observations organized by Audit and including the full comment history.
- Keyword search all observations using the search box—enter a whole word and press "Enter"

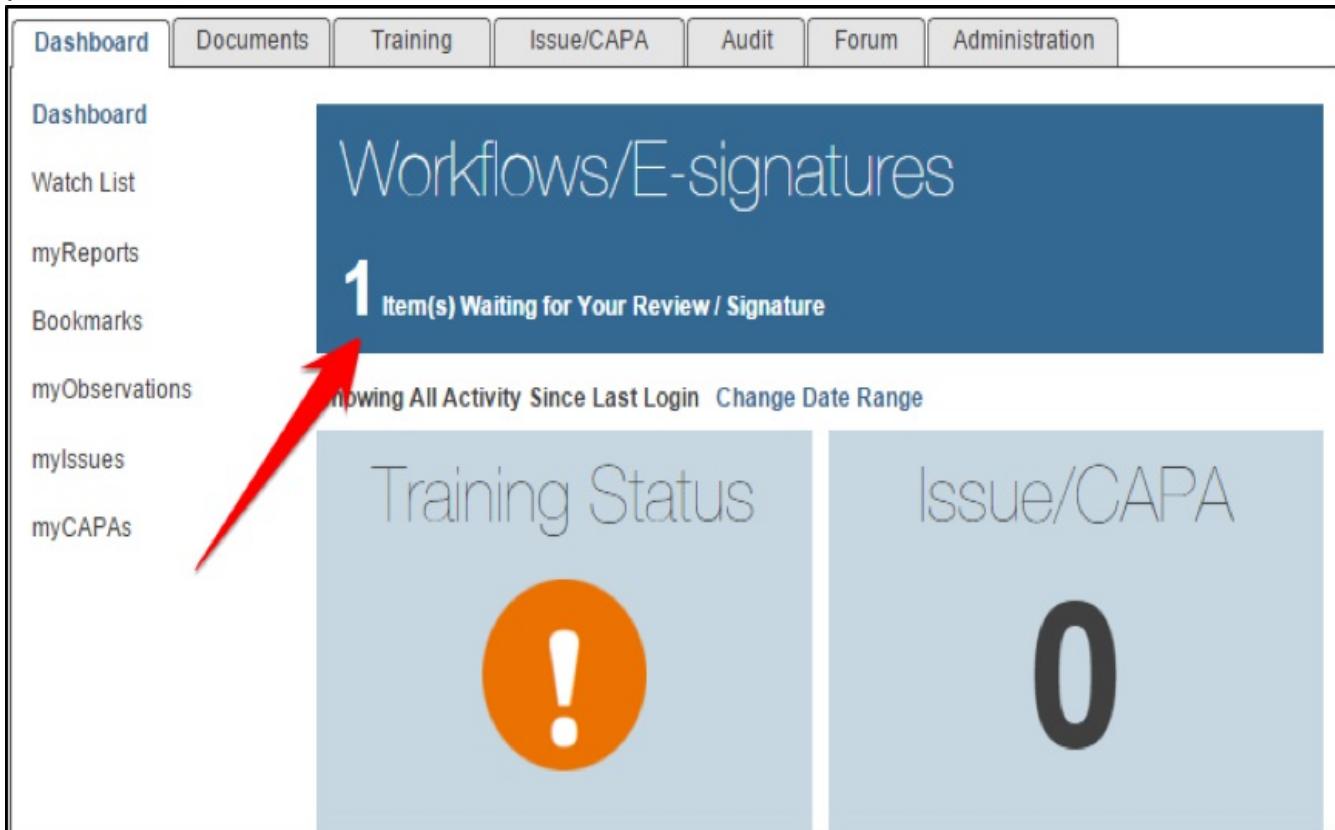
key.

- Select 2 observations and click the "Assign" button to assign both observations to a user—these will be "Auditee Assignees." Assignees will receive a notification of their new assignment, and all assignments will be logged in the audit trail and comments section.

7.03 Auditee: Receiving an Audit

Your company must be registered and active with ZenQMS to be able to receive an audit.
Visit www.ZenQMS.com/onboard or email onboarding@ZenQMS.com to get registered—it's easy!

1. Navigate to the Home > Dashboard > Dashboard page. If the audit report has been published by your Auditor and the "Send to Auditee" workflow has been initiated, the user defined as the first step in your "Send to Auditee" workflow will have a workflow item in their dashboard (see picture below).



INTERNAL AUDITS: You don't necessarily have to initiate the Send to Auditee workflow to have an internal user log in and begin entering responses. If you don't want documented receipt of the audit by a site Quality Leader, then simply skip steps 1–3 of this section.

2. Click on the workflow item to open a window that looks like below. In order to formally receive the audit report and be ready to respond you must simply "Approve" the audit report. You can also click on the "Review PDF" link to download a copy of the report.

Workflow Action Item

AUDIT #16103 of Test Site Northeast by Maura Pharma, LLC

Workflow Details	
Workflow Type	AUDIT / Send to Auditee
Purpose of this Workflow	Complete this workflow to formally receive the audit you recently hosted.
Review Documents	Download PDF Review/Edit in ZenQMS
Actions You Can Take	
Sign/Approve	Allows you to complete this workflow with an e-Signature.
Delegate	You can delegate this workflow step to another authorized user.
Reject	Stops the workflow process after recording your rejection reason.

Instructions
 You can complete this workflow with a compliant electronic signature after reviewing the details of this workflow and any attached/linked documents

1. Review 'Workflow Details' section and click 'Download PDF' link to see documents for review.
2. Approve or Reject the workflow by clicking the buttons of the same name. In some cases you can also 'delegate' the workflow to another authorized user.
3. You will be required to verify your identity in a new window.

Auditees can immediately respond to findings after completing the 'Send to Auditee' workflow by navigating to the Home > Audit > Observations page, selecting 'Client Audits of My Sites' and clicking the 'Review' link for each finding.

3. Click the "Approve" button. A notification will be sent to the Auditors and you can now begin responding to the findings.

7.04 Making Sure Your Site is Ready to Receive Audits ('Getting Green')

Every site must meet a few key requirements to be ready to receive and respond to audits using ZenQMS. Sites that have accomplished all requirements will include a green badge with a check mark in the header of their Qsheet profile as seen below. If your site is showing a red badge with an exclamation point, please note the requirements listed below and refer back to Sections 1.08 – 1.13 for directions.

The screenshot shows the ZenQMS Site Management interface for the site 'Maura Pharma'. At the top right, there are links to 'Jump to Qsheet: Start typing Site o' and 'Return to Site Management'. Below that, the site's name 'Maura Pharma' is displayed with a green checkmark badge, followed by a link to 'Report this site as a duplicate'. The site's ID 'Q-ID: MAU001001' and location 'College Station, Texas, United States of America | Phone: 267-687-0603' are also shown. A navigation bar below includes tabs for 'Overview', 'Issue/CAPA', 'Reports', 'Consultants', 'Forum', and 'Documents'. Under 'Overview', there are buttons for 'Snapshot', 'Update Site Info', 'Log a New Issue', 'Send Message', and 'Booking'. To the left, there are links for 'Virtual Tour' and 'Audit Reports'. A status message indicates the Qsheet was last updated on 29-DEC-2015, has 2 completed audit reports, and 2 draft audit reports awaiting approval.

- Log in to Your Account: Your account has to have at least one active user who has logged in within the last 90 days. You will accomplish this requirement as soon as you log in for the first time. As long as any user logs in once every few weeks this will always be green.
- Assign a Default Messaging Contact: Your site has to have a default messaging contact assigned to it. This is very easy to do—follow instructions from Section 1.11 to do this.
- Define Your Workflows: 3. A Member's "Audit Report: Send to Auditee" workflow must have at least one step with at least one active user assigned to each step (requires member admin rights). See Section 1.17 for directions.
- Make sure your site has been verified by ZenQMS staff. If the Qsheet status badge indicates "Site Not Verified" then please contact us directly at help@ZenQMS.com, call us +1.610.572.2871 or log a support ticket.
- Update Your Qsheet: Take a moment to provide a full, updated profile of your site, including key contacts, GPS tags, Service profile and certifications for the site, and brochures/virtual tours. Though not all this information is required to 'get green', it does make the audit easier and increase your visibility with clients. Detailed instructions are in Section 1.10 – 1.12.
- Internal Sites: If you want internal sites to formally receive audits the same way as your external suppliers do, you still need to log a valid workflow step and approver for the "Send the Auditee" workflow.

7.05 Getting Started

If you and your company/site are new to ZenQMS, please take a moment and run through Section 1 first to ensure that your personal and member settings are correct, and to verify that your Site Qsheet Profile(s) are updated (especially Sections 1.08 – 1.13). Section 2 & 3 are useful background to see how your auditors use information in Qsheet and complete audit reports.

If this site is an INTERNAL SITE (e.g. this is an internal audit of an internal site), then we will note some exceptions to the process below.

