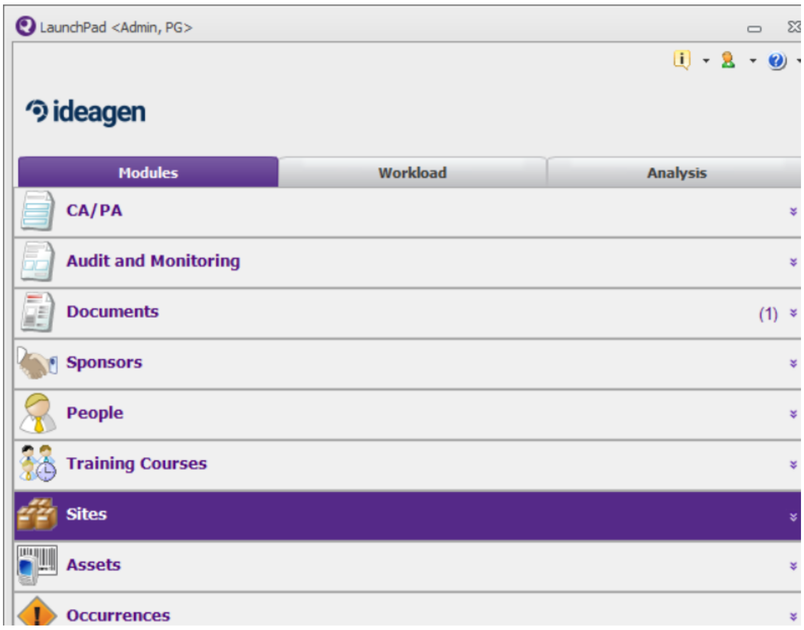
Use of Q-Pulse for Vendor Assessment Guide

Contents

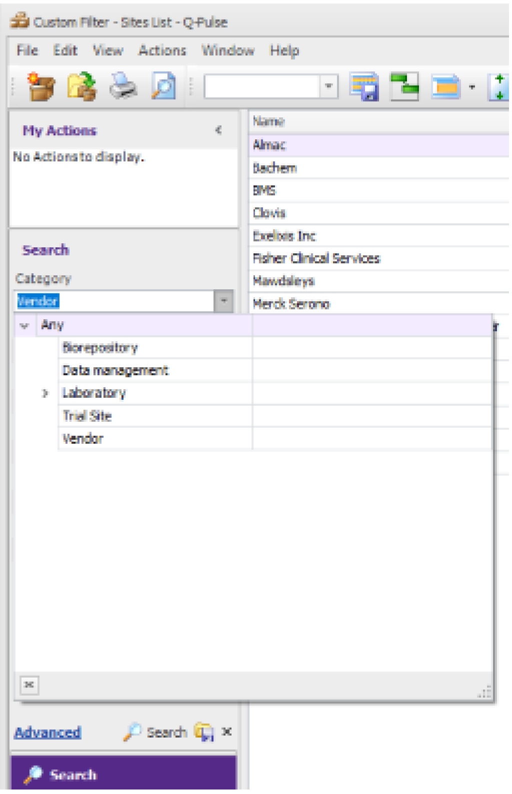
1. Managing Vendor List

1.1. Vendor Records

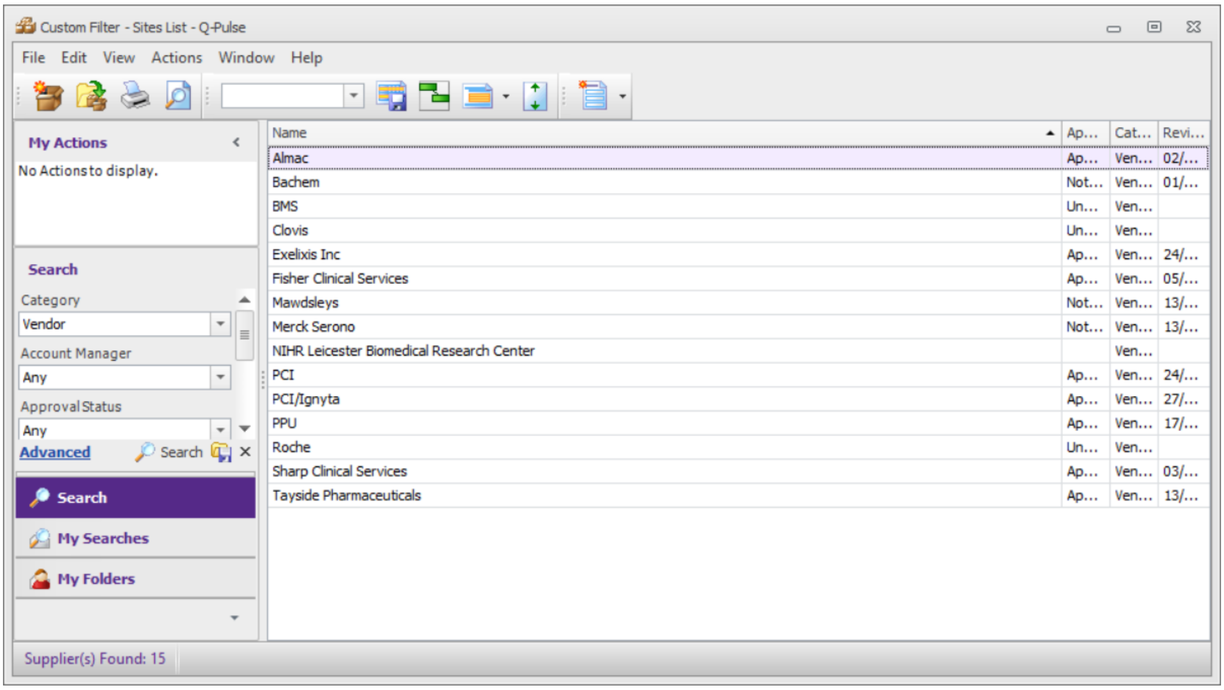
Q-Pulse contains a list of all Vendors which have undergone review or been approved for use within a Sponsored/Co-Sponsored Trial. This list is held within the “Sites” module in Q-Pulse and can be accessed to determine if there is an existing record for a Vendor or if a new record is required.



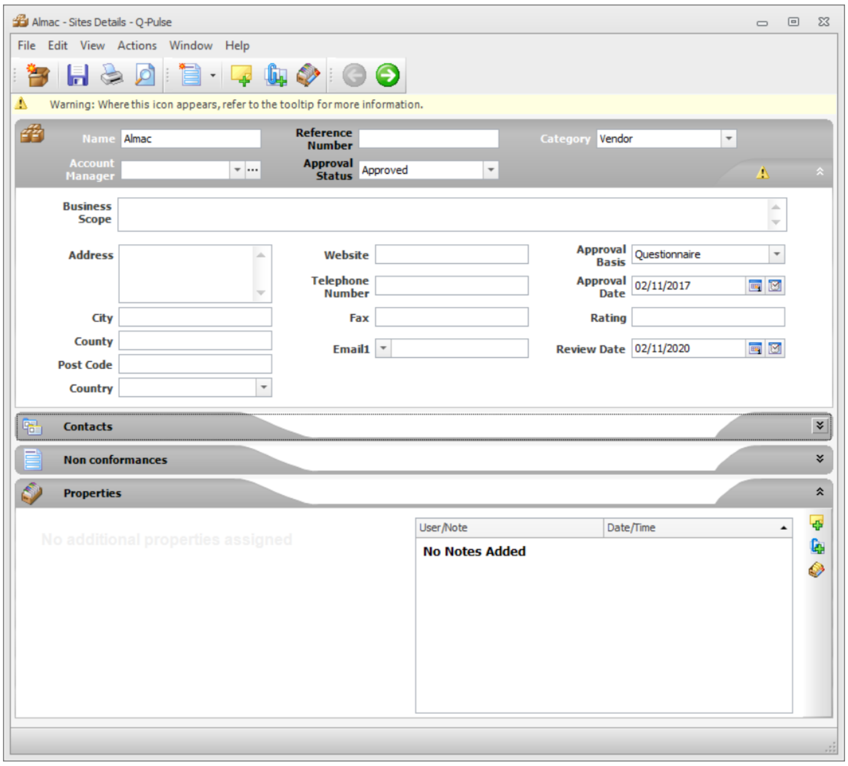
A list of Vendors can be returned in the Sites window by searching for all sites categorised as Vendors, this is achieved by selecting “Vendor” as the category and selecting “Search” on the left hand side of the window.



This will produce a list of all recorded Vendors held in Q-Pulse, each Vendor will hold their own record.



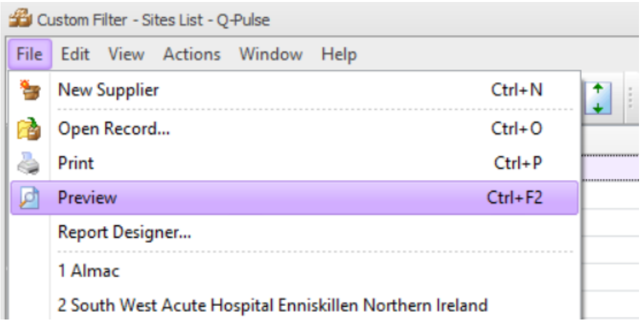
Each Vendor record will have space to record a number of details about the services they provide, contact details, review history and any non-compliances associated with them.



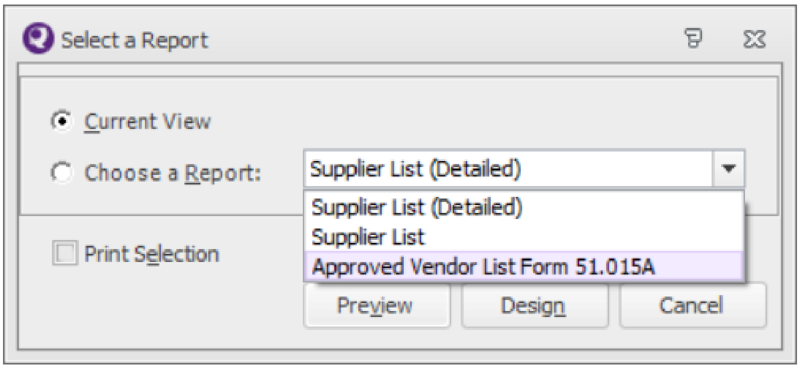
In the Properties tab there is also space to keep documents relevant to the Vendor that are deemed necessary.

1.2. Extracting Vendor List

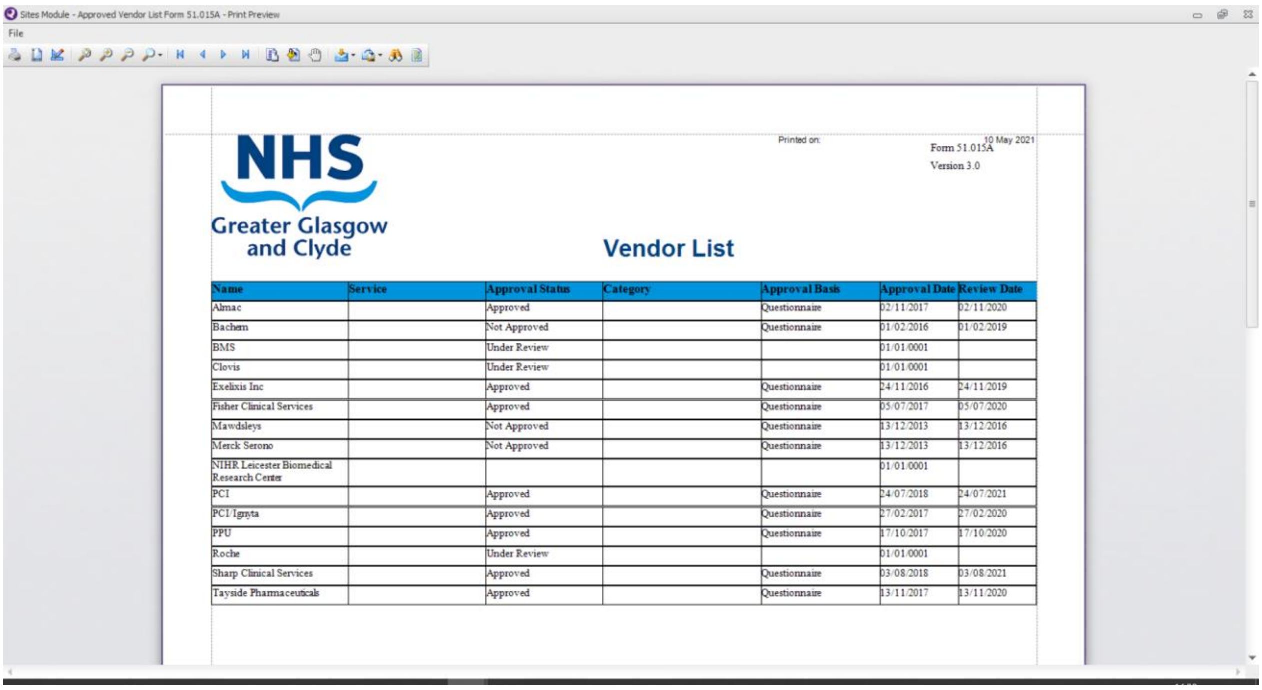
When the list of Vendor has been produced from the search function it is possible to produce a report listing the details for all recorded Vendor by selecting "File> Preview".



This will then open a new window from which you can select "Approved Vendor List Form 51.015A" from the drop down and select "Preview".

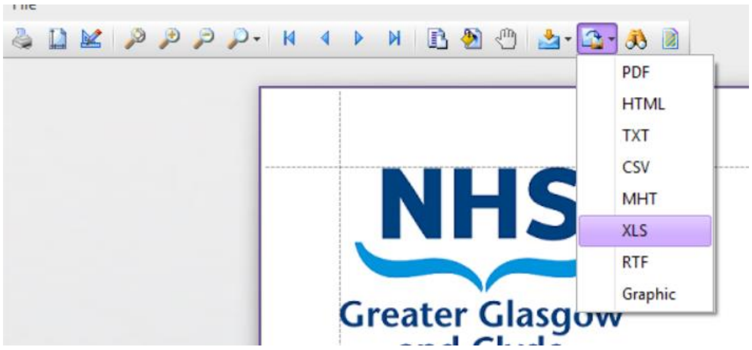


This will then open a new window with a report showing a list of all Vendors and their associated information.

