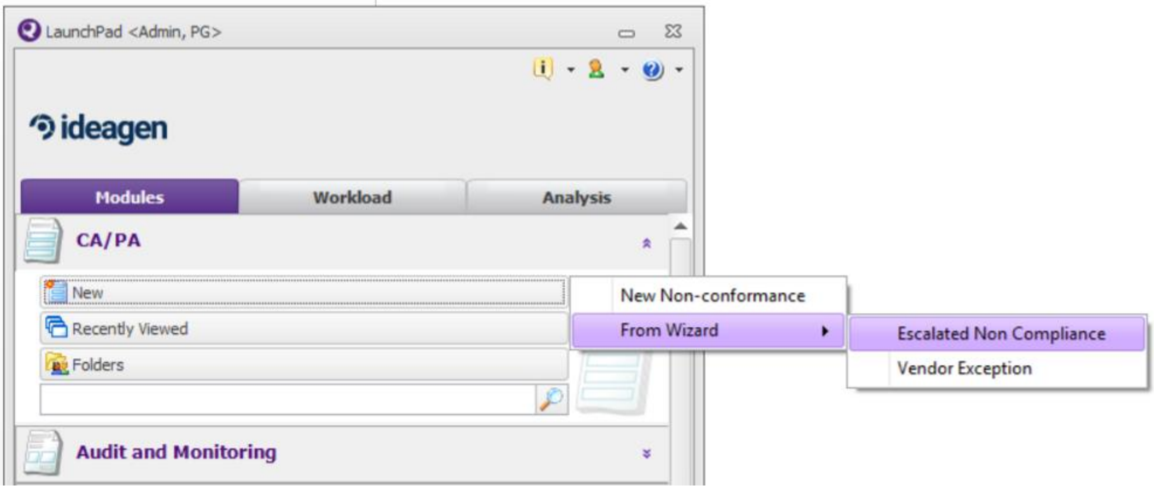
Non-Compliance Q-Pulse Guide

GUI 51.008A

Version: 1.0

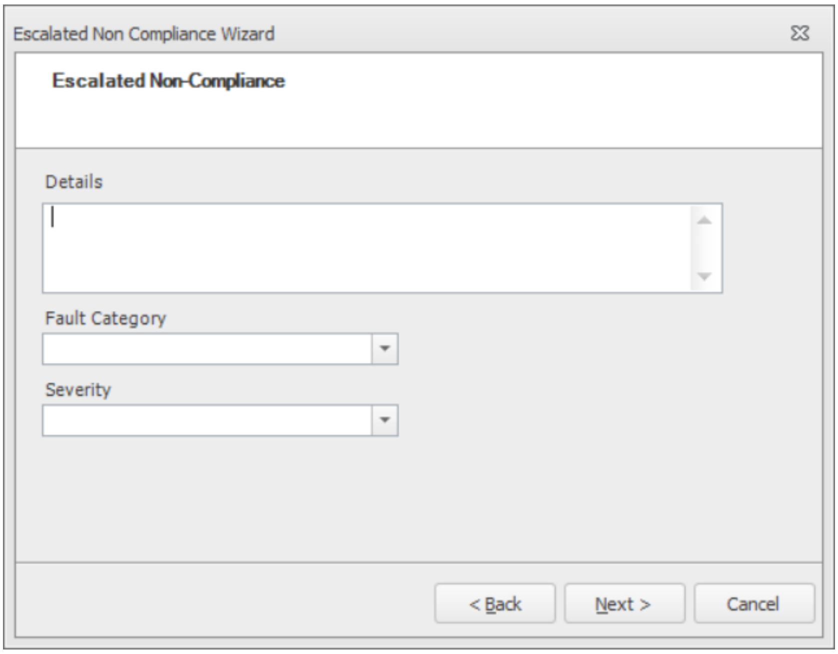
This Guideline is intended to provide instructions on how to raise and manage a Non-Compliance in Q-Pulse. Step by Step instructions are detailed below with the intention of enabling an individual to navigate the process.

The Non-Compliance logging process can be accessed from the CAPA module, this appears on the front Launchpad in the Q-Pulse Application. The first step is to expand the CAPA banner to reveal the options shown below and select the "New" option which expands to then allow you to select "From Wizard". This will then provide a final list from which you can select "Escalated Non Compliance".

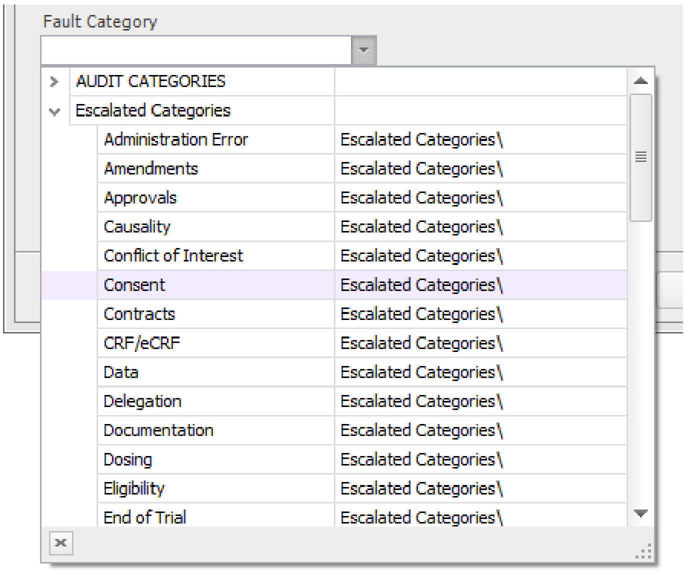


This action will then open the front screen of the Non-Compliance Wizard, to continue select "Next".