8.0 Auditor: Creating & Managing Audit Reports

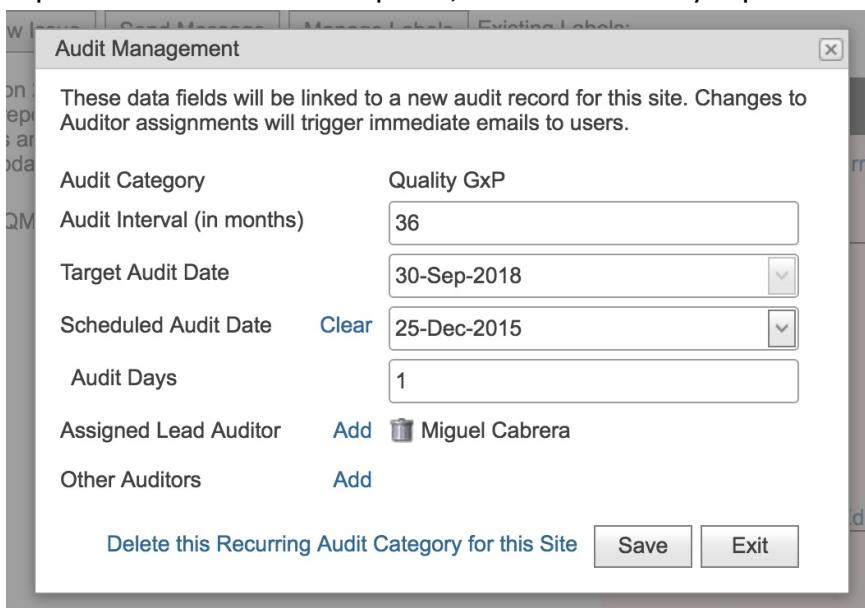
8.00 Uploading Your Existing Audit Plan as Recurring Audits

If you are transitioning to ZenQMS, please ask us to help you upload your existing Audit Plan—even if it's MSWord or Excel.

8.01 Deleting Recurring Audits

You can delete any recurring audit using the Audit Management window that appears in several places in the application and clicking the "Delete this Recurring Audit Category for this Site" link as it appears below:

1. Open the Audit Management window for the recurring audit you want to delete. You can do multiple ways:
 - o Navigate to Qsheet > Snapshot and clicking on the EDIT link next to the recurring audit
 - o Launch the Audit Management window by clicking on the Audit State link when it is "Target", "Scheduled", or "Execution". You can find the Audit State column in all three reports tables: Audit > Reports, Dashboard > myReports and Qsheet > Reports.



2. Click on the "Delete this Recurring Audit Category for this Site" link
3. Confirming your decision will do the following: a) It will remove the audit category as a recurring audit; b) It will leave all existing, completed audits of this Category in place; and c) it will also leave the draft audit that was linked to this recurring audit in place until you open and delete it manually.
4. Click on the Qsheet > Reports tab to find and delete the DRAFT audit report of this category.

8.02 Managing Recurring Audits / Global Audit Planning

You can manage any recurring audit (or even a non-recurring audit) using the Audit Management window that pops up in all of the Reports pages and the Qsheet > Overview > Snapshot page. But the easiest way to manage your global audit plan is right from the Audit > Reports page.

1. Navigate to Audit > Reports page
2. Filter the columns to identify your interest. For instance, if you were trying to find all audits that are due in the next 6 months that have not been assigned to an auditor yet, you could set the "State" column to "Targeted" and sort the Target Audit date in ascending order.
3. State values of Targeted / Scheduled / Execution will appear as hyperlinks. Click on the State value for any row where you want to edit the recurring audit settings.

The screenshot shows the 'Audit Management' dialog box. It contains the following fields:

- Audit Category:** Quality GxP
- Target Audit Date:** (dropdown menu)
- Scheduled Audit Date:** 29-Feb-2016 (with a 'Clear' link)
- Audit Days:** 0
- Assigned Lead Auditor:** Andrew McCutchen (with an 'Add' link)
- Other Auditors:** John Riggins, Anil Kumble (both with 'Add' links)

At the bottom are 'Save' and 'Exit' buttons. The status bar at the bottom of the dialog box displays: Phake Pharma / PMI Site XYZ | Awaiting Approval | 16-Oct-2015.

This page truly allows you to manage all compliance audits in an evergreen state.

8.03 Creating / Deleting Recurring Audits for a Site

ZenQMS makes it simple to manage compliance requirements around recurring audits for all of your suppliers. You can do this directly in a site's Qsheet and manage/assign tasks from any Reports table.

5. Navigate to a site's Qsheet using the "Jump to Qsheet" search box at the top of any the page. In the Qsheet >Snapshot page, notice the Future Audits section in top right of the page:

Future Audits

Private

[Add a New Recurring Audit](#)

[See Rescheduling History](#)

This Site has Not Listed Any Future Audits

6. If you don't see the "Add a New Recurring Audit" link as it appears above, then ask your system administrator to grant you the "Can Create New Audit Reports or Manage Recurring Audits" permission.
7. Click on the "Add a New Recurring Audit" link. Select an Audit Category and edit the audit interval (or accept the default). Now Save. After saving your entry, you will notice your new audit category has been created as seen below.

Future Audits

Private

[Add a New Recurring Audit](#)

[See Rescheduling History](#)

Quality GxP	Edit	Targeted
Last Audit of This Type		07-JAN-2014
Audit Interval		24 month(s)
Target Audit Date		07-JAN-2016
Scheduled Audit Date		None
Audit Days		
Assigned Lead		
Other Auditors		

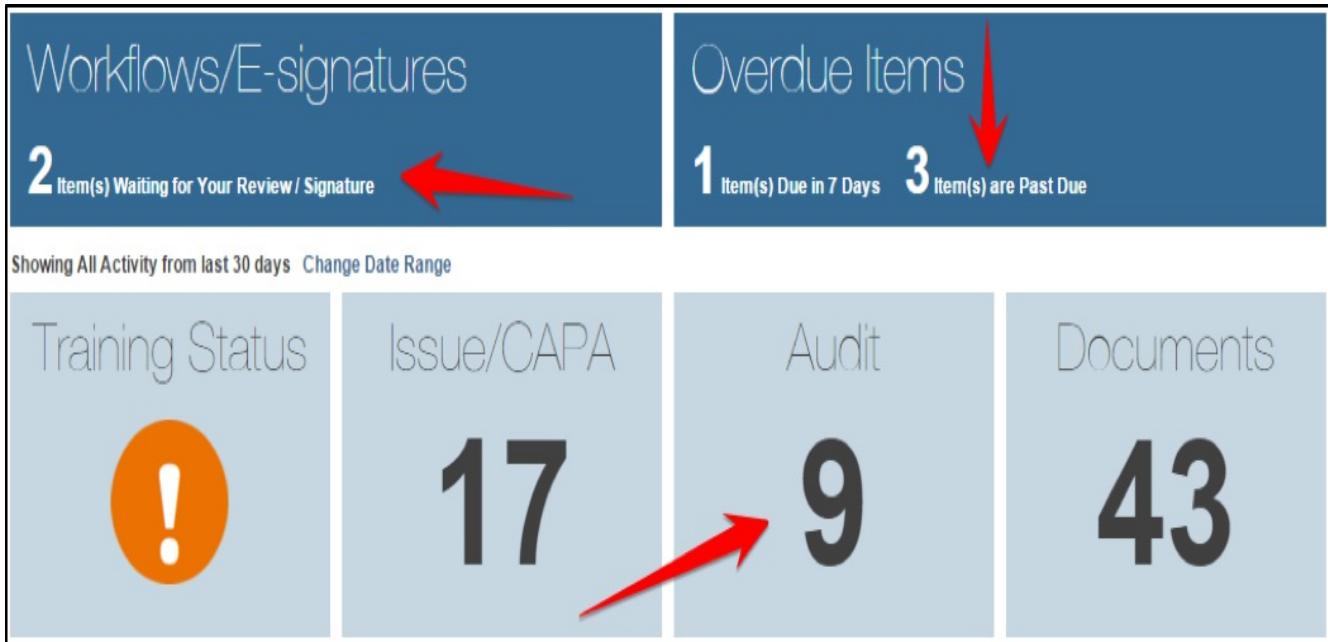
8. Here is what happens now:
 - o A new DRAFT audit with a State of "Targeted" has been created for this site. You can see it if you click on the Qsheet > Reports page
 - o As soon as this new draft completes the "Publish Final Report" workflow the app will automatically create a new DRAFT audit with a Target Date based on the set interval defined in your Future Audit settings.
9. Click on the "Edit" link to add more details for this audit, including Target or Schedule dates, Audit Days and Assigned Lead or Co-Auditors. Note: Auditors will receive an immediate EMAIL notification whenever they are assigned or removed from an audit.

8.04 Managing Your Assigned Observations

Per 3.06, Auditors and Auditees can assign responsibility for one or more observations to any active ZenQMS user in their account (on either the Auditor or Auditee side). Users are immediately notified of the assignment and all assignments appear in that users on the Dashboard under the Audits tile.

Also, users can find the assignment under Dashboard > myObservations page, which has all the same functionality as the Audit > Observations page.

Any observations that are past due will also appear in the user's dashboard in the "My Overdue Items" table. Clicking on a row will bring up the Observation Review Modal window. (see pictured below)



8.05 Accessing Audit Reports and Using the Audit Reports Tables

1. Authorized users can access ALL audit reports from your account in all stages by navigating to Home > Audit > Reports.
2. Users with the same permission can also access audit reports from any site's Qsheet>Reports page.
3. All users have a table that works the same way at Home > myReports which only lists reports that a user has been an auditor/author of.
4. These three pages work almost exactly the same. Key functions include:
 - o "Map" button will map the locations of every selected audit report auditee
 - o "Customize" button allows you to add/remove columns
 - o "Export to PDF" downloads selected audit reports as PDFs
 - o "Export Table" exports the all data from the current filter (including all rows no displayed) into a CSV file that can easily be opened in Excel.
 - o Key word search box allows you to look for any whole key words anywhere in the audit report text, observation text, and attachments.
 - o Site Names in the tables are hyperlinked to the site's Qsheet
 - o "EDIT" hyperlinks in a row appear if you have edit privileges to an audit report. Clicking on it takes you to that audit report
 - o "PDF" downloads a PDF copy of the selected audit report.
 - o "State" values indicate where the audit report is in its lifecycle. Clicking on these links at different times allows authorized users to schedule/assign an audit, launch the Send

to Auditee workflow or close out an audit report.