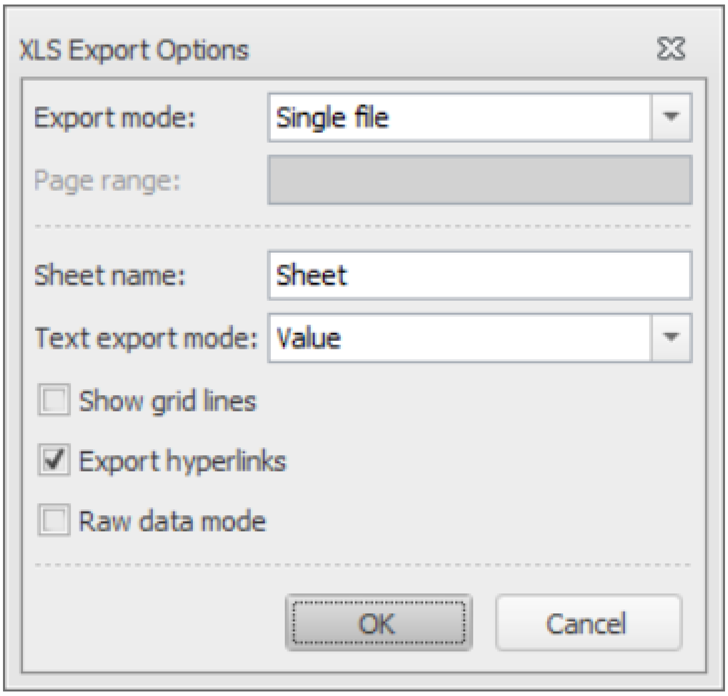


Name	Service	Approval Status	Category	Approval Basis	Approval Date	Review Date
Almac		Approved		Questionnaire	02/11/2017	02/11/2020
Bachem		Not Approved		Questionnaire	01/02/2016	01/02/2019
BMS		Under Review			01/01/0001	
Clovis		Under Review			01/01/0001	
Exelixis Inc		Approved		Questionnaire	24/11/2016	24/11/2019
Fisher Clinical Services		Approved		Questionnaire	05/07/2017	05/07/2020
Mawdsleys		Not Approved		Questionnaire	13/12/2013	13/12/2016
Merck Serono		Not Approved		Questionnaire	13/12/2013	13/12/2016
NIHR Leicester Biomedical Research Center					01/01/0001	
PCI		Approved		Questionnaire	24/07/2018	24/07/2021
PCI/Ignyta		Approved		Questionnaire	27/02/2017	27/02/2020
PPU		Approved		Questionnaire	17/10/2017	17/10/2020
Roche		Under Review			01/01/0001	
Sharp Clinical Services		Approved		Questionnaire	03/08/2018	03/08/2021
Tayside Pharmaceuticals		Approved		Questionnaire	13/11/2017	13/11/2020

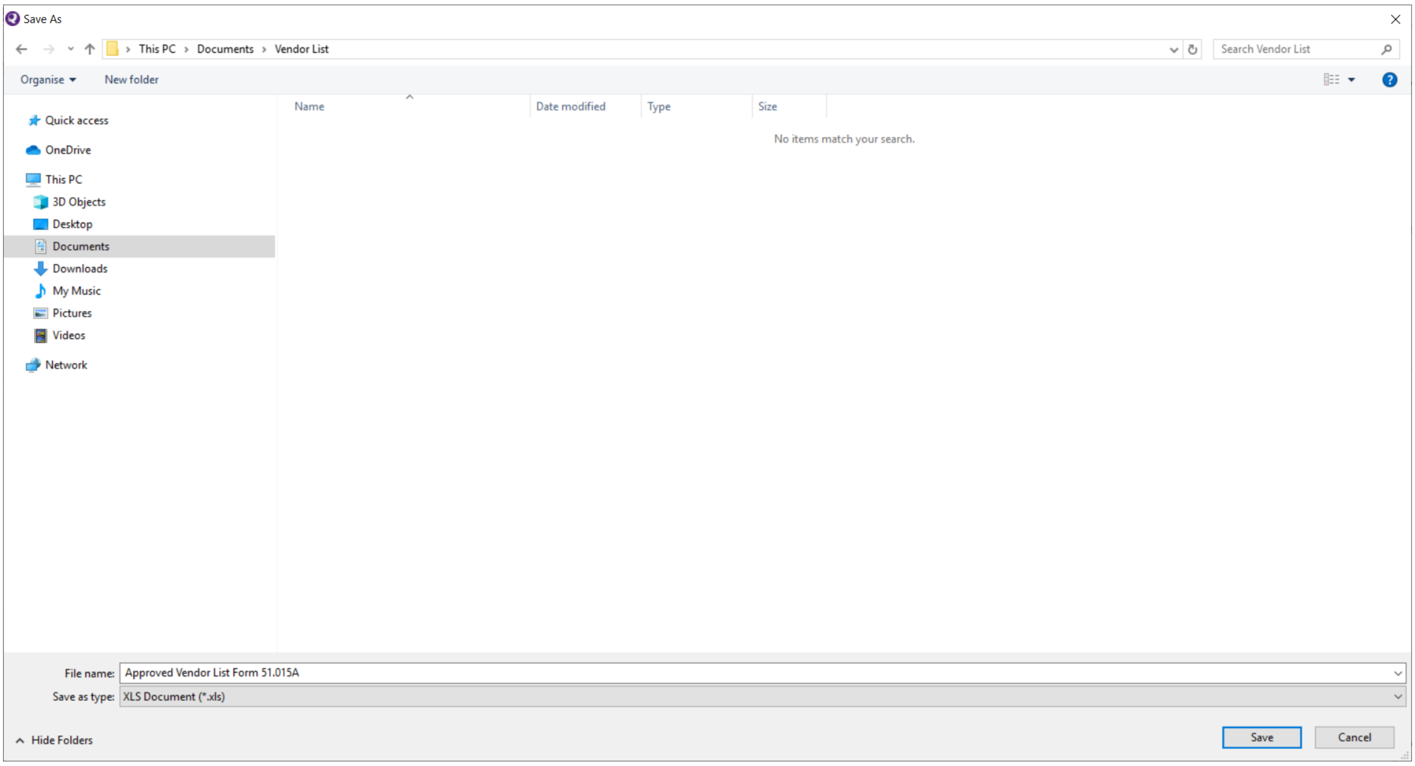
This report can then be extracted to Excel by selecting the extract button from the top of the window and select “XLS” from the drop down.



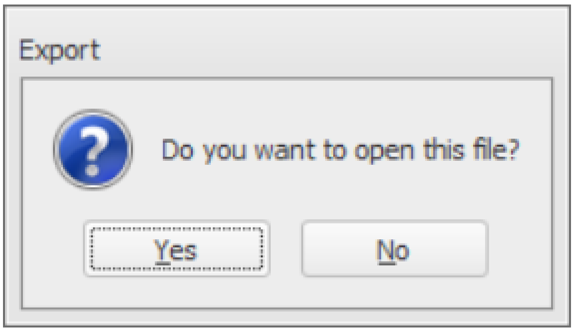
This will then open a new window asking to confirm the extract details, select “OK” without any changes.



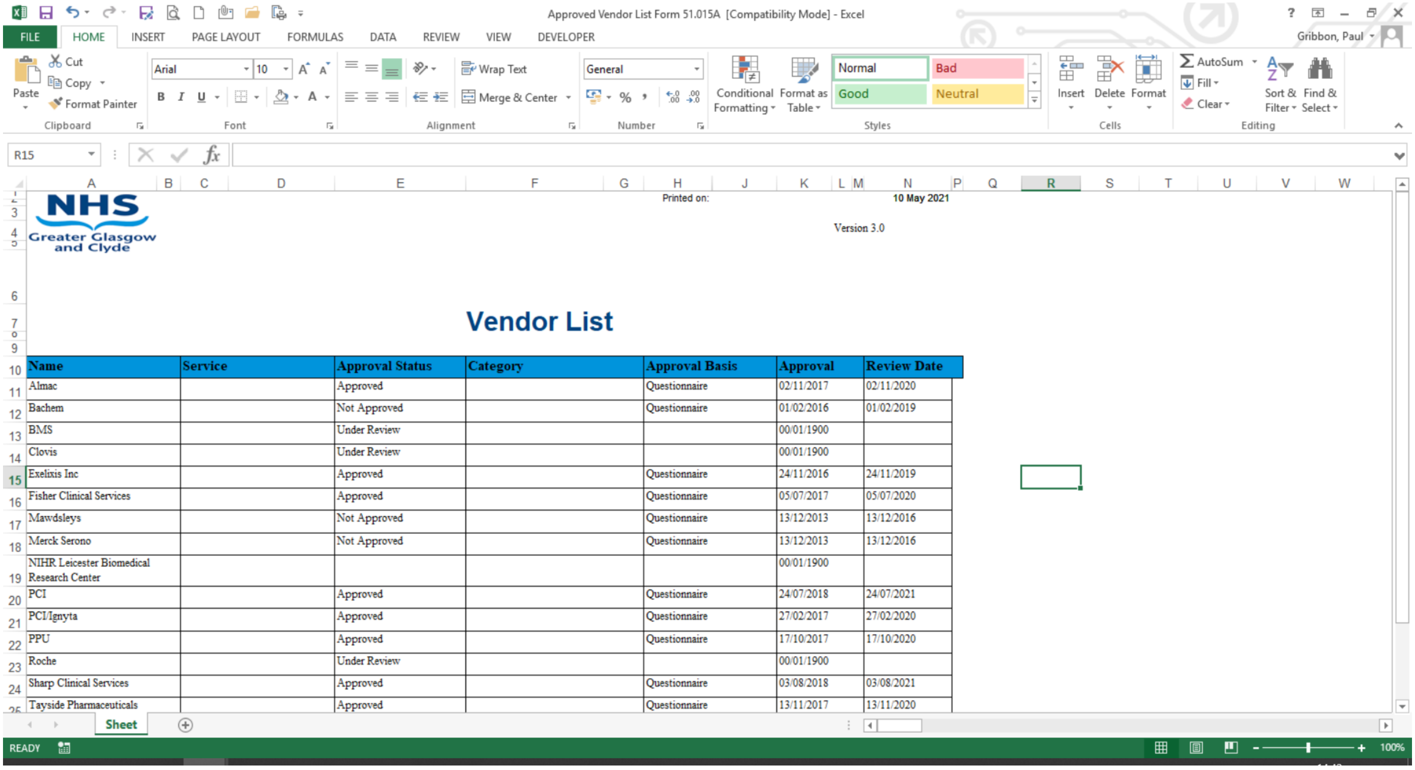
The next window will open asking you to select a location to save the extracted file, select an appropriate location and save the file.



Once you have saved the file, a new window will open asking if you wish to open the file you have just saved. If you select yes the file will open.



Following this process, you will have a copy of a file which contains the status of all Vendors held in Q-Pulse. This file can then be shared if required.


Printed on: 10 May 2021

Version 3.0

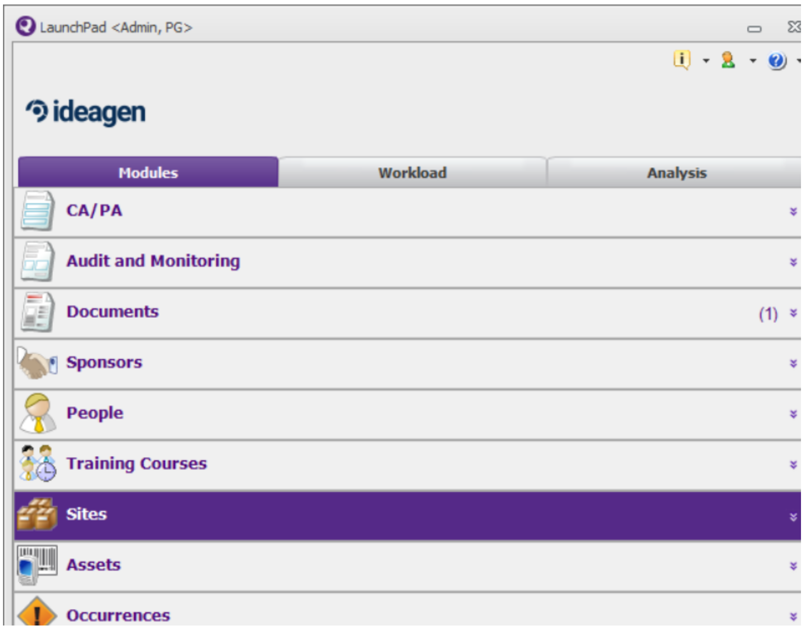
Vendor List

Name	Service	Approval Status	Category	Approval Basis	Approval	Review Date
Almac		Approved		Questionnaire	02/11/2017	02/11/2020
Bachem		Not Approved		Questionnaire	01/02/2016	01/02/2019
BMS		Under Review			00/01/1900	
Clovis		Under Review			00/01/1900	
Exelixis Inc		Approved		Questionnaire	24/11/2016	24/11/2019
Fisher Clinical Services		Approved		Questionnaire	05/07/2017	05/07/2020
Mawdsleys		Not Approved		Questionnaire	13/12/2013	13/12/2016
Merck Serono		Not Approved		Questionnaire	13/12/2013	13/12/2016
NIHR Leicester Biomedical Research Center					00/01/1900	
PCI		Approved		Questionnaire	24/07/2018	24/07/2021
PCI/Ignyta		Approved		Questionnaire	27/02/2017	27/02/2020
PPU		Approved		Questionnaire	17/10/2017	17/10/2020
Roche		Under Review			00/01/1900	
Sharp Clinical Services		Approved		Questionnaire	03/08/2018	03/08/2021
Tayside Pharmaceuticals		Approved		Questionnaire	13/11/2017	13/11/2020

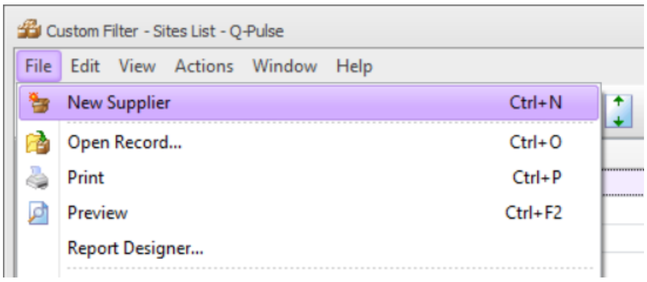
Alternatively, an individual Vendor record can be reviewed to determine their status if required.

1.3. Adding a new Vendor

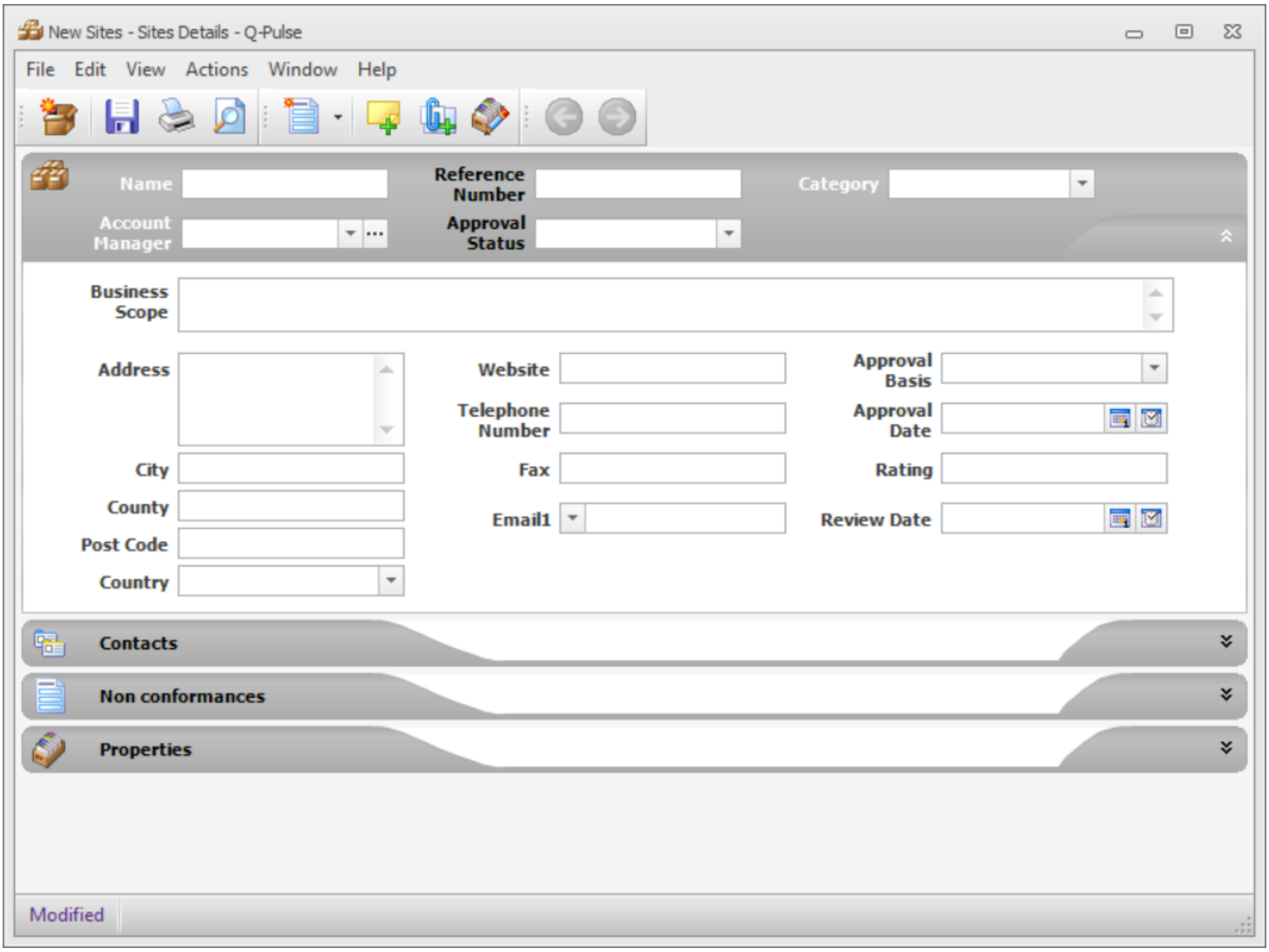
In the event a new Vendor is identified and they must be added to Q-Pulse, this can be achieved by opening the “Sites” Module. This activity is completed by the appropriate member of the Vendor Assessment team with the correct level of Q-Pulse privileges.