This will then lead to the next window of the wizard which presents you with a number of fields to be populated, the first box is a space for a free text description of what the reported issue is. This allows you to provide a sufficient level of detail for others who may later read the details of this Non-Compliance to understand and follow the details



The "Fault Category" field is a drop down list in which the fault can be categorised in a broad manner, this allows for later reviews of trends. The available options are grouped under the header of "Escalated Categories", in the event an appropriate option is not available you may select "other" from the list and a new category can be added.



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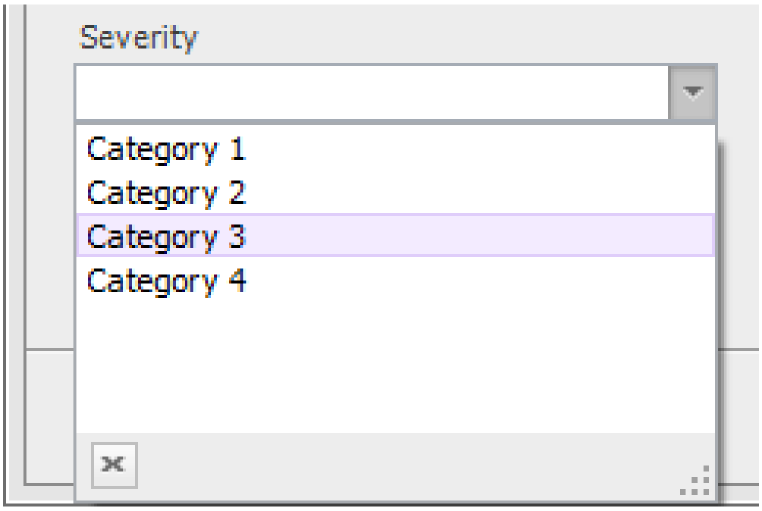
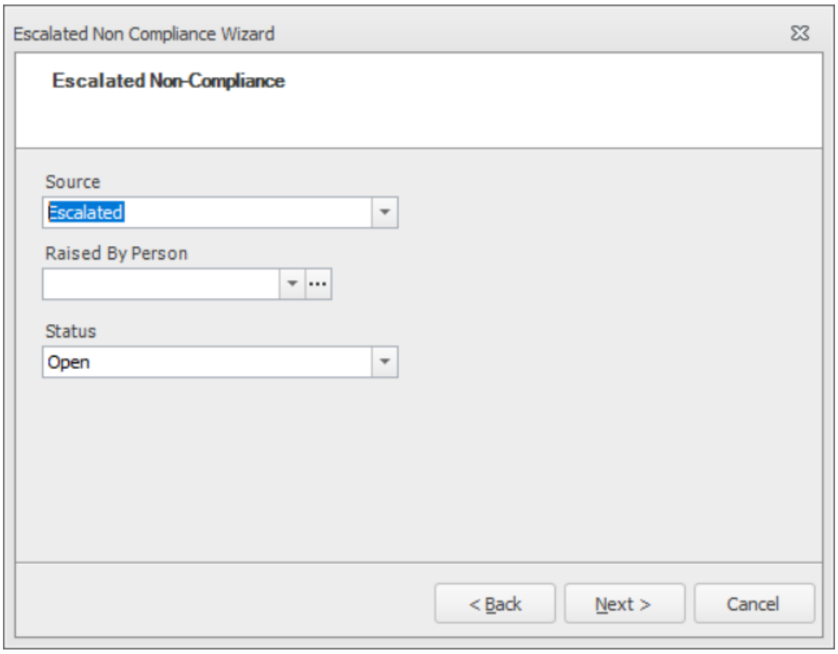
The final field to be completed on the first page is the classification of Severity, as standard it will only be Category 3 or 4 non-compliances reported in this way. From the drop down list you must make the appropriate selection.

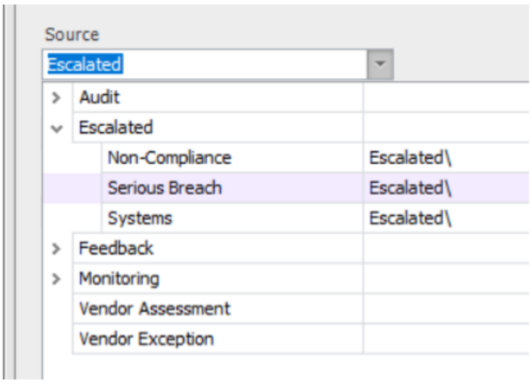


Once all 3 fields have been completed, select "Next" to continue to the next page. All fields are mandatory and must be completed before continuing.