	Site Name	State	Audit ID	Audit Date	Audit Type	Category	# Obs.
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Report	16089	25-Jan-2016	Routine	Quality GxP	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Report	16089	25-Jan-2016	Qualification	Quality GxP	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Report	16089	21-Jan-2016	Routine	General Compliance	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Published Final Report	16063	19-Jan-2016	Routine	Quality GxP	1
<input type="checkbox"/> Edit PDF	Maura Pharma	Execution	15892	18-Jan-2016	Due Diligence	Quality GxP	1
<input type="checkbox"/> Edit PDF	Test Site Northeast	Scheduled	15974	13-Jan-2016			0
<input type="checkbox"/> Edit PDF	Supplier Complaint Tests	Awaiting Approval	16123	12-Jan-2016	Qualification	General Compliance	0

8.06 Auditor: Assign & Manage Findings

The Observations page is where an authorized user can review any observation that is part of a non-draft audit that either *i*) your company issued on an external supplier or internal site; *ii*) your company issued to an internal site; *iii*) a client issued to you directly through ZenQMS; or *iv*) a client or regulatory audit of your site that you logged in ZenQMS.

Quick Links to a Reports Observations

- Take advantage of the quick links in any of the reports tables to find related observations right away! In any audit reports tables (myReports or Audit>Reports or Show All Reports), you will see each listed report has a column called "# Obs." which stands for "Number of Observations" where any non-zero values are listed as hyperlinks. You can also add another column using the Customize button called "Unresolved Observations".

	Site Name	State	Audit ID	Audit Date	Audit Type	Category	Unresolved Obs.	# Obs.
<input type="checkbox"/> Edit PDF	QAB Test Site 3	Scheduled	463	15-Jan-2014	Routine	PanosNew	0	0
<input type="checkbox"/> Edit PDF	Test Site 2	Published Final Report	464	10-Jan-2014	Routine	panos2	2	2

- Click the hyperlinks from either column to go immediately to the Audit>Observations page prefILTERED to show the selected observations.

Search/Filter Observations

- Navigate to the Home > Audit > Observations tab. The default view of the table is all observations that your audit staff issued in audits of external or internal Auditees.
- Click on a column heading to sort the table by that column. You can change column order by dragging/dropping the column. Or click the "Customize" button to add/remove columns.
- Select a few observations using the check boxes in left column and click the "Export to PDF"

- button to download a PDF of the selected observations organized by Audit.
4. Keyword search all observations for a keyword you know to be in the observations.
 5. Enter search terms in any column heading to instantly filter that column's data

Group Assign or Edit Observations

1. Select two observations and click the "Assign" button to assign both observations to any user in your company. Since these are your 'outbound' audits, these assignments would be "Auditor Assignees". Assignees will receive a notification of their new assignment and appear in that user's myObservations page and on the dashboard. All assignments will be logged in the audit trail and comments section and assignees will be notified of items that are past their due date.
2. Select two observations and click the "Edit" button to easily reset the Status or Action Due Date for all selected observations. Any actions will be logged in the audit trail and comments section.

Review/Manage Observations

1. For the same observation, click on the "Review" link to open the Observation Review window for that observation (See picture below). Again, you can see the Action Due Date that was just assigned and can toggle it.
2. You can also change the audit due date and review any Auditee or Auditor Assignee Names.
3. If you don't want a particular observation to count against the audit score, click the "ZenQMS Scoring Algorithm" dropdown field to change the option.
4. If the auditee has already supplied a response, you can review the response in this window under Observation Response. Auditors are able to edit the Audit Response section to enter an audit response on behalf of the auditee so long as the auditee has not yet completed the Send to Auditee workflow. Once the response is complete, you can click submit final response. If need be, there is a hyperlink to unlike the final response.
5. Click the "Upload Attachments" link to upload any relevant documents. Both Auditors and Auditees can do this for an observation.
6. If the observation has resulted in a CAPA, you can create and issue and add the CAPA directly from this screen by clicking the "Create an Issue/CAPA" button.
7. You can choose to resolve the observation straight from this screen by clicking the "Resolve Observation" button at the top. You can reset the status to unresolved by clicking the blue hyperlink if need be.
8. Note that all actions are logged in the audit trail and comments section.

Observation Review

Observation ID#: 15844-01 | Unresolved

Observation Details

Resolve This Observation

All work is autosaved every 5 minutes

Site Name / ID	Maura Pharma / MAU001001
Observation Headline	Review Compliance measures
Severity	Minor / New Observation
System	Quality System
Category	Registration Compliance > Annual Reporting
Action Due Date	07-Feb-2016
Auditor Assignee	Ned Flanders
Auditee Assignee	Select User
ZenQMS Scoring Algorithm	This Observation Will Be Scored

Detailed Observation
Observation here

GxP Citations

No GxP Citations.

Observation Response - DRAFT

Submit Final to Auditor

Import file

This window's works differently depending on a user's permissions and whether they are from the Auditor or Auditee. So if you can't do some of the actions listed below make sure that you are correctly listed as the Auditor Assignee or Auditee Assignee user. Once an observation has been "RESOLVED", it will remain locked for editing by most all users unless the Auditor Assignee unlocks it.

Instructions for Auditors

1. Set 'Auditor Assignee' to yourself and click the **Save** button to be able to edit this observation.
2. Change the 'Action Due Date' if needed
3. Review the 'Observation Response'. Auditor Assignees can edit the DRAFT response directly until the Audit has been Sent to the Auditee. When that happens, Auditors will only see the FINAL version of the Auditee's response.
4. Click the **Resolve This Observation** button to set status to "Resolved". You can always reverse this by clicking the 'Click to Reset Status to 'Unresolved'' link.

You can upload files at any time. If the Auditee has linked an Issue investigation or related CAPAs to this Observation, you will not see them here unless they have explicitly added you as an External Notification.

Observation Response - FINAL

Unlock the Final Response

No response has been entered.

File Attachments [Upload More](#)

No attachments.

Primary Issue / CAPA Link

[Create an Issue/CAPA](#)

There is no issue/CAPA associated with this Observation.

Links

[Add Link](#)

There are no links to this item.

Comments [Add Comment](#)

27-JAN-2016 **All Reviewers**
 ** Observation Alert: Elizabeth Lemon changed observation status to Unresolved at 4:27:28 PM UTC

27-JAN-2016 **All Reviewers**
 ** Observation Alert: Elizabeth Lemon changed observation status to Resolved at 4:26:16 PM UTC

8.07 Sending Your Final Audit Report to the Auditee

Experienced users can still launch the Send to Auditee workflow from the Audit Report > Workflows page. Here we detail a simpler/faster way of sending audit reports below directly from any of the Audit Reports tables. Best of all, you can use the same approach to reflect an audit sent the old fashioned way.

1. Any report that has been issued will have a State of "Published Final Report". Click on myReports page right from your dashboard and find your recently issued report. Note: you can also repeat the same exact steps the other two places we display reports: in Audit > Reports and Qsheet > Reports pages.
2. Find the column called "State"—if it's not visible use the Customize button to drag it into your table.
3. In the row with the audit you want to send, the State field should say "Published Final Report" (see below). Click the hyperlink. Audit reports that you authored will always appear as hyperlinks.

Dashboard	Documents	Training	Issue/CAPA	Audit	Forum	Administration
Dashboard	Customize	Bookmark	Map	Export to PDF	Export Table	Search whole keywords
Watch List	Drag a column header here to group by that column					
myReports	Clear	Site Name	State	Audit ID	Audit Date	Audit Type
Bookmarks	<input type="checkbox"/> Edit <input type="checkbox"/> PDF	Test Site Northeast	Published Final Report	16099	25-Jan-2016	Routine
myObservations	<input type="checkbox"/> Edit <input type="checkbox"/> PDF	Test Site Northeast	Published Final Report	16103	25-Jan-2016	Qualification
myIssues	<input checked="" type="checkbox"/> Edit <input type="checkbox"/> PDF	Test Site Northeast	Published Final Report	16089	21-Jan-2016	Routine
myCAPAs	<input type="checkbox"/> Edit <input type="checkbox"/> PDF	Test Site Northeast	Published Final Report	16063	19-Jan-2016	Quality GxP
	<input type="checkbox"/> Edit <input type="checkbox"/> PDF	Test Site Northeast	Published Final Report	16845		GxP
	<input type="checkbox"/> Edit <input type="checkbox"/> PDF	Maura Pharma	Published Final Report	15847		GxP

4. A small window will appear as below. The instructions will differ slightly depending on the auditee's registration status with ZenQMS (e.g. are they "Green"). Select the hyperlink that make sense:
 - "It Only Takes a Few Minutes" If the site is NOT registered, please direct the auditee to the onboarding page that is referenced here.
 - "Send to Auditee" If the site IS registered, clicking the "Send to Auditee" link allows you to launch the workflow
 - "Manually change the Audit Status" if you have already sent the auditee the report using email/fax.
5. If you launch the workflow:
 - You will be prompted to select appropriate users for each step of the workflow that the Auditee has defined for receiving audit reports. Then click the "Launch Workflow" button.
 - Select the appropriate components to share with them (e.g. you may only want to send them the Observations). Then click the "Launch Workflow" button.
 - The auditee will receive the workflow notification as you saw in the last section. You will be kept apprised of all approvals/rejections/comments through your Dashboard and the comments section of each observation.