This will open a new window, from here you can select “File> New Supplier” or click the “New Supplier” button.



This will open a new Record to enter the details of the Vendor.

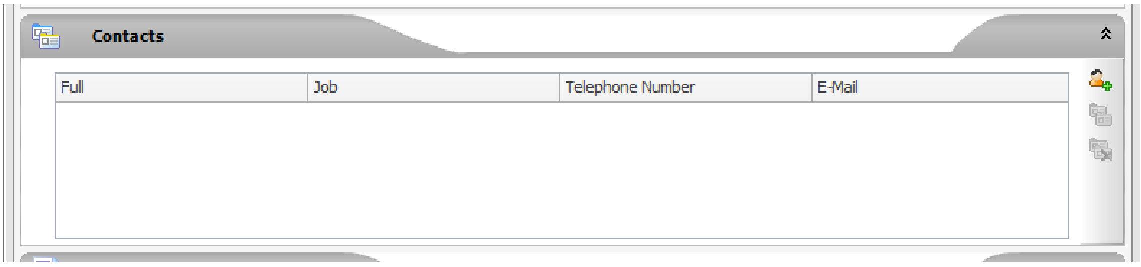


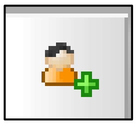
In this window you must then enter the relevant details for the Vendor.

Field
Name
Category (Select Vendor)
Approval Status (Select Under Review for new Vendors)
Business Scope (Enter services provided
Address
City
Postcode
Country
Contacts (expand and add known contacts)

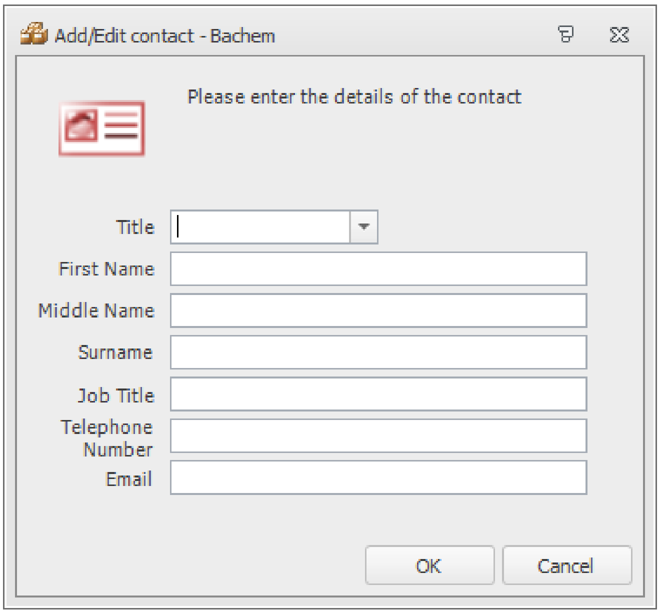
When the relevant details have been added, save the record and the new Vendor will be added.

In the same window, contacts can be added for a specific Vendor. This will be a record of individuals who are contactable in relation to activity conducted with this particular Vendor. To achieve this, expand the contacts tab in the Vendor record and from here you can add new contacts by selecting the “Add Contact” button.

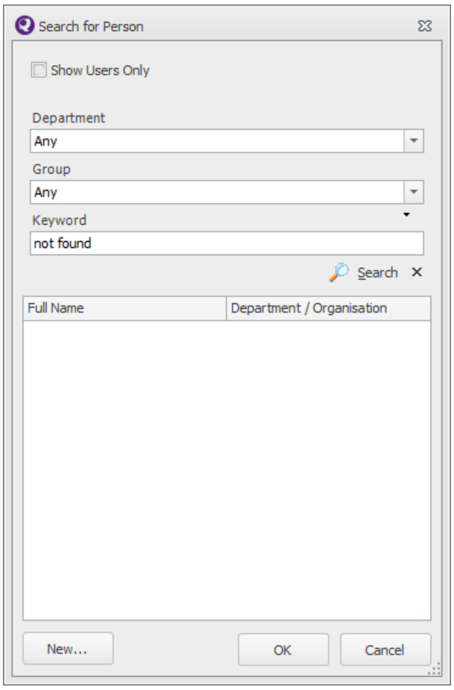




This will then open a new form to be completed with the relevant contact details, when saved this will allow you to select this individual as a contact during Vendor Assessments.

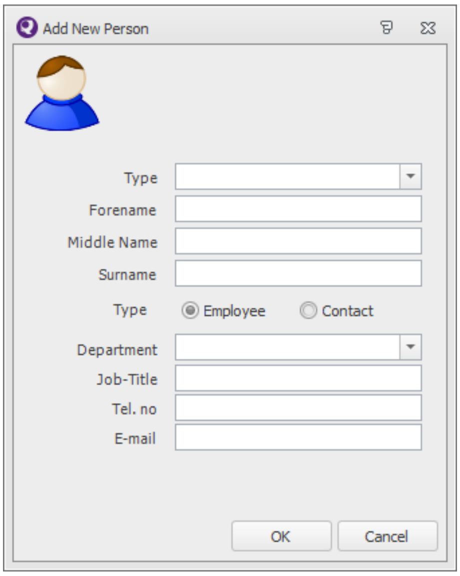


If during the set-up of a Vendor Assessment, detailed below in section 2, you are not able to find the name of the contact you are also able to add at this time.



In this example, the contact “not found” has returned no search results. You can at this time add a new contact by select the “New” button in the bottom left.

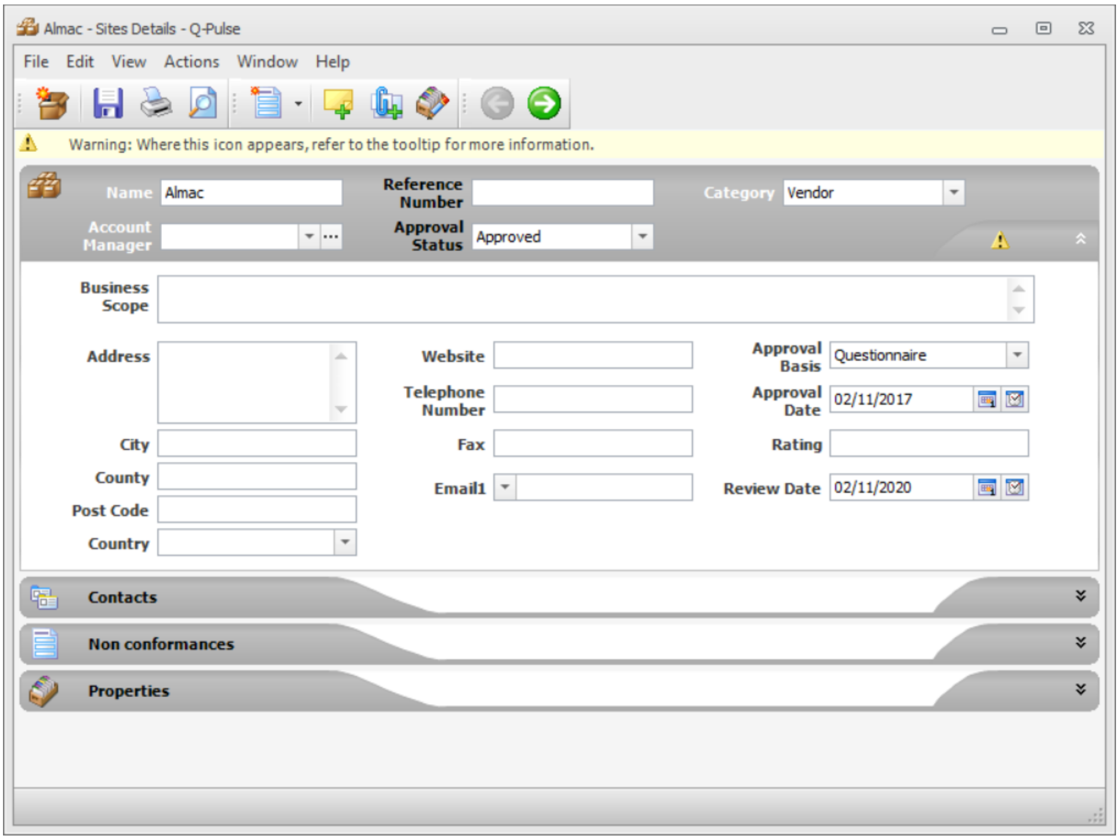
This will open a new window as shown below, as before fill in the relevant details for the contact and in the middle section change the selection from “Employee” to “Contact”. This will change the field from “Department” to “Organisation”, click on the 3 dots beside this to open a search window and search for the name of the Vendor this individual is a contact for. Make the appropriate selection and when all the details are completed for the individual save the record. This will now mean the contact has been saved and is a selectable option as a contact for this Vendor.



1.4. Updating Vendor following Assessment

Following an assessment, a Vendor record can be updated by locating the relevant record in the sites module and search for the specific vendor name or return a list of all Vendor as detail in section 1.1 and selecting the name from the list.

By double clicking on the Vendor name in the list their record will open.

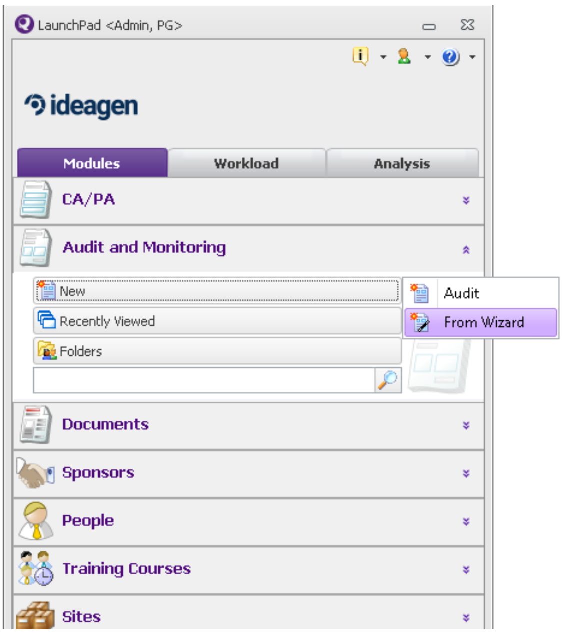


When the record is open you are then able to update their approval status, approval basis, approval date and renewal date.

The details held for a Vendor can be updated in the event new information is made available at any time, for example their business scope, address or contact details.

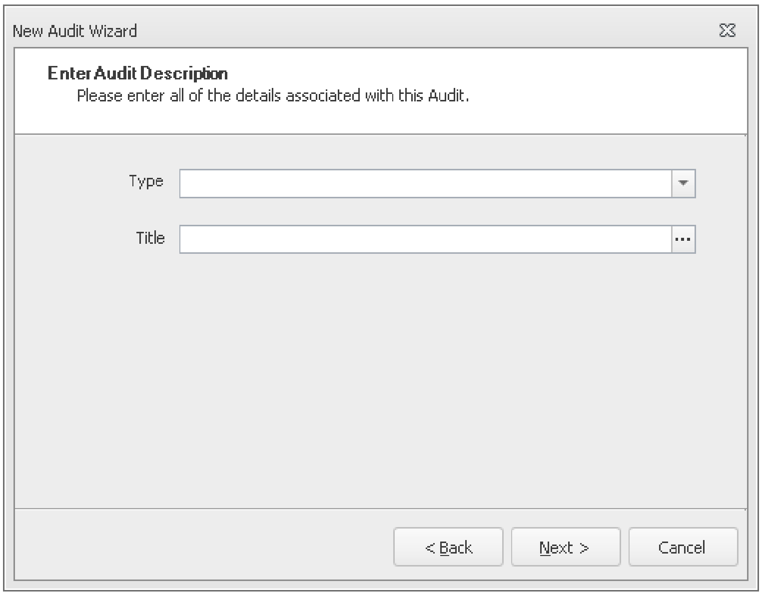
2. Creating a Vendor Assessment Record

A vendor assessment record can be created in Q-Pulse to track the process of conducting assessments of potential vendors, to do this, expand the Audit and Monitoring tab from the front launch pad and then select “New > From Wizard”.

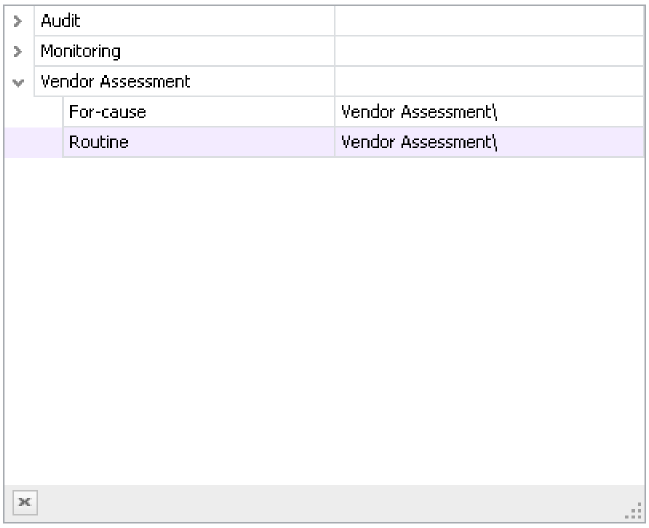


This will then launch a wizard which will guide you through the process of creating a Vendor Assessment record, the first window to appear is a confirmation of the action to be taken, select Next to continue.