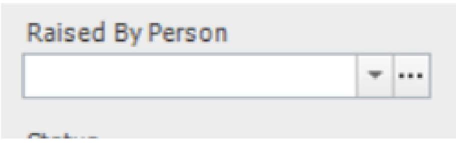
The next page will then have 3 fields to populate, the status field should be pre-populated and source will have a place holder of "escalated".



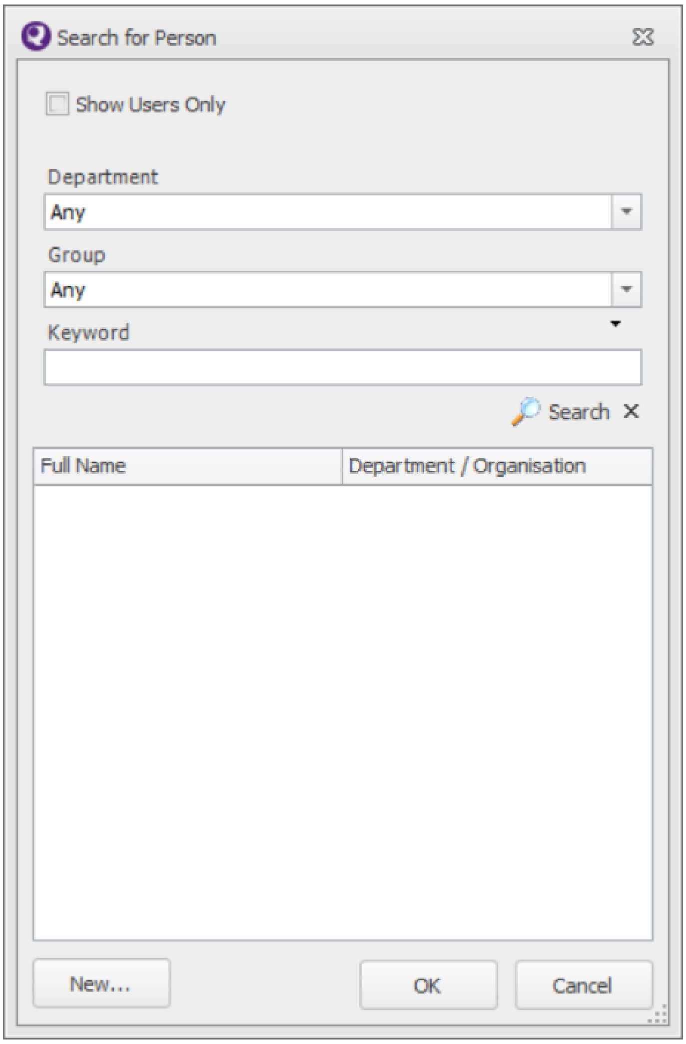
The first field with the title of “Source” will default to being pre-populated with “Escalated”, from this you must then drill down and select from the available options. If it is a standard Non-Compliance then this option may be selected, alternatively if the Non-Compliance relates to Systems or is a Serious Breach these options may be selected.



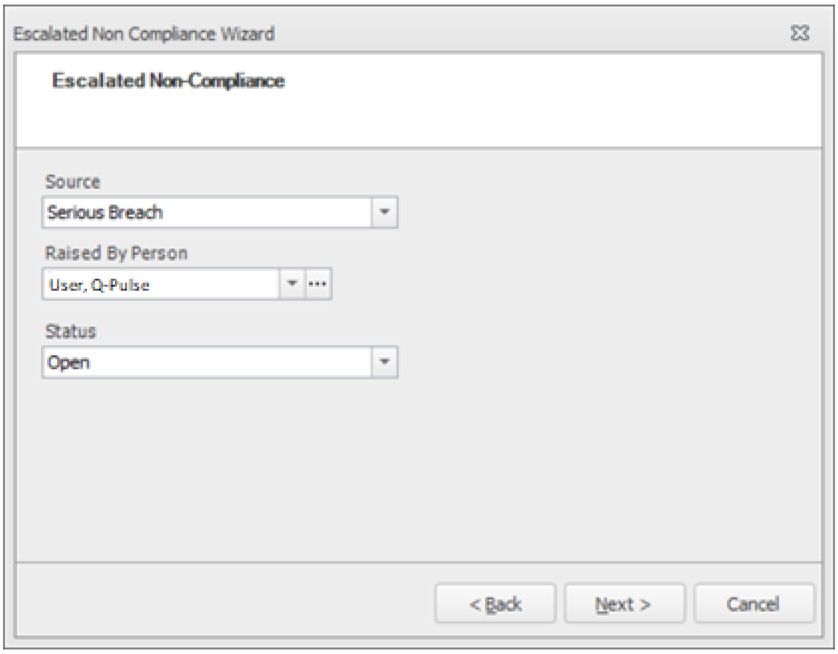
The next field is to state who the non-compliance was raised by, this is the person who has reported the issue to Sponsor. If the non-compliance was reported by the monitoring team it will be the name of the Monitor who reported it for example. There is the option to type the name directly (starting with surname), select from the drop down list, or by pressing the button with 3 dots perform a search.