- The Audit's State field will appear as "Pending Auditee Receipt".
- Once the auditee completes the Send to Auditee workflow, the State will change to "Pending Auditee Response". This is also the what the State is set to if you choose the Manual option from step 51.

8.08 Creating an Audit Report: Issuing the Final Report

1. Click on the Workflow tab to launch the workflows required for publishing/sharing your audit.
2. Make sure the "Require Lead Auditor Approval" option is checked if you want all auditors to also execute this workflow.
3. Click the dropdown box to see what workflow options are available. If this is a new audit that is in draft mode, the only option listed will be "Publish Final Report", which issues the final report and makes it available within your company only.
4. Select the "Publish Final Report" workflow.

5. The Workflow Settings window will display the steps required to publish the final report, starting with the Lead Auditor if you selected that option. You must select an authorized person for each step. Then click the "Launch Workflow" button at bottom.
6. When finished, you will see a summary of all your workflow steps and current status of each step.

Note a red padlock appears at the top of the page with a link "Unlock Report for Editing" next to it. Clicking this link erases all completed workflows and allows you to edit the document. This linear approach protects the integrity of the document.

Note the "Cancel/Delete this Workflow" link at the top of the new workflow—clicking this link will cancel just the selected workflow.

Note that the Comments section in the workflow page logs all workflow actions.

7. Each person in the workflow will receive a notification in the "Workflows/E-Signatures" section of their Dashboard that looks like the snapshot below. The workflows are linear, so only one person has an active workflow waiting for them at any given time. The auditors/authors of the report can always check on the status of these workflows by logging in to the workflow tab for an audit.

Dashboard Documents Training Issue/CAPA Audit Forum Administration

Dashboard

Watch List myReports Bookmarks myObservations myIssues myCAPAs

Workflows/E-signatures

1 Item(s) Waiting for Your Review / Signature

Showing All Activity Since Last Login Change Date Range

Training Status Issue/CAPA

8. Click the "Home" link to navigate to your Dashboard page. If you were the first person in the workflow the workflow will be waiting for you.

Workflow Action Items

AUDIT #16123 of Supplier Complaint Tests by Maura Pharma, LLC 12-JAN-2016

Page 1 of 1 (1 items) [1] Page size: 5

9. Click on the workflow item. It will open a window that looks like below. You can approve or reject the workflow. You can also delegate the workflow step if you are not the correct authorized approver for the step. All users can also download a PDF copy of the report components that were shared with the workflow participants. Any auditors/authors can also link directly to the edit view by clicking the "Edit" link.

Workflow Action Item

AUDIT #16123 of Supplier Complaint Tests by Maura Pharma, LLC

Workflow Details	Instructions
Workflow Type	AUDIT / Publish Final Report
Purpose of this Workflow	Complete this workflow to issue the Final Report internally.
Review Documents	Download PDF Review/Edit in ZenQMS
Actions You Can Take	Instructions
Sign/Approve Delegate Reject	You can complete this workflow with an e-Signature. You can delegate this workflow step to another authorized user. Stops the workflow process after recording your rejection reason.

Instructions

You can complete this workflow with a compliant electronic signature after reviewing the details of this workflow and any attached/linked documents

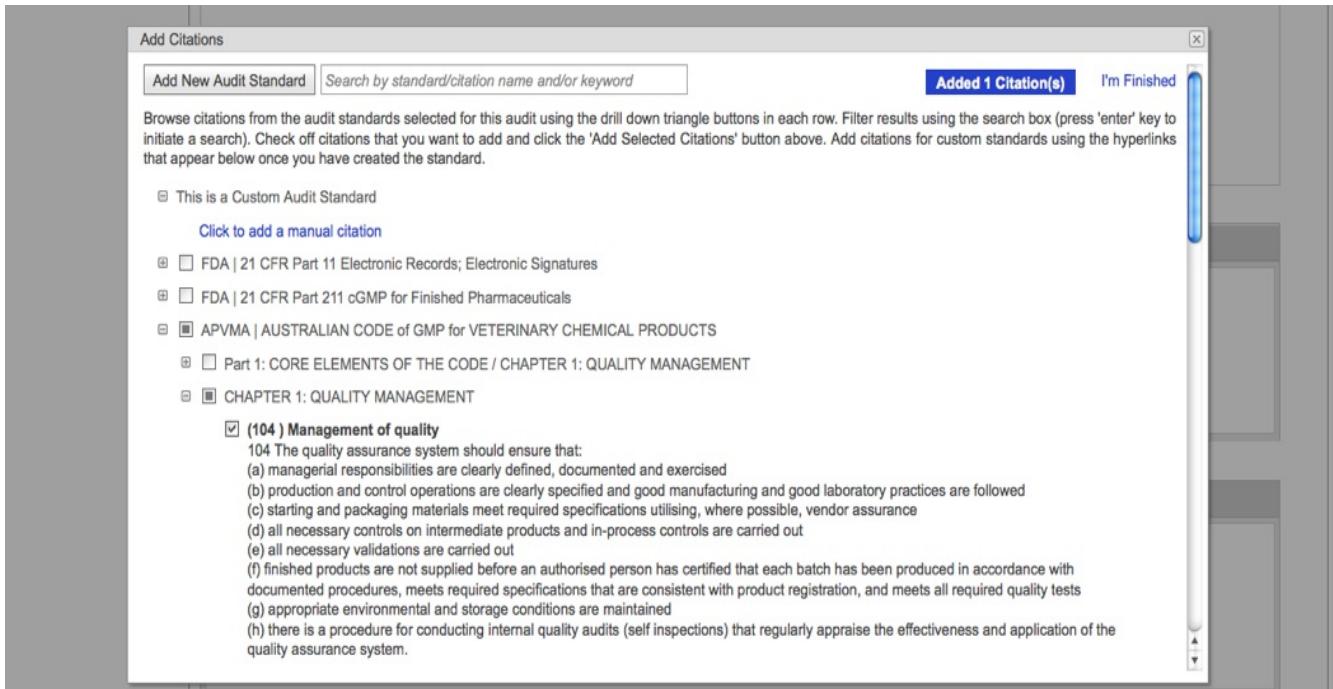
1. Review 'Workflow Details' section and click 'Download PDF' link to see documents for review.
2. Approve or Reject the workflow by clicking the buttons of the same name. In some cases you can also 'delegate' the workflow to another authorized user.
3. You will be required to verify your identity in a new window.

Auditees can immediately respond to findings after completing the 'Send to Auditee' workflow by navigating to the Home > Audit > Observations page, selecting 'Client Audits of My Sites' and clicking the 'Review' link for each finding.

8.09 Creating an Audit Report: Observations/Citations

Auditors must enter each finding separately in the Observations tab.

1. Select the "Observations" tab.
2. Click the "New Observation" button to go to the observation editor view.
3. REQUIRED: Click the first dropdown to select a Severity (Comment/Minor/Major/Critical or custom names). Observations tagged as "Comment" will not be scored and are automatically set as "Resolved".
4. If the finding is a Repeat, change the field from the default.
5. REQUIRED: Enter a Scorecard Headline for the finding (short sentence or heading)
6. Assign a Quality System/Category using the word filter at top/right. You can keyword search using keyword fragments from ~900 system/category1/category2 tags—enter a word or fragment (e.g. 'valid' and any category with that word or fragment will appear. The more detailed the more valuable your analytics will be later when looking for observation trends. Please send us your suggestions for System/Category tags if you find something missing.
7. Enter a Detailed Observation using the text editor.
8. Click the "Save" button at the top or bottom of the page. Note that the "Add Citations" hyperlink appears at the BOTTOM of the page after you save the new observation
9. Click the "Add Citations" hyperlink to open the 'Add Citations' window (See below)



10. Click the 'Add New Audit Standard' to add more standards. Or keyword search all the standards in the search box. Or simply click the +/- boxes next to any already selected standards to browse all subparts and citation text.
11. Tick the box next to a citation to assign it to the observation. The counter in the top right of the window lets you know how many standards are assigned.
12. To paste in a custom standard/citation (e.g. Quality Agreement or ISO 9001) use the "Click to add a manual citation" link, paste in your text (using Edit/Paste or Ctrl-V) and Save.
13. Click "I'm Finished" when done.
14. Back in the editor view, note that the citations you added now appear as hyperlinks at the bottom. Click one to see the citation. It may look like the screen shot below:

15. Click the "Save & Create Next Observation" button at the top of the page if you want to practice creating multiple observations. Note—this page will auto save your edits every 5 minutes.
16. Click "Exit Observation Editor" button at the top when you are finished with the first observation.
17. In the summary view, click the "Full View"/"Summary View" links to see more/less detail in your observations list.
18. Note—each observation is automatically assigned a unique ID linked to the Audit ID and is grouped and sorted in descending order by Severity.