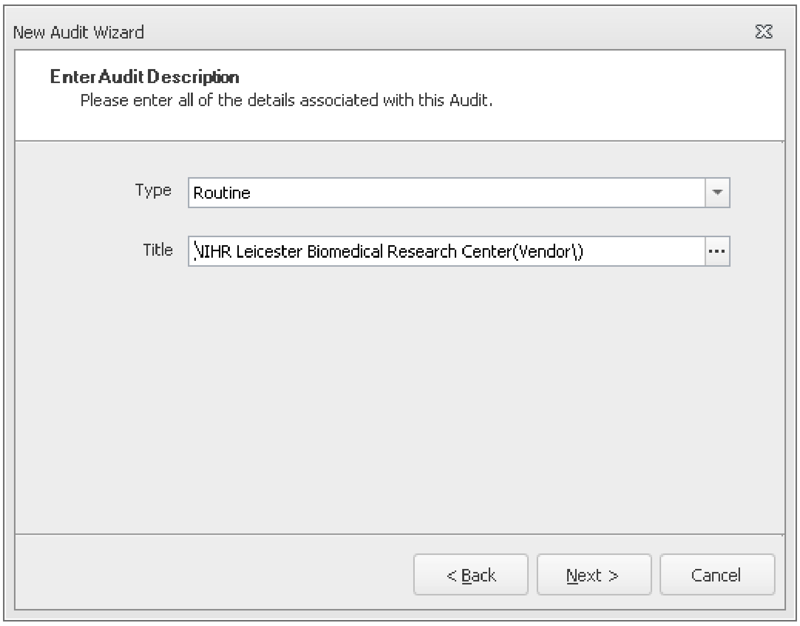
The next page of the wizard will ask you to select the audit type and a title.



Under the field "Type", you can select the drop down list and expand "Vendor Assessment" and select either Routine or For Cause. Routine is used in the event a new Vendor is up for review or a vendor is to be reviewed again within its set review cycle. For Cause is used in the event we have been notified of significant changes with the Vendor or Non-Compliances have been raised.

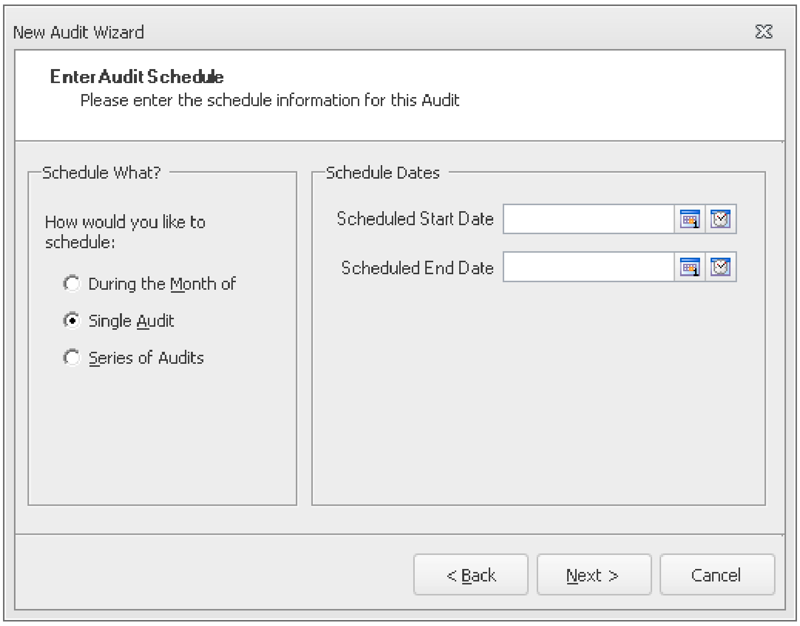


In the title field, you can search a number of different categories to select a title. For Vendor Assessments the title should be the name of the Vendor which will appear under the “Supplier” category. In the event the Vendor is not available from the list, refer back to section 1.3 which details how to add a Vendor to the list.



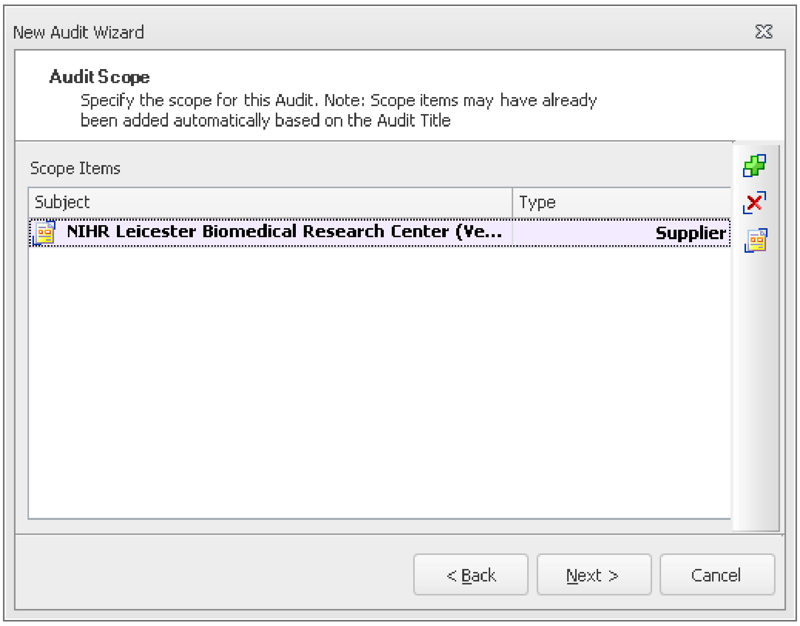
Once this has been completed, select the Next button to continue.

The next page of the wizard is when you select the Audit schedule, for Vendor Assessments you should select “Single Audit”, in the Scheduled Start Date field you should enter the date the assessment is first sent to the vendor, the Scheduled End Date is when it is expected that the Vendor returns the assessment. By default this should be 20 working days as per the standard timeline, however this can be adjusted to meet particular circumstances.



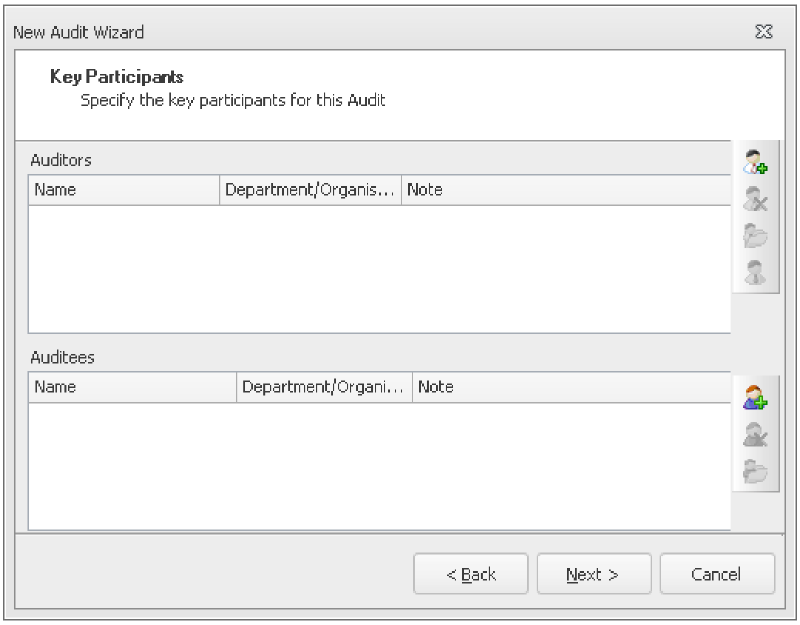
Once the appropriate dates have been entered, select Next to continue.

The next window in the wizard is to set the scope of the audit, this allows you to add as many scope items as is required to define the audit activities.

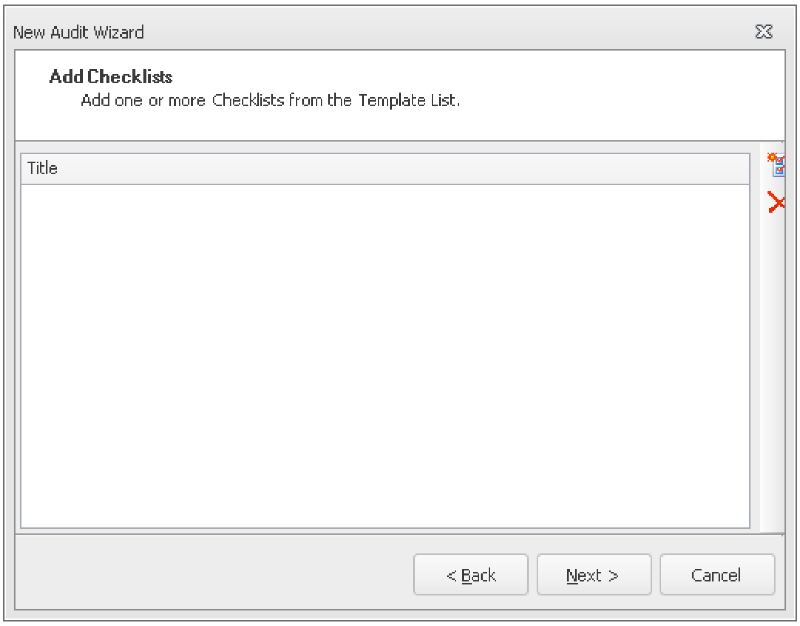


Once this has been completed, select Next to continue.

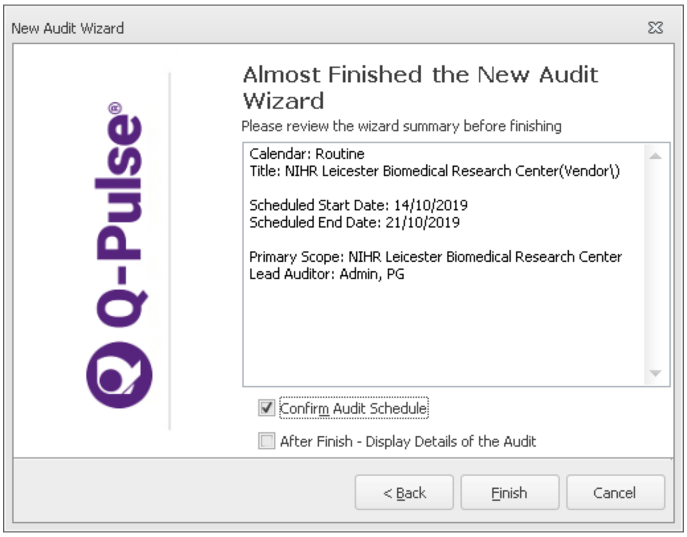
This will open the next page in the wizard, in this page you can select the Auditor and the Auditee. The Auditor will be the person who is responsible for carrying out this activity with the Vendor, the Auditee will be the point of contact at the vendor and can be multiple names. If the names are not present, again refer to section 1.3 which details how to add names to the Vendors record. Once this has been completed, select Next to continue.

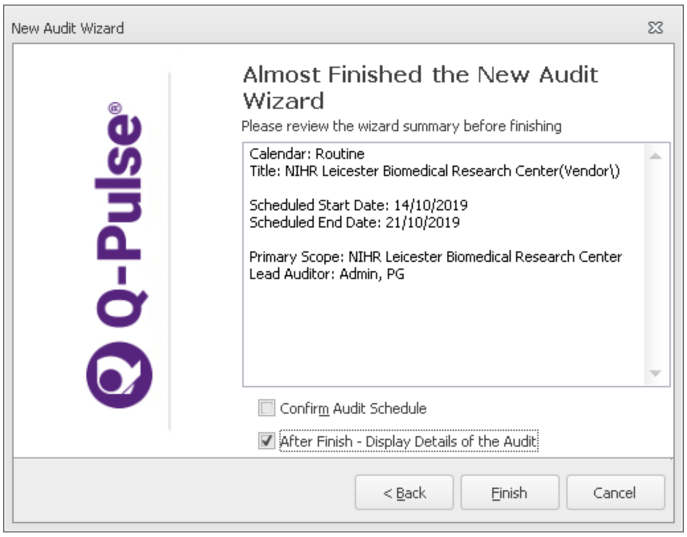


The next page in the wizard will be to add a checklist, this is not applicable for a Vendor Assessment so select Next to continue.



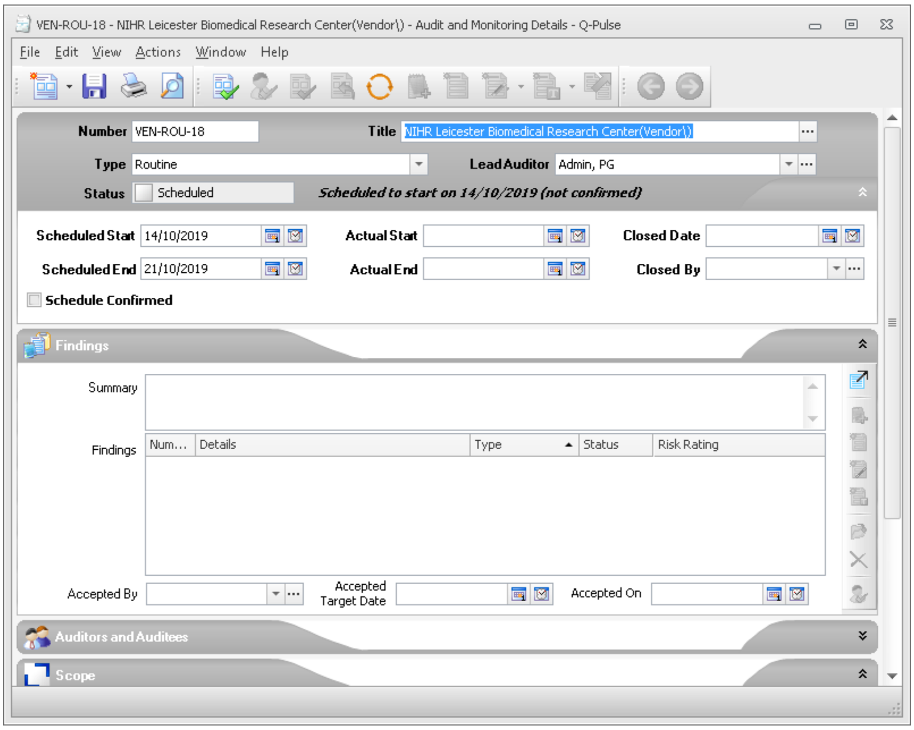
This will then bring you to the final page of the wizard, this will confirm all the details which have been entered, by default the tick boxes will be select to confirm the Audit Schedule and not display the Audit Details. Reverse the order of the tick boxes.





When you untick to confirm the schedule and tick to display the audit details, select Finish to create the Vendor Assessment record.