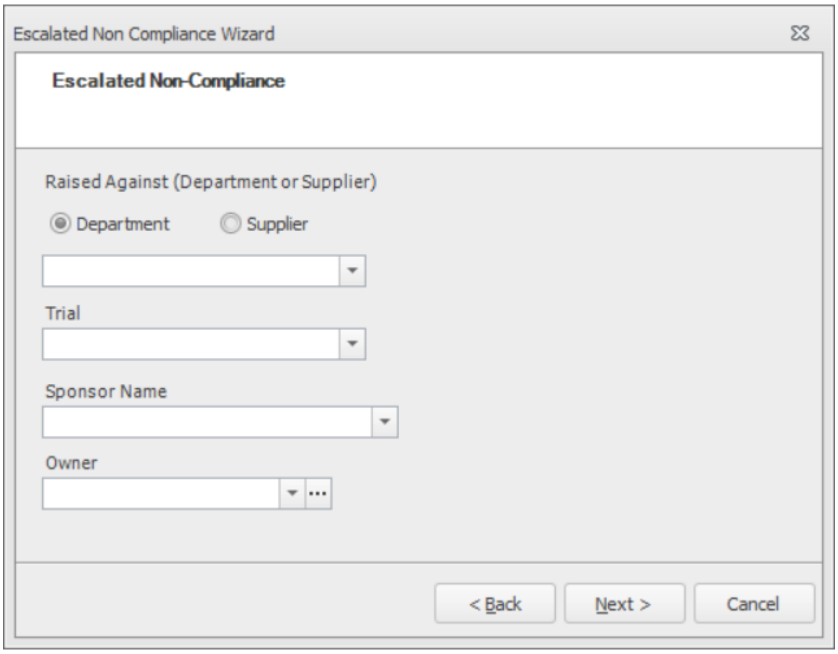
The final option will open a search window in which you can perform a search for the name of the individual, if a name is not avilable then they are not currently registed on Q-Pulse. New names can be added to Q-Pulse by appropriate users as detailed in Appendix A.



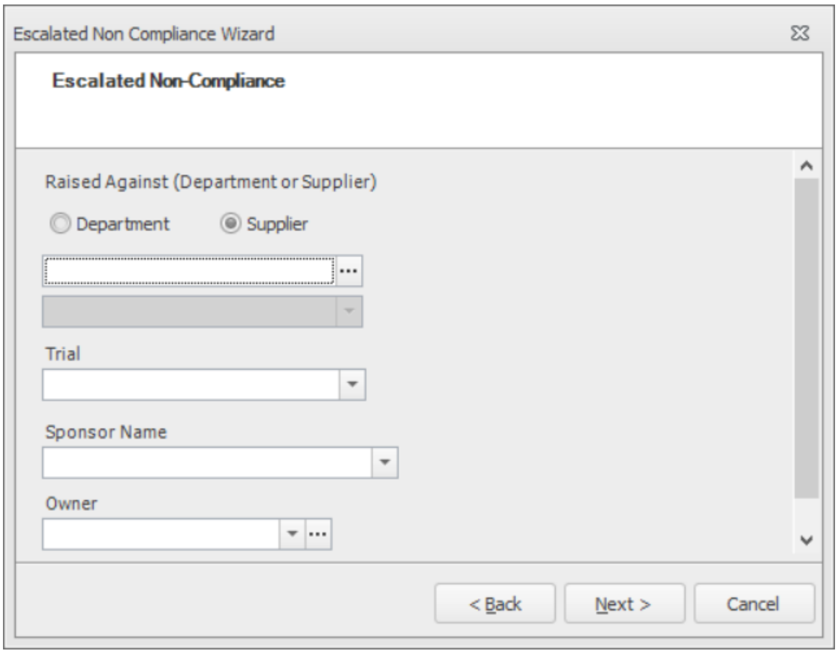
The final field to be populated is the "Status" field, this will default to be prepopulated with 'open' and should be left at this. Press "Next" to continue to the next page.