8.10 Creating an Audit Report: Create or Upload the Audit Report Body

1. Click on the "Audit Report" tab to create or upload your audit report.
2. You can upload a finished audit report in PDF format by clicking on the "Click here if you would rather upload a finished audit report instead" link. Doing so will replace the report editor controls with a file upload control. Any uploaded PDF is appended to the final report.

If you uploaded a PDF to test this, click the "Export to PDF" button at the top of the page to see how it looks.

3. Most auditors will compose their audit reports using the word processing editor on the page. If you hid these controls in the previous step, click the "Click here if you would rather draft a new report in the text editor" link at the top of the page.
4. Click the "Edit This Version" button to open up the report editor.
5. Click the "Insert Template" link that appears above the editor window. If your administrator

added any templates, you could select it here and have it inserted. Your administrator can add as many templates as needed (ZenQMS Staff can help convert any MSWord based document).

6. Click "Save New Version" to manually save the current version and exit the editor. When you do so, notice that a new version is logged with your name in the table to the right. You can compare versions, including from different auditors/authors.

Note: this page will autosave your work every 5 minutes.

7. Click the "Save New Version" button when you are finished editing to close the editor.
8. Enter comments that you want to share with your colleagues/fellow auditors regarding the report—make sure they are marked as "Private" comments to ensure they are only visible to your colleagues. Any comment marked "All Reviewers" will ultimately be visible to the Auditee users if you share the audit with them.
9. Upload attachments in the bottom section by clicking the "Upload Files" link.
10. Your audit report may look something like the image below.

The screenshot shows the ZenQMS Audit Report editor. At the top, there is a navigation bar with tabs: Audit Details, Audit Report (which is selected), Observations, Workflow, and Scoring. Below the navigation bar are several buttons: Save/Exit, Delete Draft, Update Site Info, Export to PDF, and a lock icon. A message says, "Click here if you would rather upload a finished audit report instead." On the left side, there are two buttons: Save New Version and Exit Without Saving. Above the main content area, there is a toolbar with various icons for file operations like Open, Save, Print, and Insert Template. To the right of the toolbar, there is a "Font" dropdown menu showing Arial and a "Font Size" dropdown. Below the toolbar, there are sections for "Audit No.", "Audit team:", "Site/section/function audited:", and "Audit date:". In the center, there is a section titled "AUDIT FINDINGS" which contains a table with three columns: Element, Code, and Findings. The first row of the table shows "Scope of EMS".

Element	Code	Findings
Scope of EMS		

8.11 Creating an Audit Report: Audit Details

1. Navigate to the Auditee's QSheet using the "Jump to Qsheet" control (Section 2.01); if the site doesn't exist, you can create a new site following Sections 2.02 & 2.03.
2. Click the "Create New Report" menu item on the left side of the page. You will be taken to the Qsheet > Reports > Show All Reports page where you will see a table of any existing audit reports you or your colleagues have created for this same Auditee site.

Note on "Show All Reports table": If you authored one of the existing audits, you can click the "Edit" link for the audit to enter the report editor. Otherwise, you will only see a "PDF" link next to the audit, which will allow you to download a PDF of the audit.

3. Select the "Compose New Audit" button on at the top of the page. After you enter an audit date a new DRAFT audit is created, and you will be taken to the New Audit > Audit Details page. The only required fields on this page are Lead Auditor (you are pre-selected), Audit Date (you have already entered), Audit Type and Audit Category. All other fields are optional, but we strongly recommend them for enhanced analytics and defer to your company's protocols.
4. Enter the number of Audit Days; for example, if the audit started/ended on the same day enter "1".
5. Note the "Response Due In" field is pre-set to 30 days. This means that all observations will have their Action Due dates set to 30 days from the ISSUE DATE of the audit report (e.g. completion of the Publish Final Report workflow). The action due date will reset a second time when the Auditee formally receives the audit report (e.g. completes the Send to Auditee workflow), but this will NOT happen if you don't send the audit to them through ZenQMS. You can reset the due date for all observations in the Audit > Observations page.
6. Quality Systems: Select relevant quality systems using the check marks.
7. Auditors: Add new Auditors using the "Add New" link above that table. (note—users will have had to configure their settings to be visible in dropdown lists per Section 1.2). You can also add registered consultants or manual names. A counter at the bottom of the window will confirm every addition.
8. Participants: If someone attends an audit as a subject matter expert but not as an auditor, add them as a participant to preserve your resource metrics. You can also easily add the names of any important participants from the Auditee. (note—users will have had to configure their settings to be visible in dropdown lists per Section 1.2). A counter at the bottom of the window will confirm every addition.
9. Audit Standards: Add relevant Audit Standards using the "Add New" link above that table and selecting from the list of pre-loaded standards. This step is required if you would like to search for and add citations to your findings. If you can't find a mainstream standard that you need, please contact us so we can add it. In addition to pre-defined regulatory standards, you can also add manual audit standards (e.g. Quality Agreement) in the event you want to tie a finding back to a private citation/document.
10. Notifications: Auditors can provide ad hoc or automatic notifications to select users or groups right from the Audit Details section. Use the search box to find/add individuals or named groups to the notification list for this audit. On completing the "Publish Final Report" workflow, those listed will receive an automatic notification to their ZenQMS Inbox which will include a link for quick download of the final report. Auditors can also share the audit report on demand by selecting the "Send Current Version Now" link and including a message.
11. Going to another tab in the New Audit section, for instance the Audit Report tab, automatically

saves any items that have not been saved on page you are leaving. Or you can also click the "Save/Exit" button from any page to save your work and be returned to the Qsheet > Reports > Show All Reports page. Let's try the latter right now:

- Click "Save/Exit" button
- From the Show All Reports page, find your audit and click the "Edit" link in that row to return to it.

Your Audit Details page might look like the one below when you are finished.

Required Fields

The screenshot shows the 'Audit Details' tab selected in a top navigation bar. Below it is a toolbar with buttons for Save/Exit, Delete Draft, Update Site Info, Export to PDF, and a lock icon. The main content area contains various audit details and participant lists. Red arrows point from the 'Audit Category' dropdown, 'Start Date' dropdown, and 'Audit Type' dropdown to their respective sections. A large red arrow points from the 'Auditors' section to the 'Auditor' list. Another red arrow points from the 'Other Audit Participants' section to the 'Add New | Delete Selected' link. The 'Auditor' list includes 'Graham Wert [Lead], CTO, The Quality Advisory Board, LLC' and 'Panos Boudouvas, CEO, The Quality Advisory Board, LLC'. The 'Other Audit Participants' list includes 'Administrative User (A), Administrator, The Quality Advisory Board, LLC, 6105551234, admin@admin.com' and several others. The 'Auditor Focus' section has two options: 'Analytical Laboratory Services' and 'Manufacturing, Cytoxic & High Potency Compounds'. The 'Audit Standards' section lists 'Australia | APVMA | AUSTRALIAN CODE of GMP for VETERINARY CHEMICAL PRODUCTS', 'Canada | DHP | Annex 14 to the Current Edition of the Good Manufacturing Practices Guidelines - Schedule D Drugs, Human Blood and Blood Components (GUI-0032)', 'International | ICH | Q7: GMPs for Active Pharmaceutical Ingredients', and 'Quality Agreement'. The 'Notifications' section includes a 'Send Current Version Now' button and a 'Select a User or Group' input field. The 'User or Group' list includes 'Quality Group', 'Panos Boudouvas, CEO', and 'Jim Johnson'.

8.12 Overview of Audit State

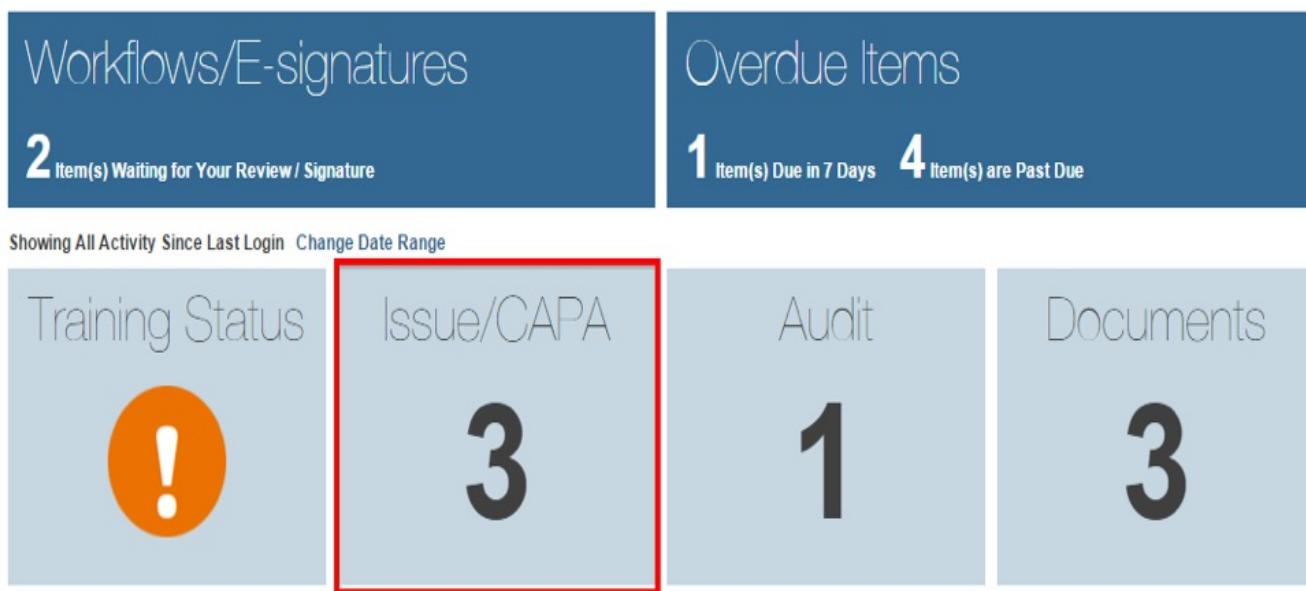
Audit reports follow a linear progression until they are considered "Closed". You can monitor an audit's current place by referring to its "State", which is visible from any of the Reports tables. An Audit's State is updated automatically by the application and includes the following progression:

- Targeted: Audit has not been scheduled yet (e.g. no Schedule Date)
- Scheduled: Audit has a Schedule Date
- Execution: Auditor has begun editing the report/observations
- Awaiting Approval: Auditor has launched "Publish Final Report" workflow.
- Published Final Report: Audit report has been approved internally.
- Pending Auditee Receipt: Auditor has launched the "Send to Auditee" workflow.
- Pending Auditee Response: Either a) the Auditee has completed the "Send to Auditee workflow; or b) the Auditor has sent the report to the Auditee outside of ZenQMS and manually changed this value.
- Closed (No Response): The audit report was closed with no formal response from the Auditee.
- Closed (Not Acceptable): The audit report was closed with an unacceptable response from the Auditee.
- Closed (Pending Observations): The audit report was closed based on an acceptable action plan, but at least one observation remains 'Unresolved'. The status will automatically revert to "Closed" as soon as all observations are closed.
- Closed: The audit report is formally closed.

9.0 Issues/CAPAs

9.00 Completing a CAPA

When a Corrective or Preventive Action is assigned to you to complete, you will receive notification via your Daily Email Summary. Once you login to your account, you can click on the number within the Issues/CAPA box.



You will see all items within the Issues/CAPA module that have activity related to your account. Click on the hyperlink that has "New CAPAs Assigned to You"

Issue/CAPA Drilldown

Issues

1 Of Your Issues Have Had Recent Activity

0 New Issues Assigned to You

0 Issues Were Approved for Implementation

0 Issues Were Closed/Completed

CAPAs

1 Of Your CAPAs Have Had Recent Activity

1 New CAPAs Assigned to You

0 CAPAs Were Approved for Implementation

0 CAPAs Were Closed/Completed

See All My Items



You will be brought to the myCAPAs table that shows the newly assigned CAPAs to you. Click the edit hyperlink for the CAPA you'd like to complete.

Drag a column header here to group by that column									
	CAPA ID	Issue ID	State	Site Name	Headline	Implementation Date	Days	Type	Assignee
Edit PDF	1826-2	1826	Draft	Maura Pharma	Preventive Action 111	04-Jan-2016	38	Preventive	Elizabeth Lemon

Page 1 of 1 (1 items) [\[1\]](#) [\[2\]](#) Page size: [15](#) [Clear](#)

[AssignedUtc] Is greater than '2/5/2016 12:00:00 AM' And [Assignee] Equals 'Elizabeth Lemon'

Type or copy and paste directly into the CAPA Details text box information about your completed CAPA. If you have a document summarizing your CAPA or supporting documentation you'd like to add, you can upload an attachment.

Site Name/ID	Maura Pharma/MAU001001
CAPA Headline (for table)	Preventive Action 111
CAPA Type	Preventive
CAPA Category	Mechanical
Implementation Date	04-Jan-2016
Assignee	Elizabeth Lemon

This CAPA is linked to this Issue # 1826

CAPA Details

Your information on the Preventive Action here.

[File Attachments](#) [Upload More](#)

Once you've added all your information and your CAPA is completed, save your work and then press "Complete this CAPA" to complete your Corrective or Preventive Action.

Save Export to PDF Exit You Have Unsaved Work On This Page

All work is autosaved every 5 minutes

CAPA Details		Complete this CAPA
Site Name/ID	Maura Pharma/MAU001001	
CAPA Headline (for table)	Preventive Action 111	
CAPA Type	Preventive	
CAPA Category	Mechanical	
Implementation Date	04-Jan-2016	
Assignee	Elizabeth Lemon	Clear

You will then enter your username and password to sign and complete the CAPA.

User Authentication/Electronic Signatures

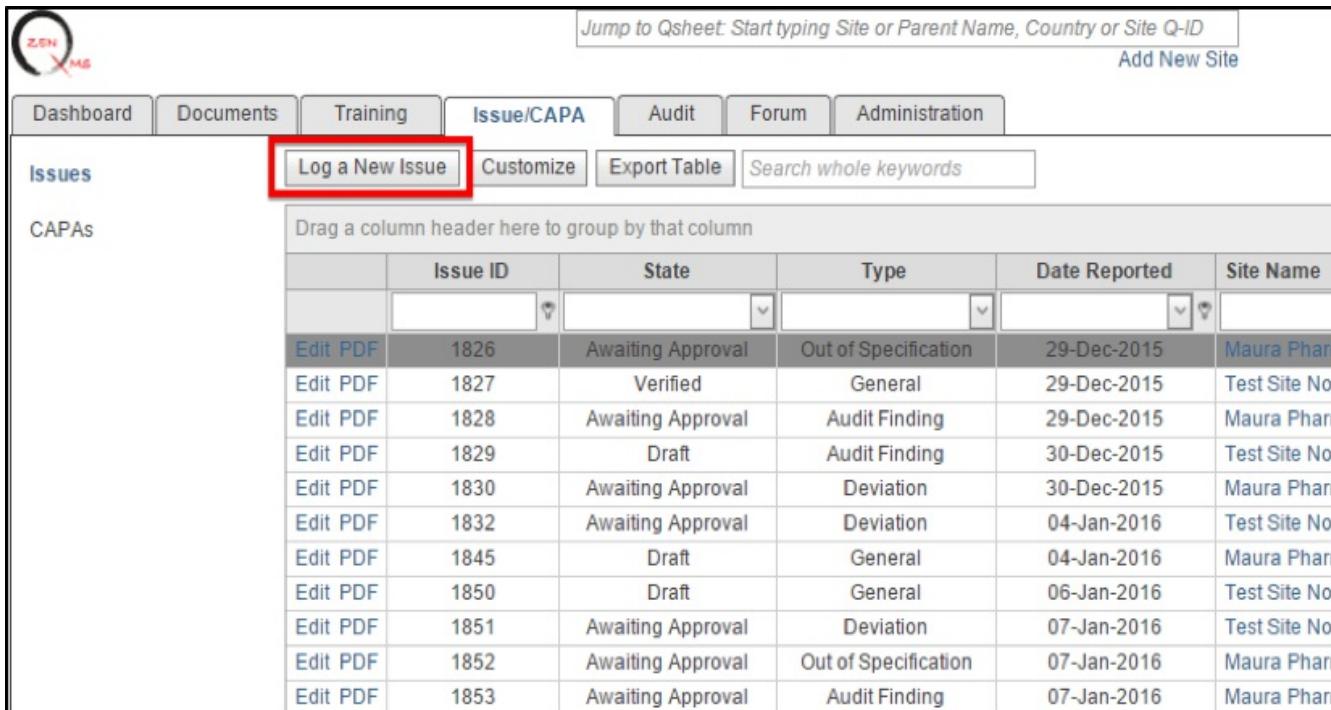
Please verify your identity [?](#)

Signature Reason
I have performed this step.

User Name	maura+demo@zenqms.com
Password	*****
<input type="button" value="Ok"/>	

9.01 Logging a New Issue

From the Issues Tab, click on the “Log a New Issue” button above the Issues table.



The screenshot shows the ZenQMS application interface. At the top, there is a navigation bar with links: Dashboard, Documents, Training, Issue/CAPA (which is highlighted in blue), Audit, Forum, and Administration. Below the navigation bar, there are two main sections: 'Issues' and 'CAPAs'. The 'Issues' section contains a button labeled 'Log a New Issue' which is highlighted with a red box. To the right of this button are links for 'Customize', 'Export Table', and 'Search whole keywords'. Below these sections is a large table with columns: Issue ID, State, Type, Date Reported, and Site Name. The table contains several rows of data, each with an 'Edit PDF' link and a unique ID. The data in the table is as follows:

	Issue ID	State	Type	Date Reported	Site Name
Edit PDF	1826	Awaiting Approval	Out of Specification	29-Dec-2015	Maura Pharr
Edit PDF	1827	Verified	General	29-Dec-2015	Test Site No
Edit PDF	1828	Awaiting Approval	Audit Finding	29-Dec-2015	Maura Pharr
Edit PDF	1829	Draft	Audit Finding	30-Dec-2015	Test Site No
Edit PDF	1830	Awaiting Approval	Deviation	30-Dec-2015	Maura Pharr
Edit PDF	1832	Awaiting Approval	Deviation	04-Jan-2016	Test Site No
Edit PDF	1845	Draft	General	04-Jan-2016	Maura Pharr
Edit PDF	1850	Draft	General	06-Jan-2016	Test Site No
Edit PDF	1851	Awaiting Approval	Deviation	07-Jan-2016	Test Site No
Edit PDF	1852	Awaiting Approval	Out of Specification	07-Jan-2016	Maura Pharr
Edit PDF	1853	Awaiting Approval	Audit Finding	07-Jan-2016	Maura Pharr

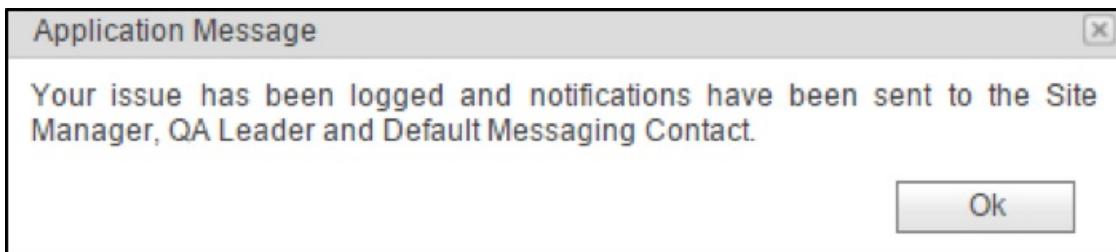
The first three fields are required to log an issue. Enter the Site Name/ID, the Issue Type from the dropdown list, and the date. There may be custom fields added to answer, these may be required fields. If you are not the reporter of the issue, include the the reporter contact name. If you would like to add a detailed description of the issue, type or copy and paste into the long text box at the bottom of the screen. To attach any files to this issue, click the “Upload Files” hyperlink and attach your document. When you are finished entering details, submit your issue.