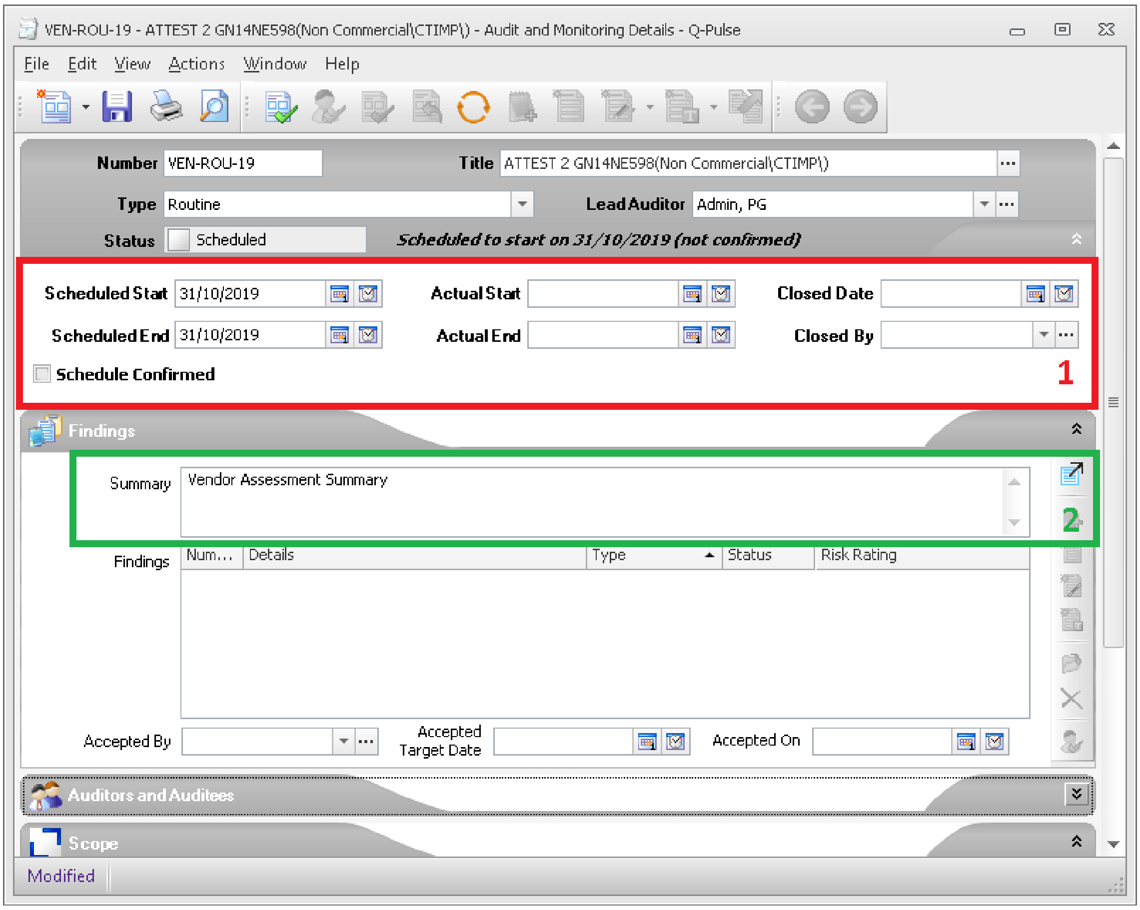
This will then open the new record for the Vendor Assessment, update the details in the Summary box to give an explanation of the activities involved in the Vendor Assessment so that those not involved with the activity can understand what is to take place.



3. Update Vendor Assessment Record

After a Vendor Assessment record has been created, certain details within this record must be updated to document the activities which have taken place which may be required at several stages through the process of conducting a Vendor Assessment.

To do this, open the audit record for the Vendor Assessment in question.

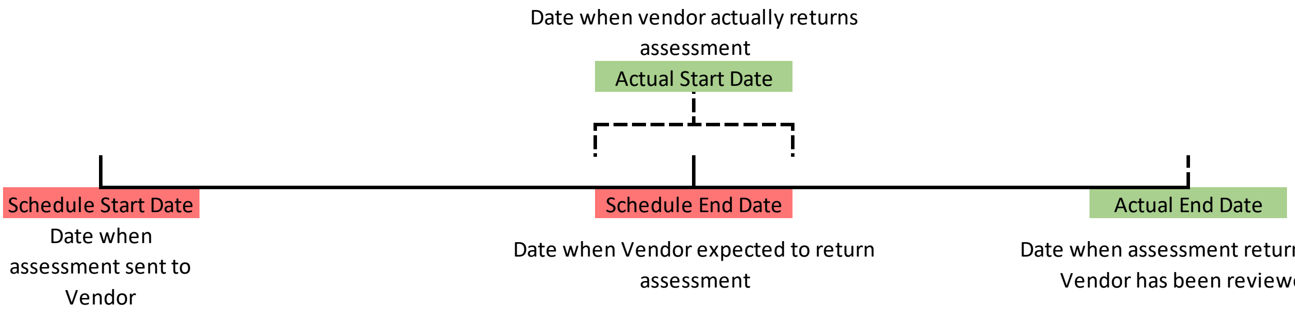


Section 1 as shown above in red is where the details are retained for the Schedule of the Vendor Assessment. The first fields which should be populated are the Scheduled Start and Scheduled End Date, the Schedule Start is the date at which the assessment was sent to the Vendor. The Schedule End is the target date at which the vendor should reply.

The next batch of dates is the Actual Start and Actual End dates, this is where, as the Auditor, you record the date at which the Vendor sends a response to the Assessment in the "Actual Start" date field. Following this, the assessment should then be reviewed and the date at which this is completed should be entered into the "Actual End" date field. If, during this review, issues have been identified with the content then a Non-Conformance can be raised for each to track the responses from the Vendor, this is discussed in section 4. At the point all follow up actions, if applicable, have been completed then the record can then be marked as closed and the name of the individual who closed the record entered.

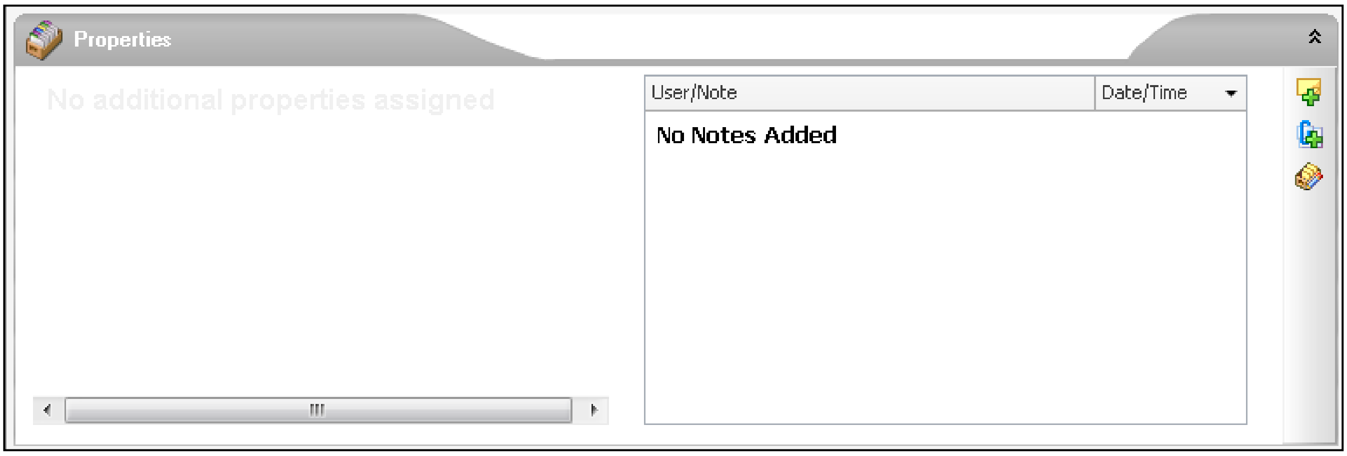
Section 2, highlighted in green, is the Summary box where the details of the Vendor Assessment can be entered. This box is used to tell the story of the activity, from planning to completion. This box should contain the intended activities before the Vendor Assessment takes place and then updated during and after the assessment to detail the activities.

The use of these date fields has been summarised in the graph below.



Vendor Assessment Timeline

The final section of the audit record which can be updated falls under the Properties tab, here it is possible to attach files to the audit record. This can be used to record any evidence, or documentation relevant to the assessment and build up the picture of the activities which have taken place, this should include the returned assessment form.



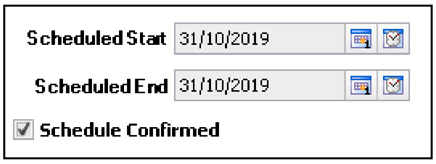
When the completed Vendor Assessment form has been returned, a copy must be added to the Vendor Assessment record. If there are delays in response from a Vendor, as well as updating the summary box, a note should be added to the properties section to record that a reminder/escalation has been sent.

3.1. Amending the Vendor Assessment Record

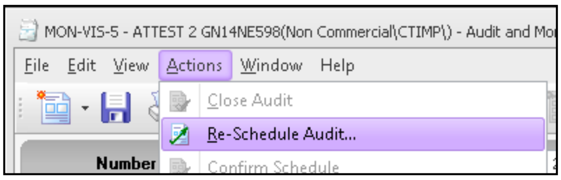
It is possible to amend the details within an Audit Record

If you have been assigned the appropriate access rights within Q-Pulse, the schedule of the Audit can be adjusted if circumstances change. If the schedule of an audit has not been confirmed, this is a simple action to overtype the dates in the Scheduled Start and Scheduled End. You are able to tell if the schedule has been confirmed by the tick box below these dates, once confirmed it is not possible to unconfirm the schedule.

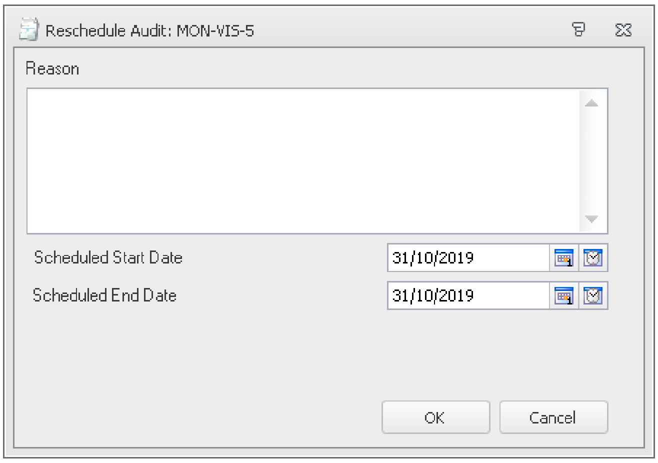
Once a Schedule has been confirmed, the dates will then become greyed out and cannot be overtyped.



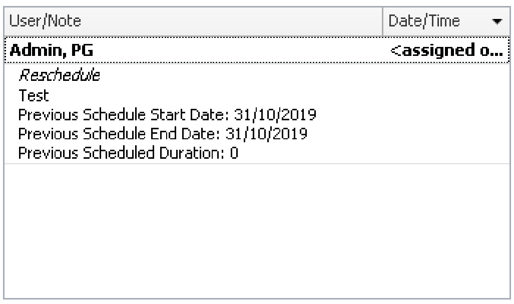
In this circumstance, you can only change these dates by selecting "Actions > Re-Schedule Audit"



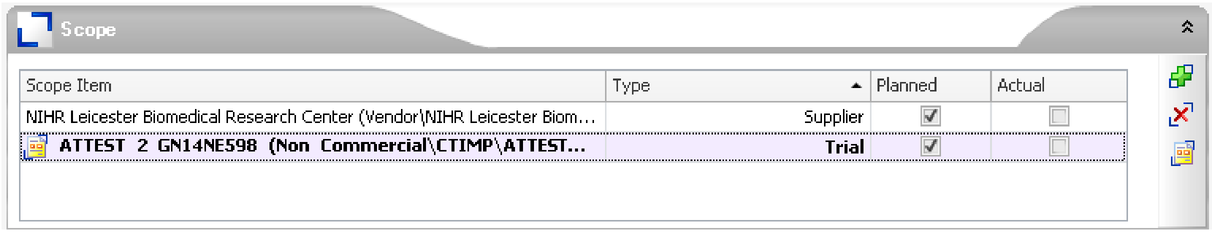
This action will then open a box where the dates can be changed and a reason for this change given.



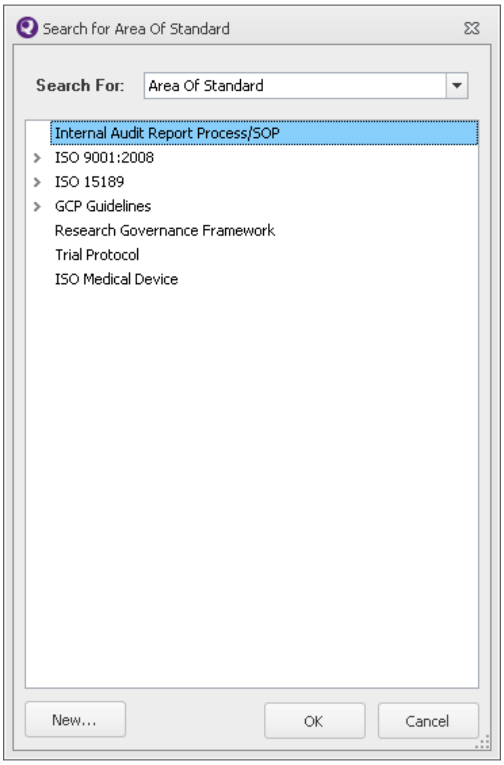
This will then add a note to the audit record to detail the change.



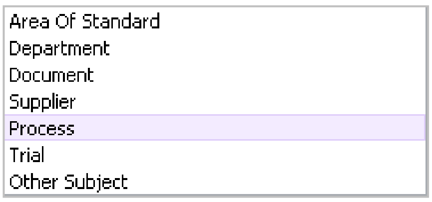
The scope items of an audit can be adjusted if the scope of an Audit Record or Monitoring visit changes, this can be done from the audit record by using the green plus and red x to add and remove items respectively.



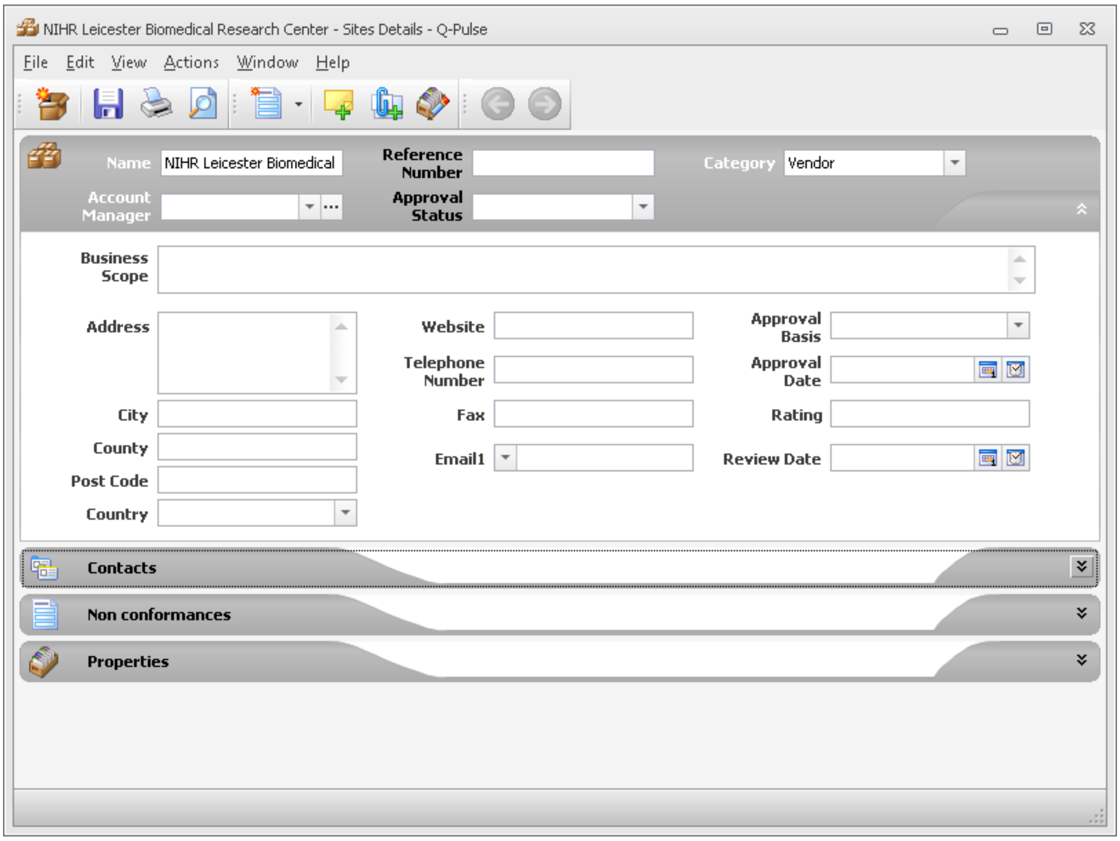
When you press the green plus to add an item, the following window will appear, from here you can search for a range of defining attributes for the visit. This list is controlled and updated by the appropriate Q-Pulse administrator, if the need arises to add further criteria to this list they must be contacted with details of what to add.