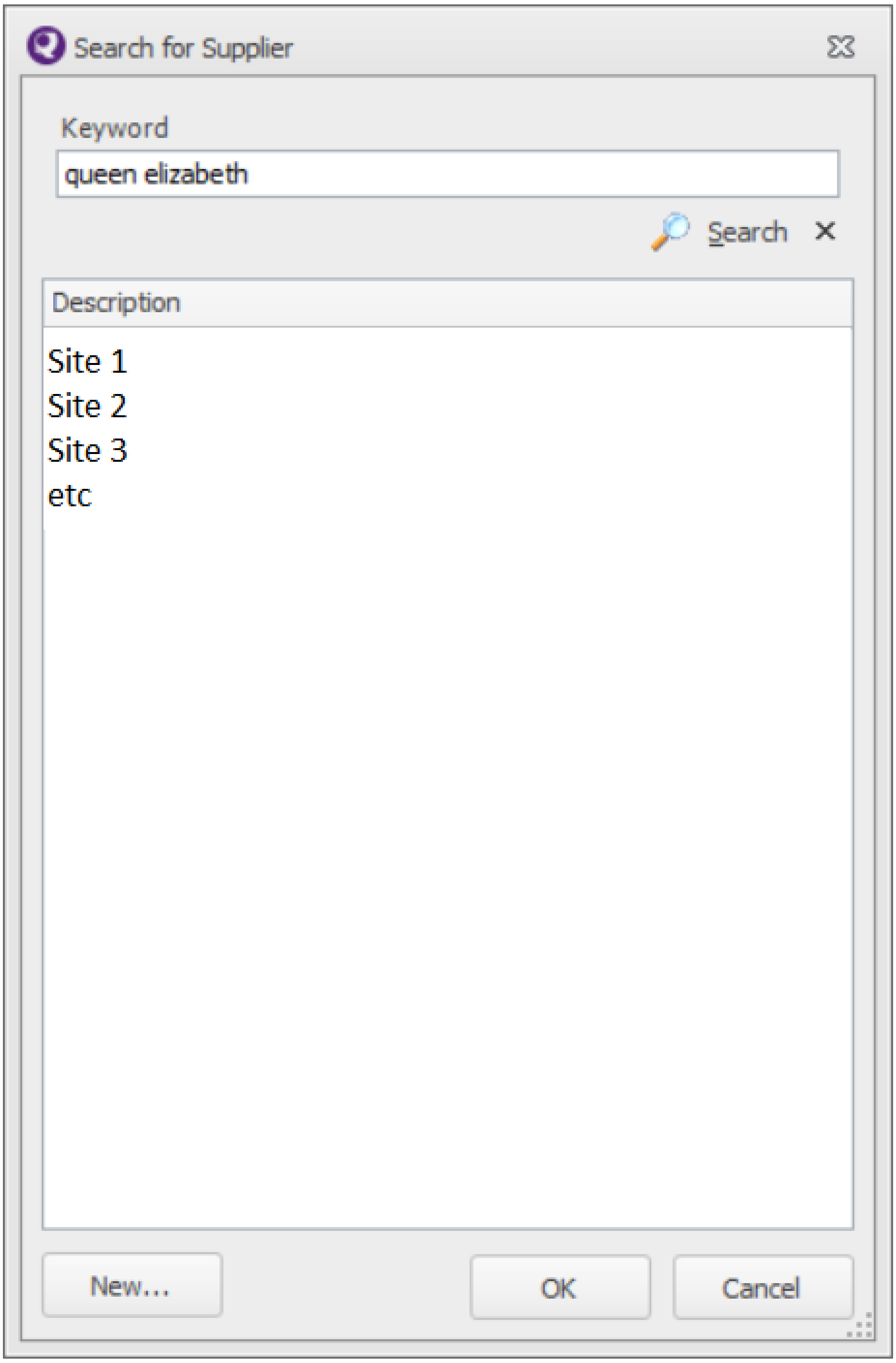
The next page will then have 4 fields of information to be completed, the first is an opportunity to highlight the area which the non-compliance will be raised against. In the event the Non-Compliance is to be raised on an area internal to R&I you must select “Department” and select the appropriate area from the drop down list.



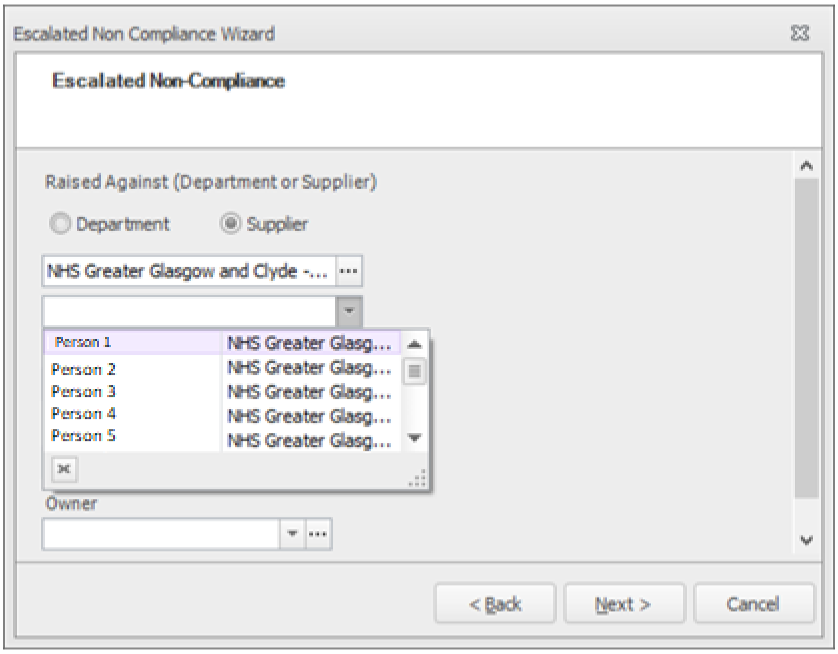
If the Non-Compliance is to be raised agianst aNHS GGC site/department external to R&I or an external participating site or Vendor you must select “Supplier” and then select the button with 3 dots to open a search box and find the appropriate ’Supplier’.