Log a New Issue

Site personnel will be immediately notified about this issue.

Site Name/ID	Test Site Northeast MAU001002
Issue Type	Client Complaint
Date of Event / Issue	03-Feb-2016
Supplier Name	Type a Value
Maura 1	Select a Date
Test	Type a Value
Custom Fields	
Reporter Name & Contact Info (if not you)	
Please enter a detailed description of the issue.	
<input style="width: 100px;" type="button" value="Upload Files"/> <input type="button" value="Submit"/> <input type="button" value="Exit/Cancel"/>	

Upon logging your issue, you will receive a message that your issue is logged and three predetermined users will be notified about the new issue. These users were determined by the Site you chose when logging the issue.



As a Super User, you can walk through the issue investigation. Using the table, search for the issue logged. Click the "Edit" hyperlink. You will be brought directly to the details information of your issue. The lead investigator has been added and determined based on the Site chosen. You can change and/or add up to two co-investigators by choosing the "Manage Team" button.

Details	Assessment	Notifications	Root Cause Analysis	Action Plan	Workflow
<input type="button" value="Save"/>	<input type="button" value="Export to PDF"/>	<input type="button" value="Exit"/>			
Investigator Team <div style="float: right; border: 2px solid red; padding: 2px;">Manage Team</div>					
Lead Investigator		Kenneth Parcell			
Co-investigator					
Co-investigator					

The Issue Details and Custom Fields are taken from the original screen where you logged in the information. You can update or change this information as necessary. All changes are tracked under the comments section at the bottom. This is an audit trail of all changes. You can add a bi-directional link to any item within ZenQMS under the Links section.

This screenshot shows the ZenQMS interface for managing issue details. At the top, there's a header with 'NO attachments.' Below it, the 'Custom Fields' section contains fields for 'Supplier Name' (with a placeholder 'Type a Value') and 'Maura 1' (with a date picker placeholder 'Select a Date'). The 'Audit Trail' section is highlighted with a red box and a red arrow pointing down to the comments area. It includes a 'Links' section with an 'Add Link' button and a message stating 'There are no links to this item.' The 'Comments' section shows a log entry from 'Elizabeth Lemon' on '05-FEB-2016' at '8:54:43 PM UTC', adding 'Bart Simpson as an Investigator'. The bottom of the page shows pagination 'Page 1 of 1 (1 items)' and a 'Page size:' dropdown set to '10'.

On the Assessments tab you can enter in information and get a basic risk assessment score and rating. This is calculated by the frequency x impact. This is an optional tool. You will log any Corrective Actions under the Assessments tab. ZenQMS separates Corrective and Preventive actions solely for tracking and trending purposes. To log a corrective action, click the “Add CAPA” button.

This screenshot shows the ZenQMS Risk Assessment form. At the top, it says 'Risk Assessment' and 'All work is autosaved every 5 minutes'. The 'Notification Received From' field and the 'Has this type of issue occurred in the past?' field are both highlighted with red arrows. A large text area below asks if preventive actions were developed and implemented. The 'Frequency of this issue (F)' and 'Potential impact on quality/safety (I)' fields are also highlighted with red arrows. To the right, dropdown menus show '3 - Frequently', '5 - Minor', and a circled '15 Undesirable' rating. The 'Risk Score (F x I)' is listed as '15 Undesirable'. At the bottom, the 'Corrective Actions (immediate)' section has an 'Add CAPA' button highlighted with a red box and a red arrow.

Enter the details of your Corrective Action – enter your headline, choose a category from the dropdown

list. If this is a true Corrective Action and it has been completed, you can enter the details in the text box or upload an attachment with the documentation press Save and then “Complete this CAPA”. If this Corrective Action has not been completed, choose the implementation date and assign a user from the dropdown list.

All CAPAs will be permanently tied to the issue. Here we have Issue 1909 and CAPA 1909-1. Once the CAPA is completed it will still be associated with the issue.

CAPA Details

Site Name/ID: Test Site Northeast/MAU001002

CAPA Headline (for table): Your Headline Here

CAPA Type: Corrective

CAPA Category: Mechanical

Implementation Date: 26-Feb-2016

Assignee: Ron Swanson

Complete this CAPA

All work is autosaved every 5 minutes

This CAPA is linked to this Issue # 1909

CAPA Details

Import file

Arial 2 (10pt)

B I U S

Text area for report content.

If you have a Root Cause Analysis, you can add it under the “Root Cause Analysis” tab. Choose a category from the dropdown list. You can type or copy and paste your report into the text box. If your organization has uploaded a template, click the “Insert Template” link. The template will appear in the text box for you to add your information to the report by typing directly into the text box. If you have a completed Root Cause Analysis outside of the software, you can upload the document under the File Attachments by clicking “Upload More” underneath the text box. There is no limit to the file size or type that you can upload. You can upload additional documents as well that may be associated with the Root Cause Analysis under the File Attachments section.

Save Export to PDF Exit  You Have Unsaved Work On This Page

All work is autosaved every 5 minutes

Root Cause Analysis

Root Cause Category: Design Update

Insert Template 

ROOT CAUSE ANALYSIS REPORT FORM

AGENCY:	Reference No.:					
Program/Facility:	Region	STS	North	South	West	
Consumer ID:	Age: M F	MR Level:	NR	ML	MO	SV PR
City/Town:	Date of Event:	Date RCA Completed:				
1. THE EVENT – Describe what happened and any harm that resulted. Identify the proximate cause, if known.	RCA Team Members:					

You can summarize your Issue Action Plan under the Action Plan tab. Start by choosing a projected implementation date. This is required. Add your summary by inserting a template and editing within the text box, typing or copying and pasting directly into the text box, or uploading a document under File Attachments underneath the text box.

Save Export to PDF Exit  You Have Unsaved Work On This Page

All work is autosaved every 5 minutes

Action Plan

Projected Implementation Date: 29-Feb-2016

Insert Template

Action Plan

Type or paste your action plan here.

If you have a Preventive Actions, click the “Add CAPA” button. This process is the exact same as adding a Corrective Action. You can add as many Preventive Actions as needed. They will be permanently associated with the Issue.

Once you have entered all of your details and you are ready to launch your investigation, go to the “Workflow” tab. Your Lead Investigator(s) will be automatically added to sign for approval. If you added any corrective or preventive actions with assigned users, they will also be automatically added to the workflow. You will need to choose an authorized user from the dropdown list under Site Workflow Approval. There may be additional users to assign to additional Site Workflow Approval steps. Lastly,

choose a user to provide a final review. If you need a user to complete an Effectiveness Check, add the appropriate step, select the user, and a due date. The lead investigators and any users assigned to CAPAs will all be notified when you launch the workflow. Once they have signed off, the user assigned to complete the Site Workflow Approval will be notified. Once the Site Workflow Approval and all CAPAs have been completed the user assigned to the final review will be notified. If Effectiveness Check is included, the user(s) assigned will need to sign and approve by the deadline chosen.

Export to PDF Exit 

Workflow Approvals Launch Workflow

These workflows will progress automatically until all stages completed or cancelled

Issue Investigator Team Review (automatically added)
Lead Investigator Administrative User

CAPA Assignee Review/Acceptance (automatically added)
1213-1 giulia umile

Site Workflow Approval for "Phake Pharma Site 1"
Approval Peter Smith

Internal and Client Approvals (only for ZenQMS Members)
No Internal or Client Approvals.

Final Review (automatically launched when all related actions are completed)
Maura Ciambetti

Add another final review step

Effectiveness Check

Add Another Step 

 Jane Smith 24-Feb-2017

Application Message

You have launched the workflows for this Issue and all users will be notified about the approval process in order.

Ok

The following are the states that an Issue may be in depending on the stage within it's lifecycle.

- Draft: New issues are set to Draft.

- Awaiting approval: Investigator has launched workflow approval for implementation.
- Implementation: Will remain in this state until all CAPAs are completed. When this happens, or if no CAPAs, go to FINAL REVIEW.
- Final Review: This state is automatically set when all CAPAs are completed. During this phase the Final Review step(s) are launched.
- Closed: This state is automatically set when all Final Review steps completed.
- Awaiting Effectiveness Check: Automatically set if any EC steps are active or incomplete.
- Effective: when all EC steps completed.