The drop down list at the top allows you to select the top level themes under which you can then select the defining criteria.

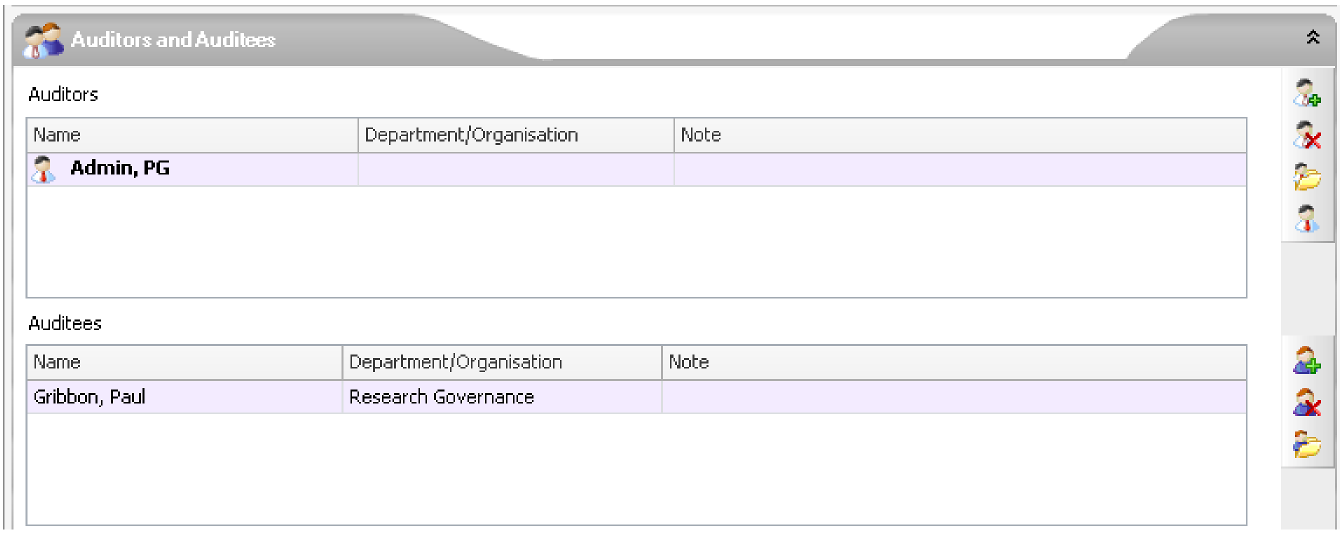


Part of the scope within a vendor assessment record should be the Vendor in question, by double clicking on the vendor's name in the scope items you are able to open a record for this Vendor.



Here, several details can be added to the Vendor's record. Contact details for the vendor can be added, files can be attached to show their approval status, etc.

The final tab of interest which can be edited from the Audit record, this is where the Auditors and Auditees are recorded. Under each section, names can be added and removed as required using the buttons with the person with either the green cross or red X to add or remove as required. In the event of the auditors, a lead auditor must be identified, this is done by selecting the button of the person with a tie while highlighting the name.

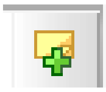


3.2. Sending Reminders/Escalation to Vendor

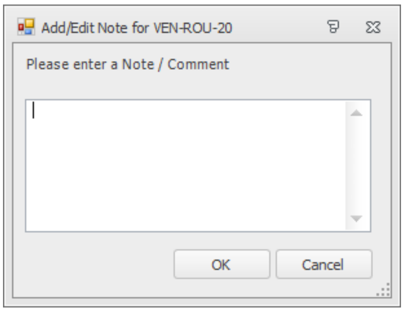
In the event a reminder or escalation needs to be sent to a Vendor as they have not met the original deadline, this must be recorded within the Vendor assessment record. Q-Pulse or any toolsets used to manage the Q-Pulse data can be used to send reminders to the staff assigned to complete a vendor assessment or directly to vendors if deemed appropriate. From this reminder, the assigned member of the Vendor Assessment team will then record this action in the appropriate Vendor Assessment record. To achieve this, in the individual record for the Vendor Assessment you can scroll down to the properties tab and complete 2 actions.

Add a note of reminder/escalation

In the properties tab, on the right hand side there are multiple options, select the "Add Note" button to add a note to the record that the Vendor has been contacted.



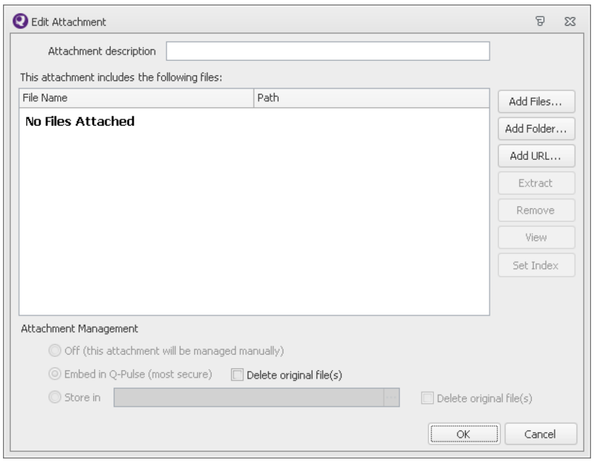
This will open a new window in which you can add a note that states that the Vendor has been contacted for the purposes of a reminder/escalation.



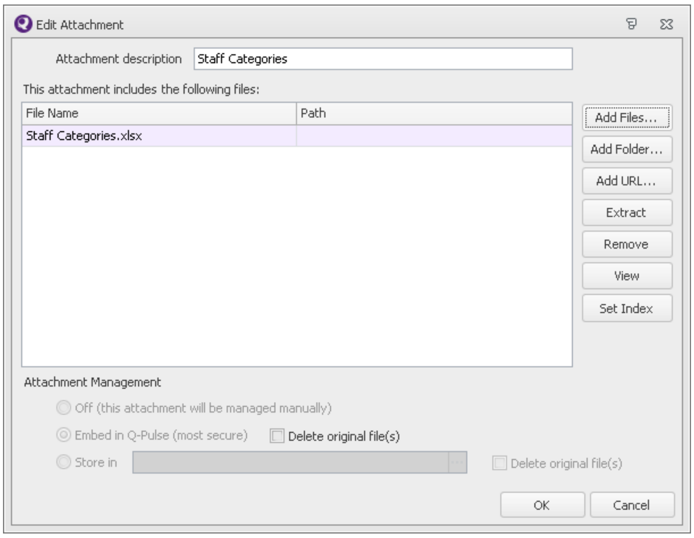
Attach reminder/escalation E-Mail

You can attach a record of the E-Mail sent to the Vendor to the Vendor Assessment record as evidence of the correspondence, you can find the button of interest for attaching a document is the paperclip with the green plus symbol.

This will open a new window where documents can be attached, from this window select the "Add Files" button.



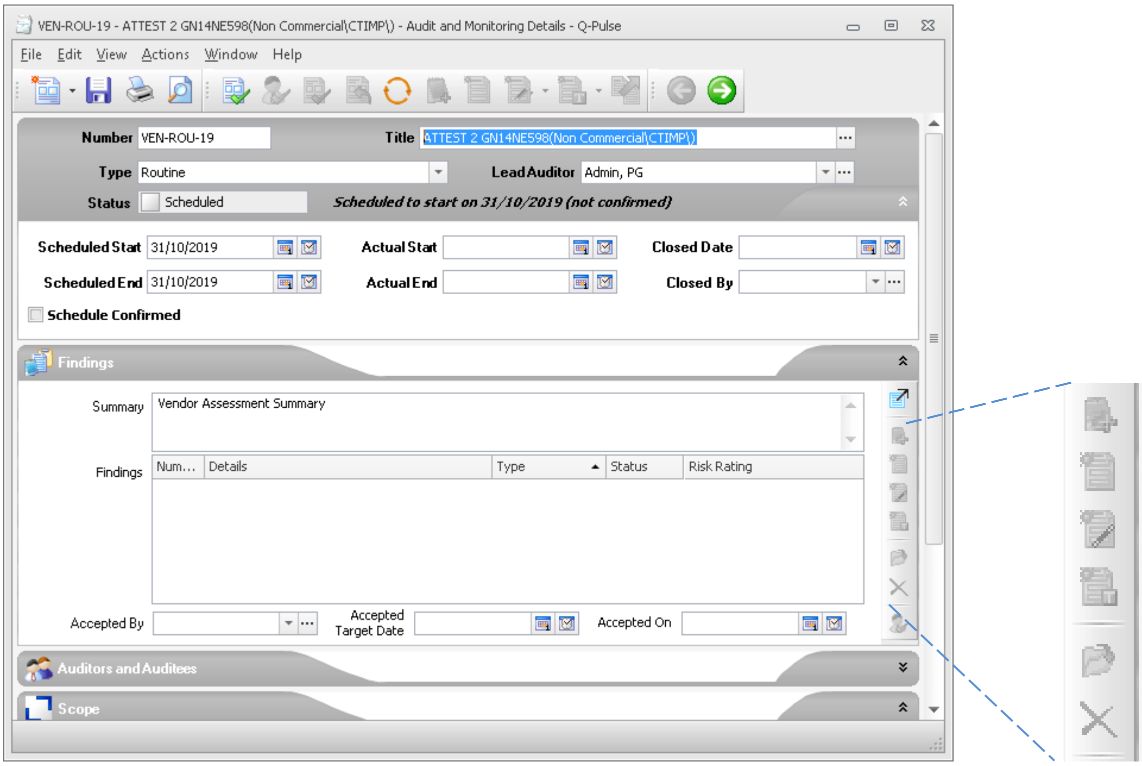
This will then open a standard document selection window, navigate to the location of the document of interest and select the file of interest and confirm, this will return the document to the window. The Attachment Description will change to the title of the top document which can then be edited as required, multiple documents can be uploaded at one time or in separate instances. If multiple files are uploaded this will act like a folder which can then be opened and document selected individually, or in the instance of one file it will be a direct link to that one file.



Once this has been completed and the files added, the attachment will appear in the properties section of the Vendor Assessment record.

4. Raise Vendor Follow Up

When raising a follow up action from a Vendor Assessment, this is done from the Audit Record in Q-Pulse. Open the record for the Vendor Assessment which the finding relates to as shown below.

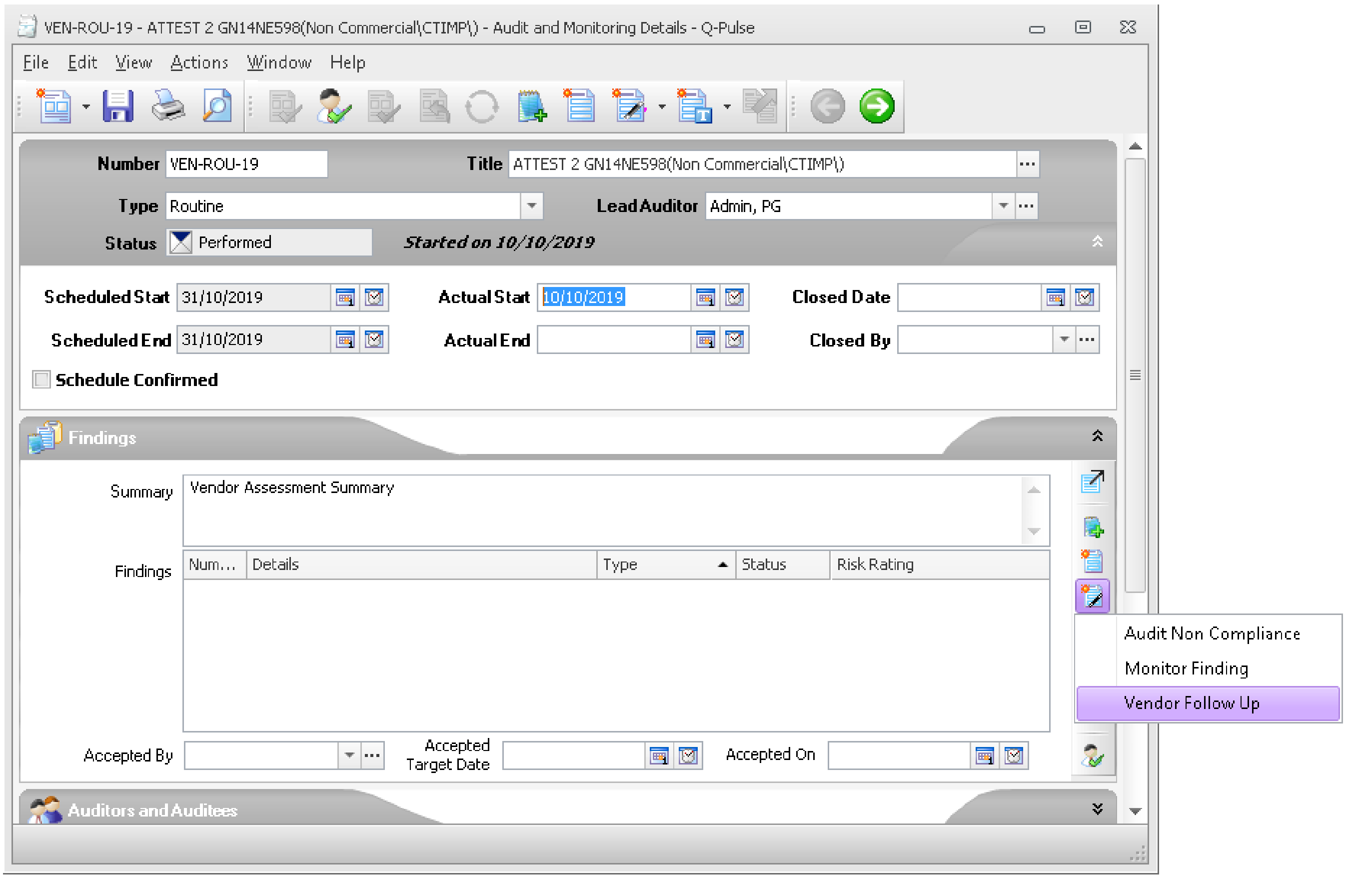


As above, the buttons to raise a Follow Up are greyed out when the Vendor Assessment record has not been marked as started. To enable the ability to raise a Follow Up you must enter an “Actual Start” date and save the record. When this is done, the buttons will light up and the functionality will be enabled.