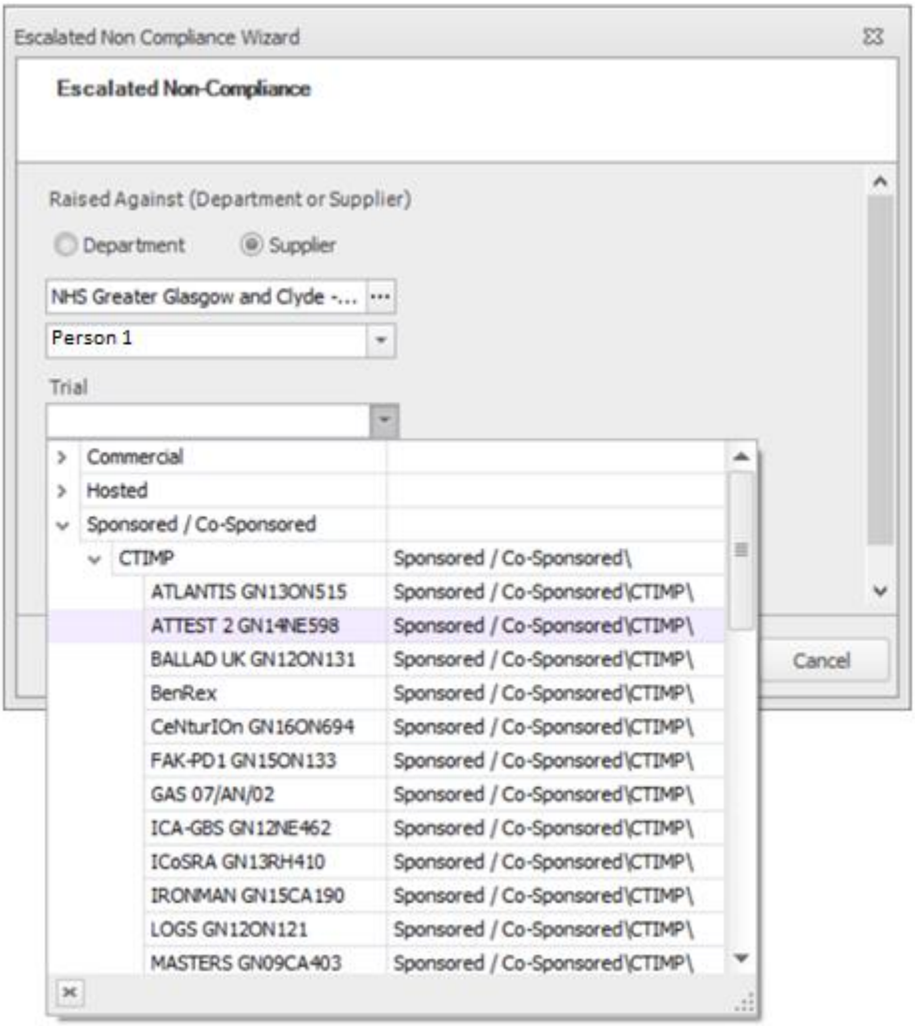
The following search box will allow you to search for the required site using specific keywords and then select the appropriate one from the list. If the desired site is not available from the list they can be added by a user with appropriate access rights, this is detailed in Appendix A.



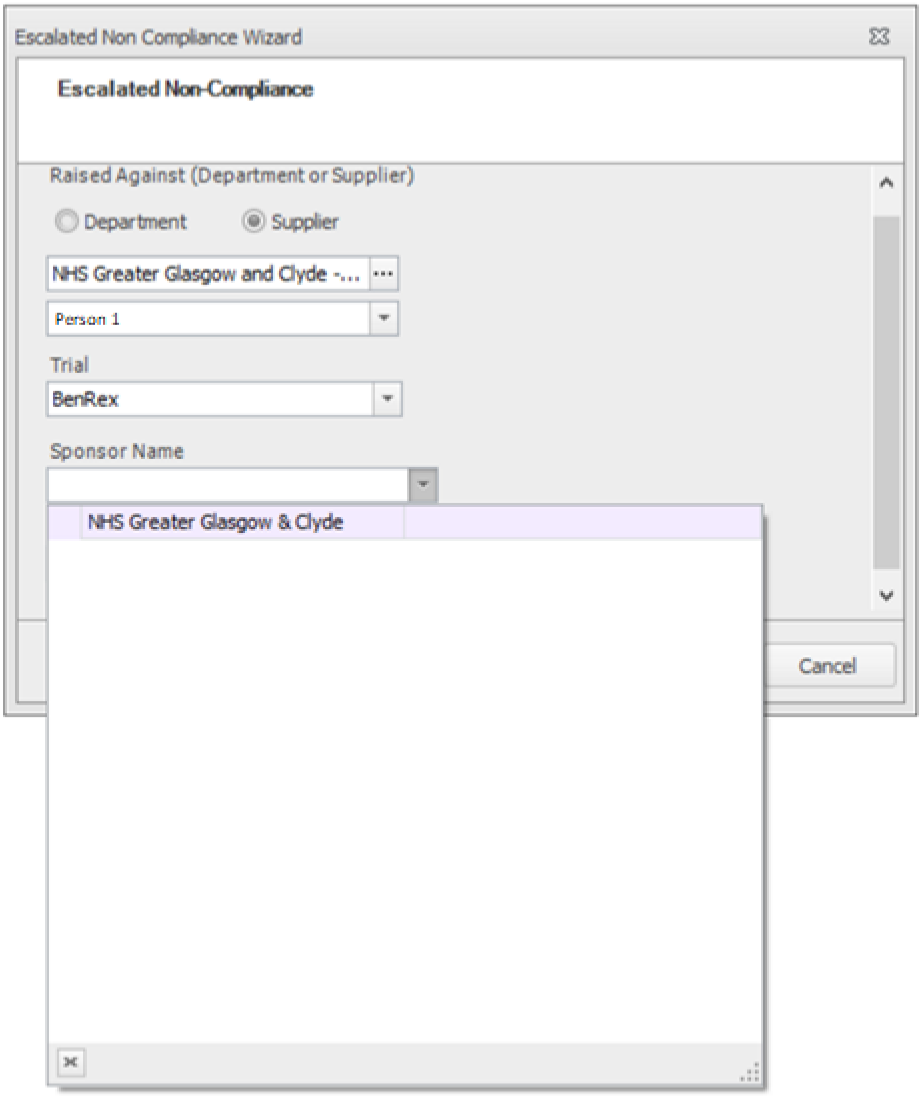
Once the appropriate ‘supplier’ has been selected, as this is external to R&I, you will then have the ability to select a contact from the site – this mayshould be the person reporting the non-complaince to the Sponsor or the point of contact at this location if reported by another source.? This will be a list of names of contacts associated with the site and can be selected from a drop down list.