Failed: if an EC step is rejected.

9.02 Using the Issues and CAPAs Tables

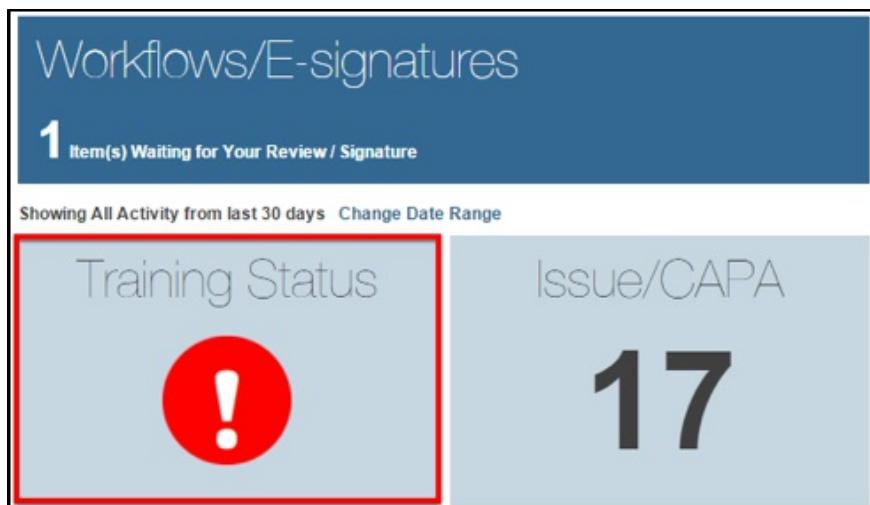
ZenQMS separates Issues and CAPAs into two tables within the module. Both of these tables function the same way as in previous modules. You can search using keywords, sort columns, refine results using filters, and export your table to CSV and Excel file formats.

To download a PDF copy of the Issue Investigation or CAPA you are looking for click the “PDF” link. If you would like to view the details within the system or edit, click the “Edit” link.

10.0 Dashboard

10.00 Completing Training from the Dashboard

Users will be notified on the Dashboard if there are assigned documents which need to be trained on. Users can find this information under the Training Status tile. If the tile has a green check mark all training is up to date. If the tile has an orange exclamation point training is due soon. If the tile has a red exclamation point, like the example below, training is past due and the user is not compliant.



Click on the Training Status tile will open up the users Training Dossier with items that need to be trained on. You will click the red “Train Now” hyperlink to access the document.

Training Dossier

Add Personal Event Dossier PDF Export Table Exit

Personal Training History Show Full Dossier

	Training Status	Training Item	Type	Training Date	Due Date
Edit Train Now	Compliant				
Edit Train Now	! Non-Compliant	QA SOP (v.02)	File Review		27-Jan-2016
Edit Train Now	! Non-Compliant	QA Template (v.01)	File Review		27-Jan-2016

Page 1 of 1 (2 items) [\[1\]](#) [\[2\]](#) Page size: [15](#) [▼](#)

[Training Status] Does not equal 'Compliant' [Clear](#)

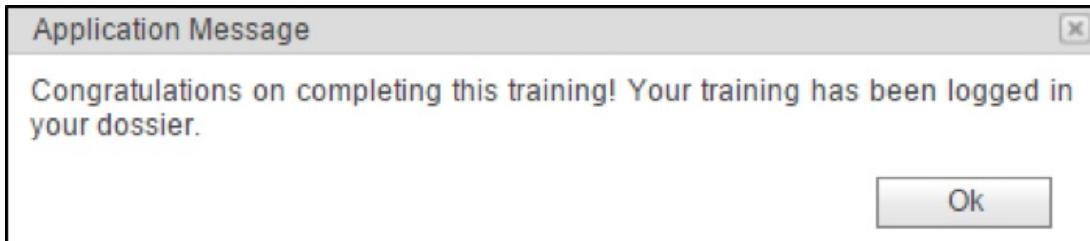
Depending on the security settings of the document, you may be able to download the document or view the document within the software (you will not be able to right click, save, or print the view only document). To download the document, click the little arrow icon. If you would like to view the document within the system, click the little eye icon. Once you have reviewed the document and are ready to submit your training click the green submit button.

Training

QA Template Version 1 - Effective

Details		User Guide Content Coming Soon!
Download & Review This File	UP_Quality_Management_Plan_Template.doc	
Category	QA Documentation	
Effective Date	29-DEC-2015	
File Description	QA Documentation	
Version Comments	Version 1	
Submit		

If there is a training challenge question you will need to answer the question before being able to sign and complete your training. After signing, you will receive a confirmation message that your training is complete and has been logged in your dossier.



10.01 Completing an E-signature and Reviewing Assigned Workflows

Users can find all items that have been assigned to them through a workflow within the Workflow/E-signatures tile. By clicking the number within the tile it will show the items assigned which could be a documents, issues investigations, CAPAs, or audits.



You will see a list of Workflow Action Items. Clicking on any of the individual item to bring up the details. In the example below we see an Audit under the Workflow Action Items.



You will be able to review the details of the workflow by downloading a PDF of the document by clicking the "Download PDF" hyperlink. You can choose to review the details within the system by clicking the "Review/Edit in ZenQMS" hyperlink.

Workflow Action Item

AUDIT #16103 of Test Site Northeast by Maura Pharma, LLC

Workflow Details

Workflow Type	AUDIT / Send to Auditee
Purpose of this Workflow	Complete this workflow to formally receive the audit you recently hosted.
Review Documents	Download PDF Review/Edit in ZenQMS

Actions You Can Take

Sign/Approve	Allows you to complete this workflow with an e-Signature.
Delegate	You can delegate this workflow step to another authorized user.
Reject	Stops the workflow process after recording your rejection reason.

Instructions
You can complete this workflow with a compliant electronic signature after reviewing the details of this workflow and any attached/linked documents

1. Review 'Workflow Details' section and click 'Download PDF' link to see documents for review.
2. Approve or Reject the workflow by clicking the buttons of the same name. In some cases you can also 'delegate' the workflow to another authorized user.
3. You will be required to verify your identity in a new window.

Auditees can immediately respond to findings after completing the 'Send to Auditee' workflow by navigating to the Home > Audit > Observations page, selecting 'Client Audits of My Sites' and clicking the 'Review' link for each finding.

Once you have reviewed the item you can choose to sign and approve, delegate to another authorized user to sign, or stop the workflow by recording your reason for rejection. Click the button of the workflow action you'd like to take. Please note, in some cases you may not be able to delegate the workflow to another user. You will be required to enter your username and password in a new window for the selection you choose.

10.02 Understanding the Dashboard

Each of the light blue tiles reflects activity within the four main modules – Training, Issue/CAPAs, Audits, and Documents. The default view for the tiles will show all activity since the user last logged in. Clicking the blue “Change Date Range” hyperlink will have the Dashboard show activity from the last 30 days.

Workflows/E-signatures

1 Item(s) Waiting for Your Review / Signature

Showing All Activity from last 30 days [Change Date Range](#)

Training Status



Issue/CAPA

17

The dark blue tiles provide the user access to items that need review/e-signatures (Workflows/E-signatures tile) and upcoming and overdue items in which the user needs to take action (Overdue Items tile).

You can click on any number within the tiles on the Dashboard to see a breakdown of the information and activity. Continue to click any hyperlink to drill down further and until you are able to open up the specific item you are looking for and take action. See pictures below for an example.

The screenshot shows the QSRM software interface. At the top, there's a search bar with placeholder text "Jump to Qsheet: Start typing Site or Parent Name, Country or Site Q-ID" and a "Add New Site" button. On the right, there are links for "Home", "Search", "Support", and a sign-out link for "Elizabeth Lemon, Maura Pharma, LLC". Below the header, a navigation menu includes "Dashboard", "Documents", "Training", "Issue/CAPA", "Audit", "Forum", and "Administration".

The main area features several tiles:

- Workflows/E-signatures:** Shows "1 Item(s) Waiting for Your Review / Signature".
- Overdue Items:** Shows "1 Item(s) Due in 7 Days" and "5 Item(s) are Past Due".
- Training Status:** Shows an orange circle with a white exclamation mark and the number "17". A red arrow points from the text "Continue to click any hyperlink to drill down further and until you are able to open up the specific item you are looking for and take action." to this tile.
- Issue/CAPA:** Shows the number "17".
- Audit:** Shows the number "10".
- Documents:** Shows the number "46".

On the left side, there's a sidebar with links: "Dashboard", "Watch List", "myReports", "Bookmarks", "myObservations", "myIssues", and "myCAPAs". Below the sidebar, there's a message "Showing All Activity from last 30 days" and a "Change Date Range" button.



E-signatures | Overdue Items

Review / Signature

0 days

Issues With Recent Activity

7 Of Your Issues Have Had Recent Activity

5 Item(s)

Issue #	Description	Days
Issue #1826	for Maura Pharma	14
Issue #1827	for Test Site Northeast	5
Issue #1828	for Maura Pharma	3
Issue #1829	for Test Site Northeast	1
Issue #1830	for Maura Pharma	6
Issue #1875	for Supplier Complaint Tests	4
Issue #1878	for Supplier Complaint Tests	1

1 CAPAs Were Closed/Completed

See All My Items