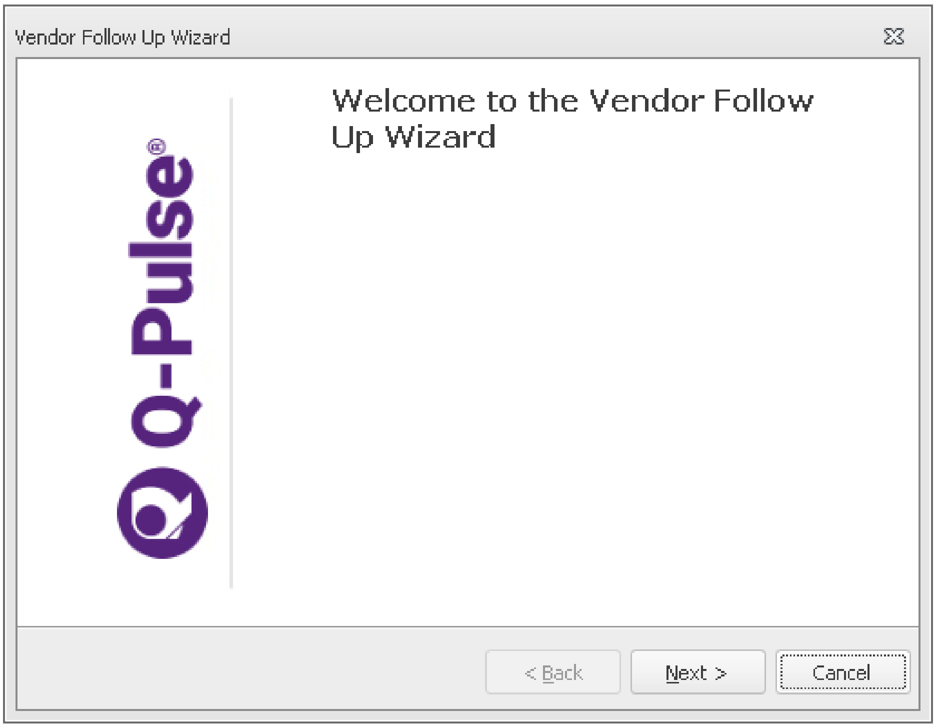
Alternatively, if the Vendor Assessment record is marked as Closed by entering details in then Closed Date and Closed By fields, this functionality will once again be greyed out and not be accessible.

To raise a Follow Up, select the “Raise Non-Conformance from Wizard” option on the right hand side in the findings section.

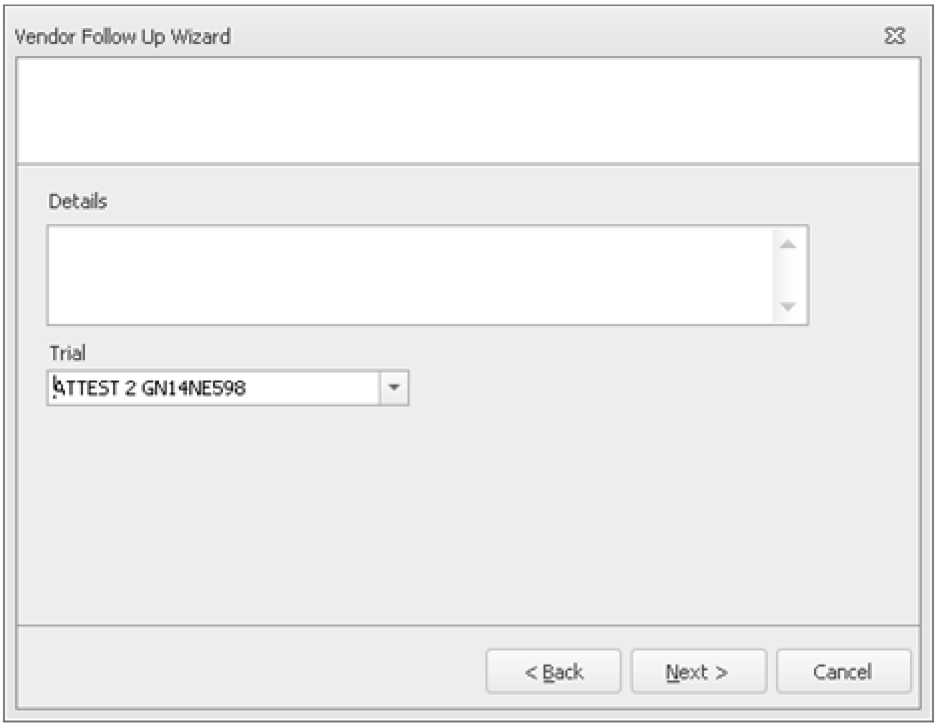
This will then present you with a list of available wizards to select, there are different options available, in this instance, select the “Vendor Follow Up” wizard.



This will then open a wizard which guides you through the process of creating a Non-compliance. The first page of the wizard will be a confirmation of the action which is to be taken, if you wish to continue then press Next.



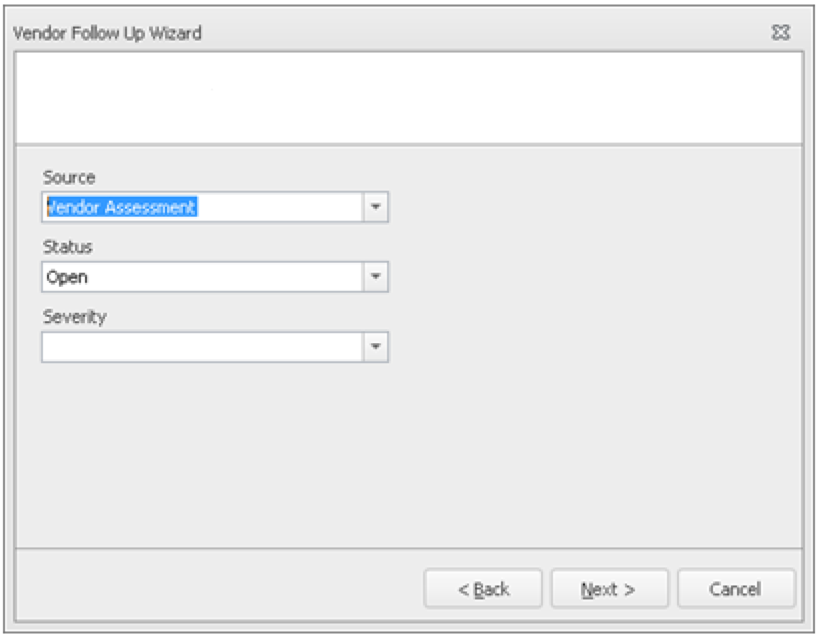
The first page of the wizard has 2 fields, the first is a free text field in which you can enter details relating to the issue to be follow up. Use this to explain what it is that has been found and make reference to any documentation or supporting information to a sufficient level that anyone who is not directly involved will be able to understand what has happened. This is an explanation of the issue and can be reviewed by others at a later date so should not be in any form of short hand or make too much use of acronyms.



The second field is to assign a Trial, this should be prepopulated as the Trial should be recorded in the Vendor Assessment record.

Once both fields have been populated, select "Next" on the wizard to move to the next screen.

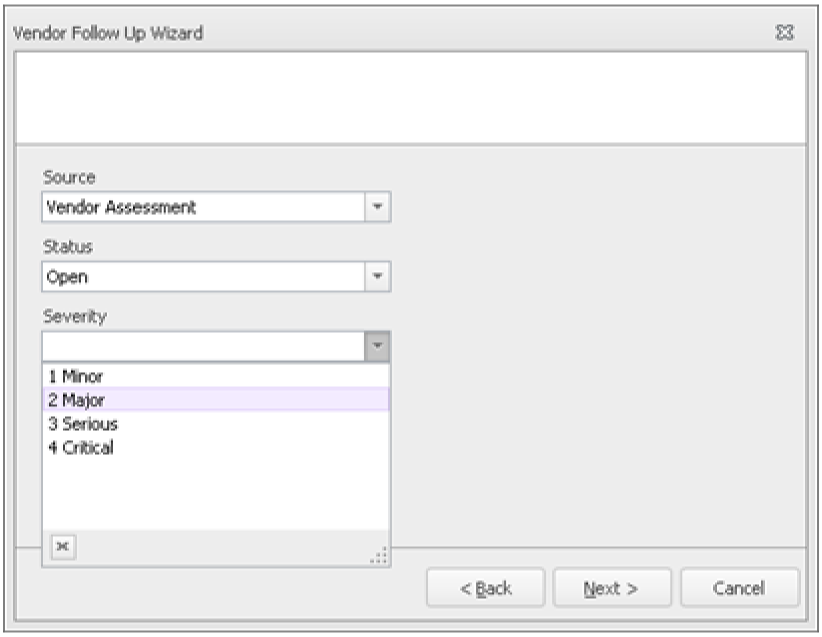
The next window in the wizard will then have 3 fields to be completed.



The first field for source will be prepopulated to "Vendor Assessment".

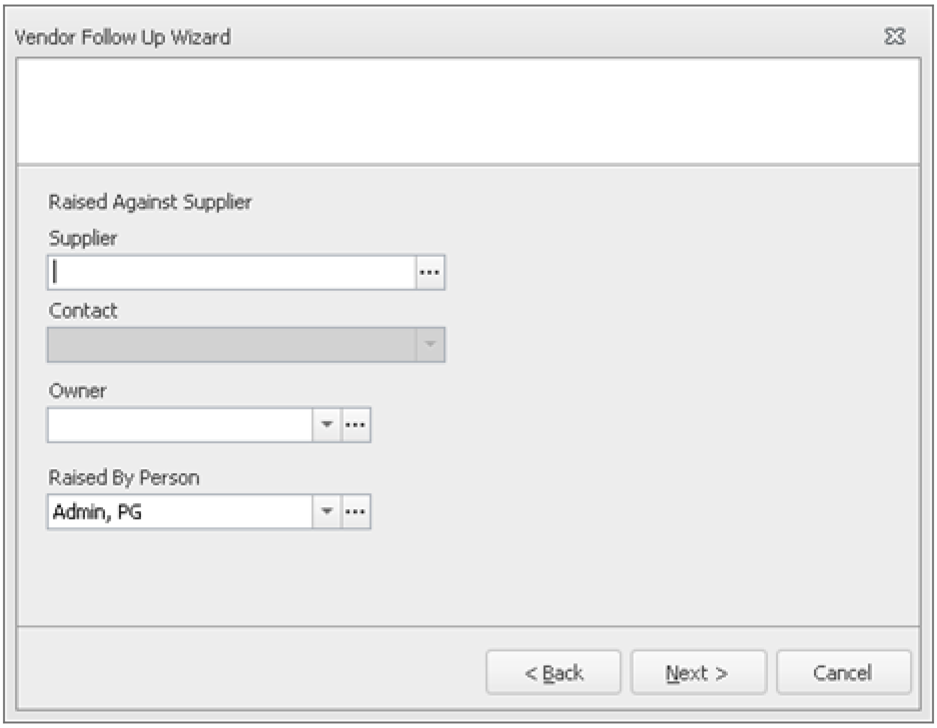
The status field of the wizard will default to Open, as the CAPA will be open with actions required when first raised.

The 3rd field is to class the severity of the finding, from the set range of 1 to 4 which are categorised in SOP 51.008.

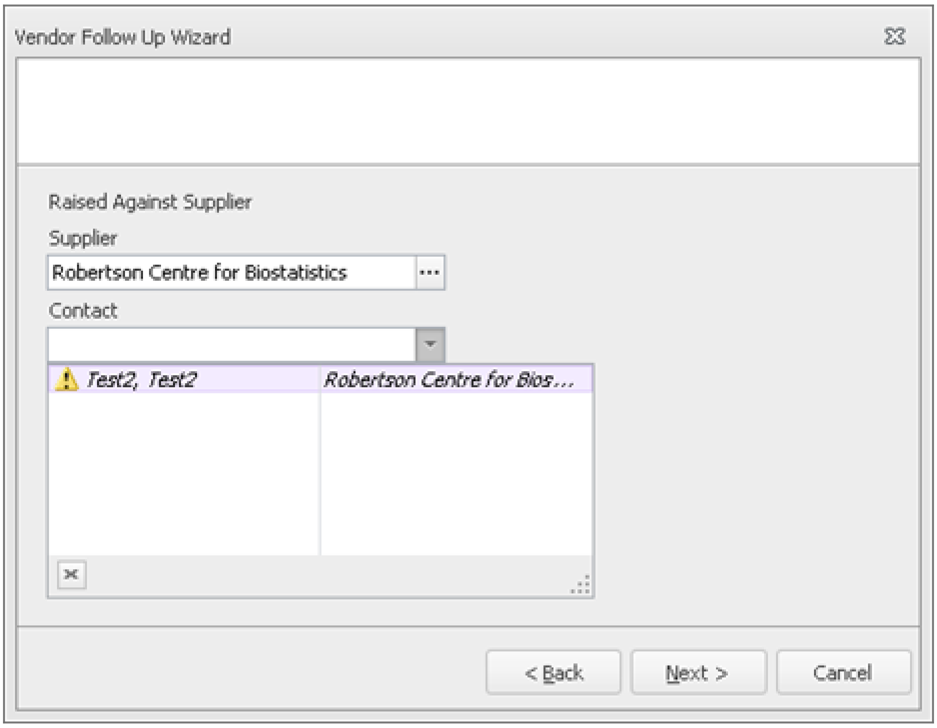


Once these fields have been completed, select Next to continue.

The next page of the wizard will have 4 fields which require details, the first which has the title “Supplier” relates to the Vendor against which the finding is being raised. To select the appropriate Vendor, click the 3 buttons to the side and search for the vendor within the window that opens.

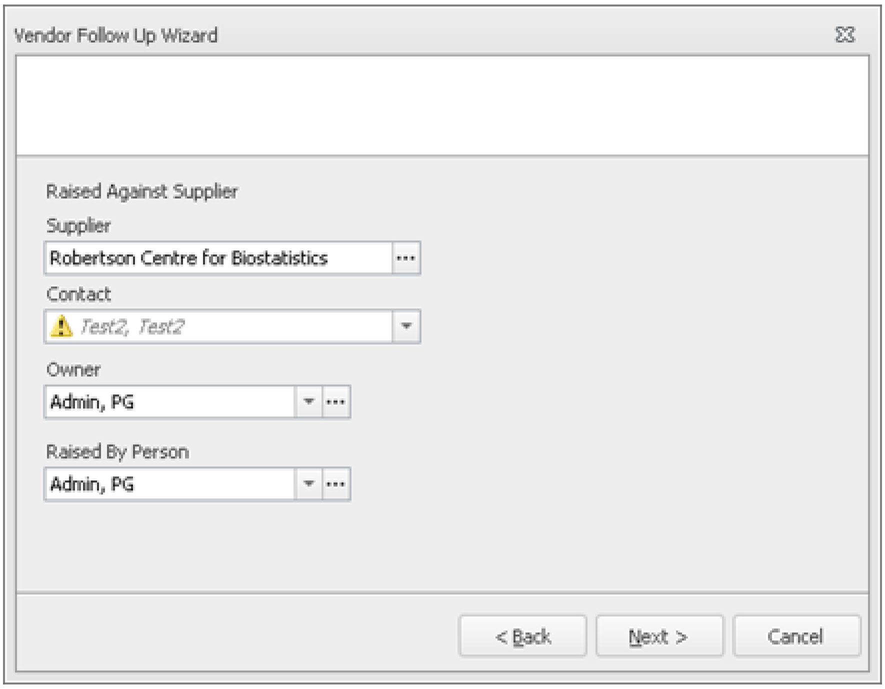


When a vendor has been selected, you must then select a point of contact for this vendor. This allows for a clear path of who should be contacted in relation to this if required at a later date.