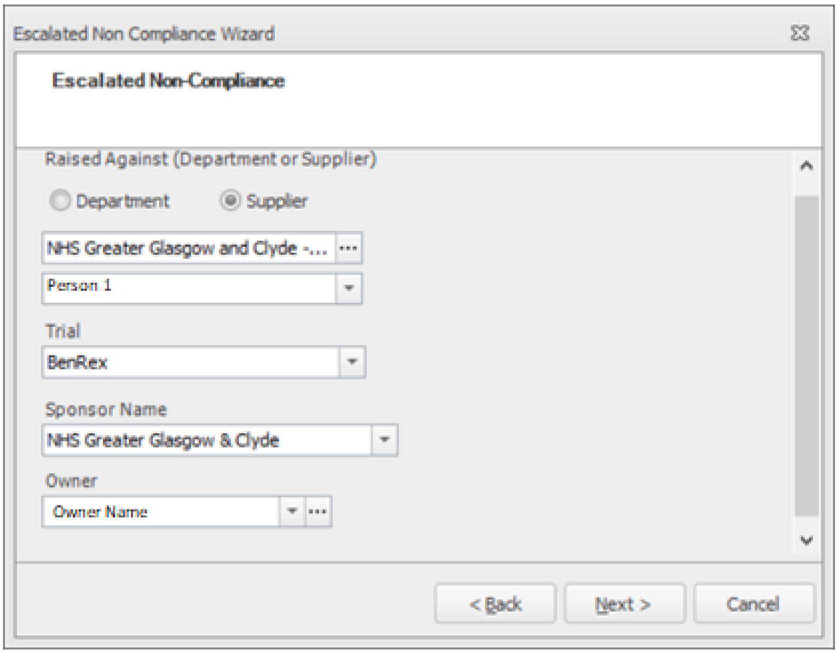
The next field is to select the trial which the Non-Compliance relates to. This can be achieved by expanding the drop down list and making the appropriate choice to select the trial in question. In the event the non-compliance relates to multiple trials, you may select one of the trials in question from the list and detail others in the non-compliance record. As with other fields, if the trial in question is not present it may be added to the list by a user with appropriate access rights as detailed in Appendix A.



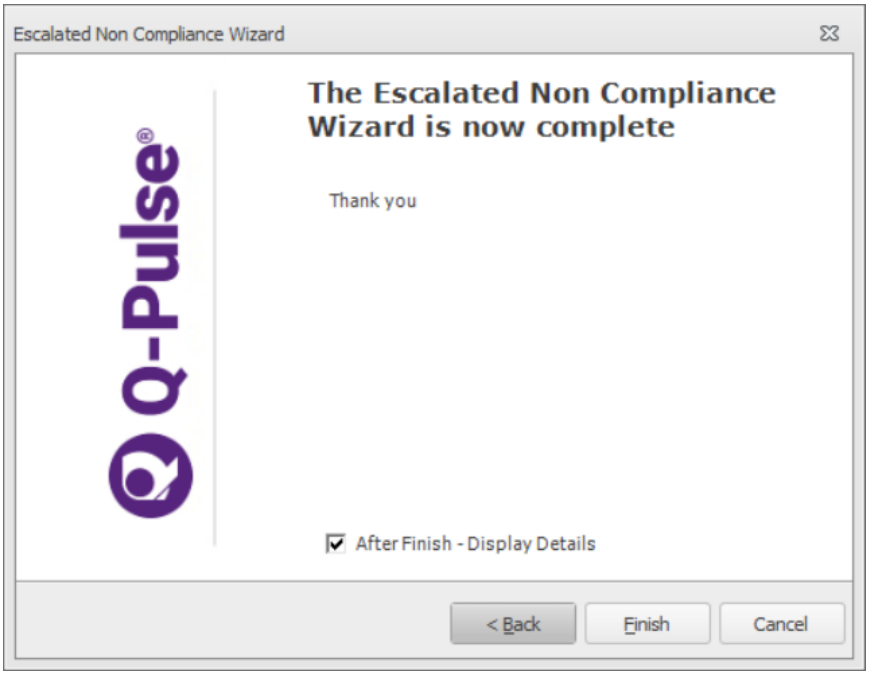
The next field is to select the appropriate Sponsor the Non-Compliance relates to, this is achieved by selecting from the list of Sponsors in the drop down list.