Finally, the Follow Up will require an Owner. This is the person who will be Accountable for the work to be carried out as a result. They will not necessarily be the one who does the work but are seen as the Owner of the issue, this could be the person named as the Auditee.

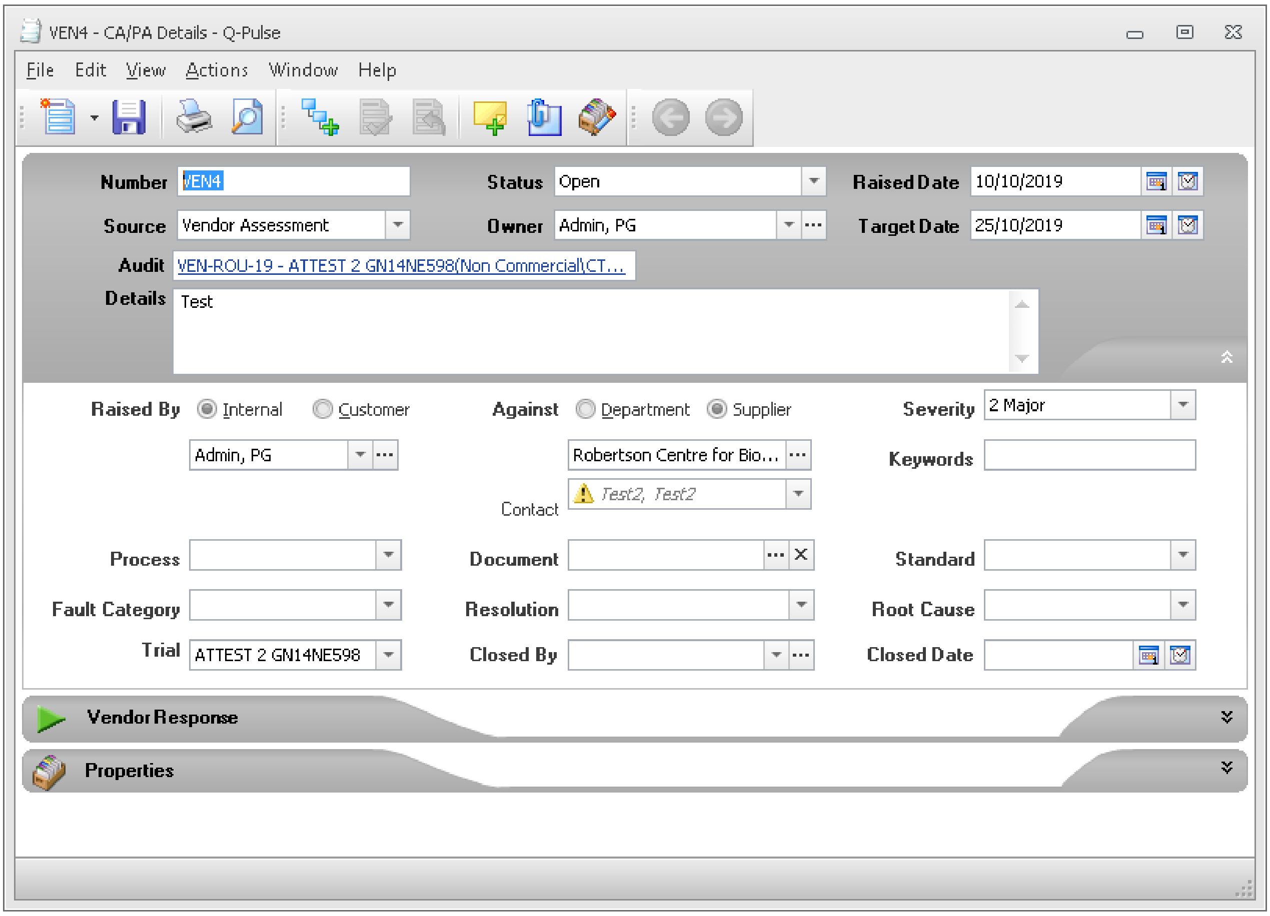
The raised by field again will be automatically completed and will be the name of the lead auditor from the audit record, this can be changed at this stage if required.



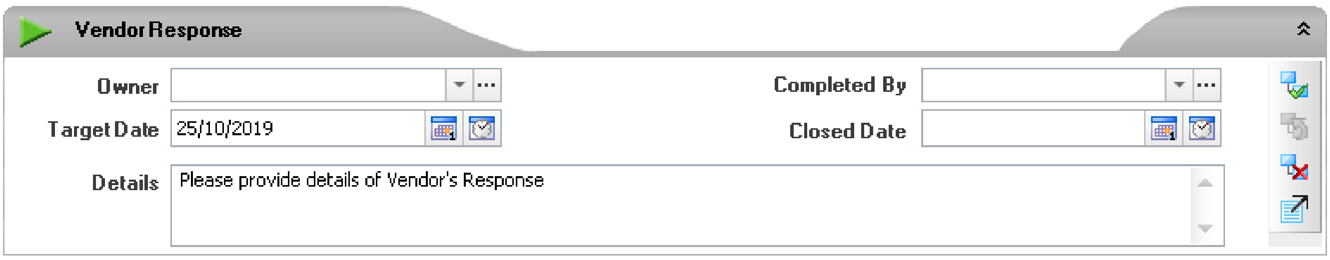
Once this is complete, click Next to continue to the Final page of the Wizard.

At this stage, the wizard will confirm that a finding is about to be raised, you can select the box to open the CAPA record which will then be raised after you click Finish.

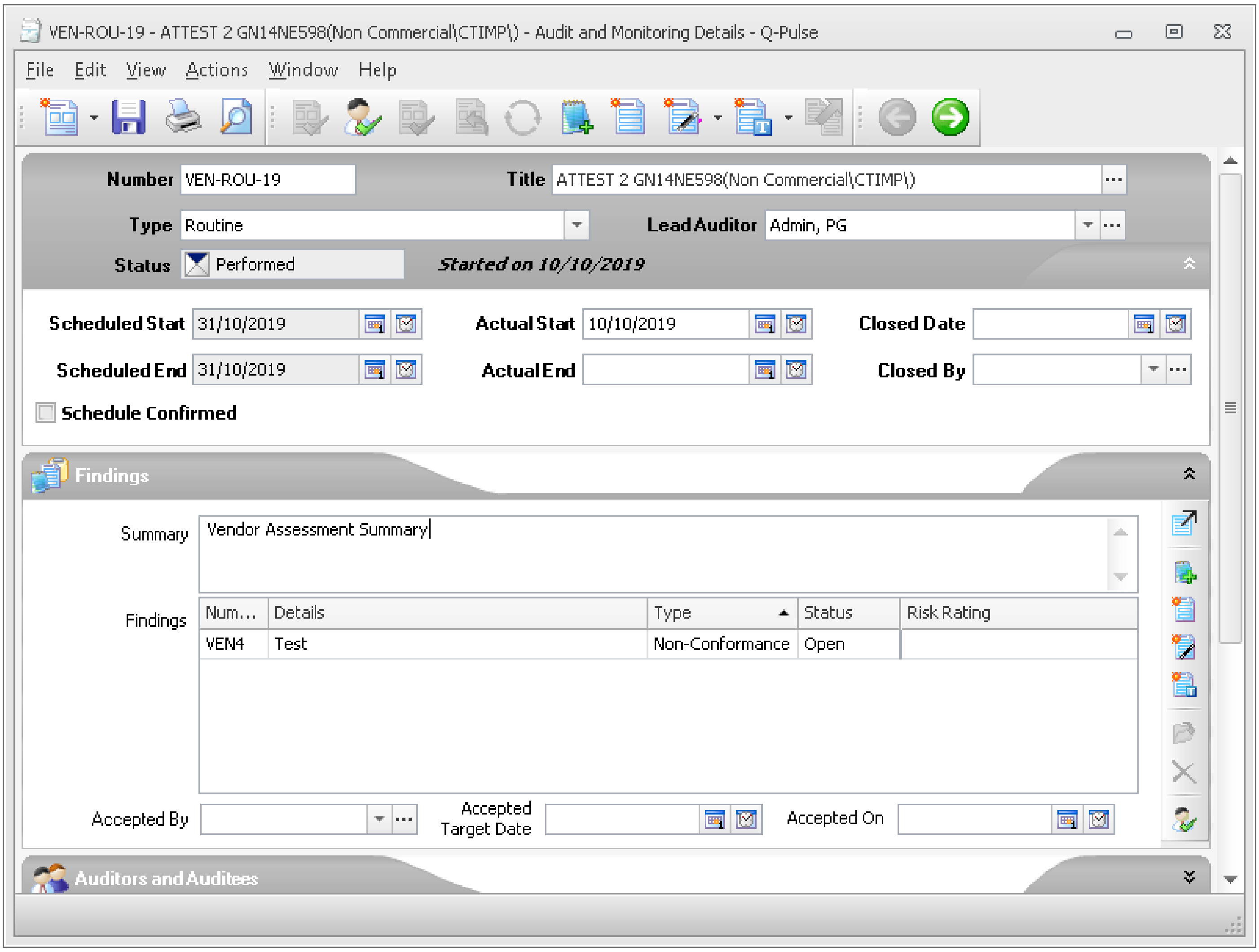
Once the Non-compliance has been raised and the record is opened, you can see all the details entered in the wizard will now be displayed. This can be edited if required.



Once the Finding is raised, the stages will not have an assigned name. Open the record immediately after raising and assign an individual who is responsible for completing this action.

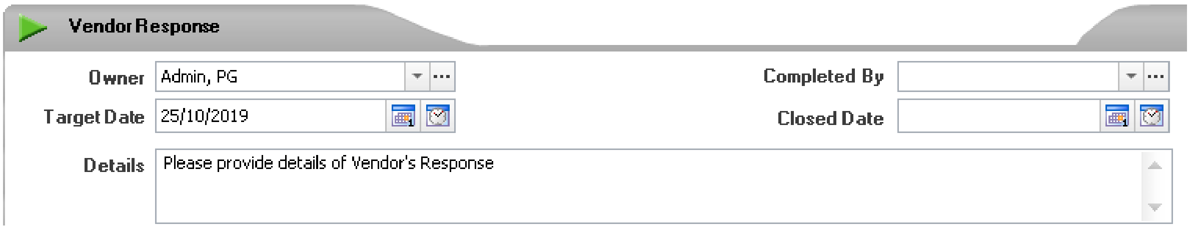


Once this has been completed, when you return to the audit record you will see that the finding has now been referenced in the "Findings" section. You can use this to see an overview of the status of all findings and double click on each to open them.



4.1. Managing a Vendor Follow up Action

A Vendor Follow Up is a CAPA which has been raised based off a Vendor Assessment, this creates a unique format of CAPA with its own structure and identifiable numbering sequence with the prefix “VEN”. All Vendor Assessment findings will only have one stage to be completed, “Vendor Response”. This stage will be assigned against the individual carrying out the Vendor Assessment and is intended to capture the response provided by the Vendor to the clarification or question related to the Vendor Assessment they have submitted.



Vendor Response Stage

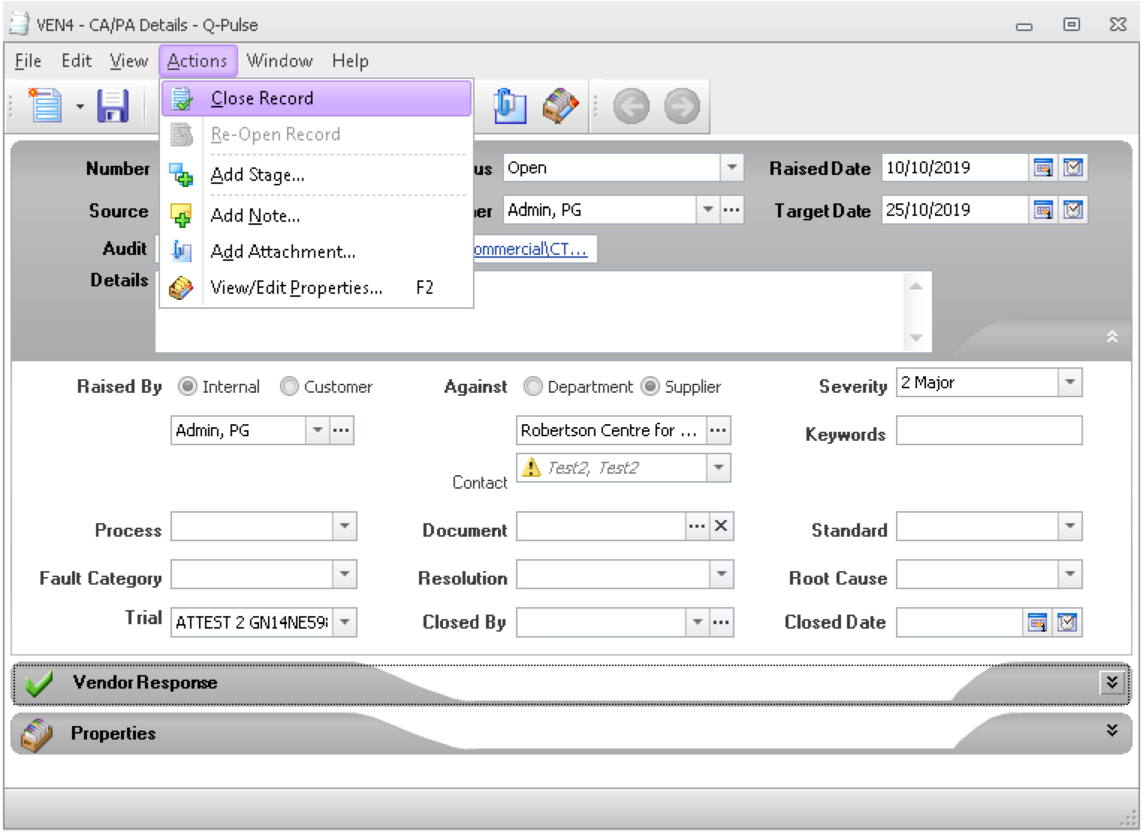
The intention of this stage is to capture the correspondence with the Vendor in relation to the follow up question or clarification. This can be the summary of a series of back and forth communications or an individual response, this can be evidenced by attaching a copy of any E-Mails or Documents they have sent to explain.

Attaching Documents

The same approach for attaching documents can be achieved for CAPAs as previously discussed in relation to the Vendor Assessment record.

Closing a CAPA

When then stage has been completed within the Vendor Follow Up, the CAPA can then be closed. This will not be automatically closed, to achieve this the “Closed Date” and “Closed By” fields must be completed. This can be done by typing the details in to the fields directly, or by selecting “Actions > Close Record”, this will automatically enter the current date and the username of the account you are logged in with.



Once this has been completed, save the record for the changes to then take effect and the record will be closed. This will then form part of the history of interactions with this vendor, if further assessments are required then a new Vendor Assessment record will be created to capture that instance.

Document Details:

Prepared by: Paul Gribbon Signed Dated

Approved by: Caroline Watson Signed Dated

Document History

Version	Date	Description
Version 1.0	24/11/2021	First Release