The final box is to then assign an Owner to the Non-Compliance, this is the individual who will be responsible for managing the Non-Compliance to completion.



Once all of the details have been entered, you may then select the "Next" button and move to the final window. On this, select the check box "After Finish – Display Details". This will open the Non-Compliance Record when you click finish.



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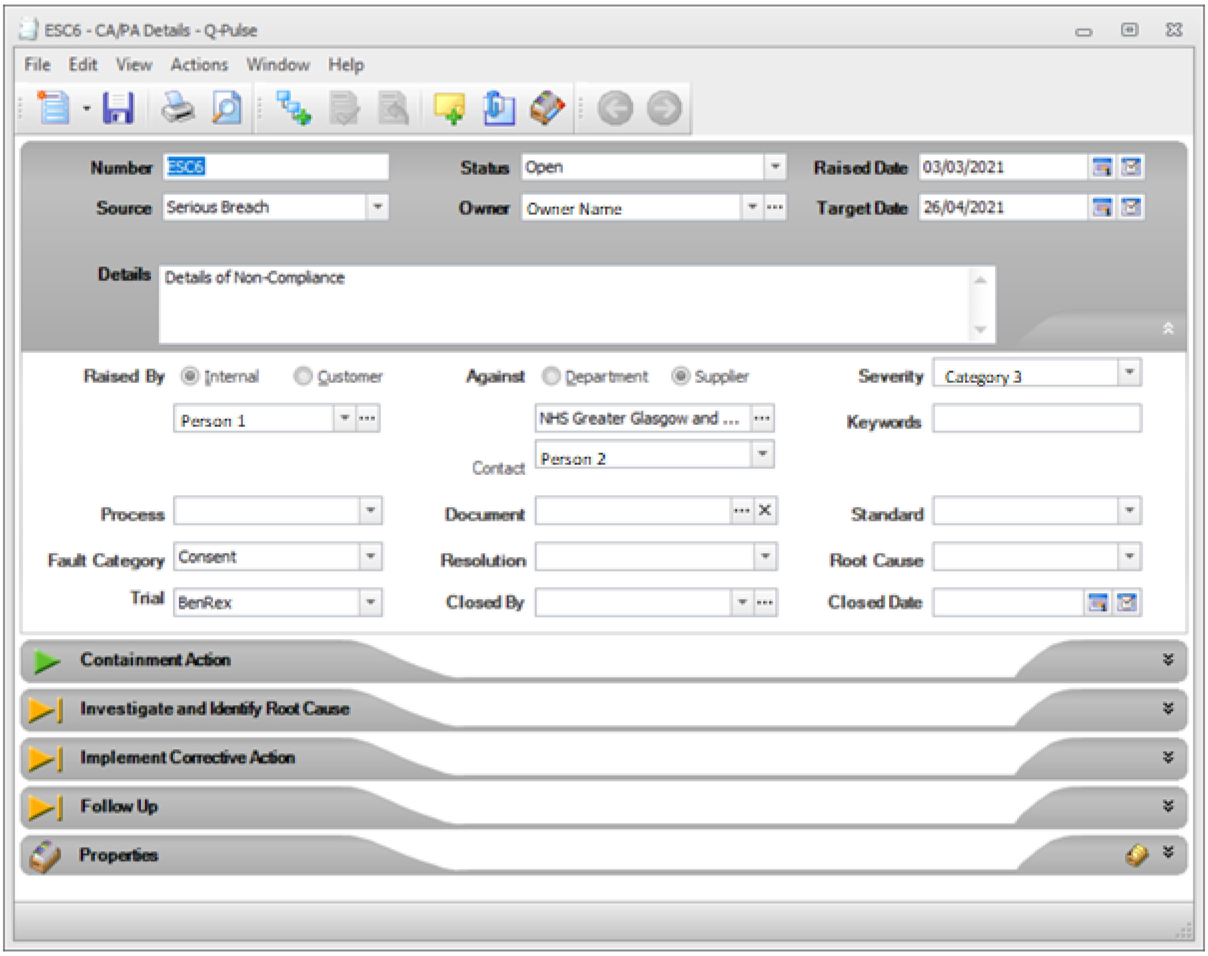
By completing the wizard to create a Non-Compliance, a new record will result which holds all of the details entered as demonstrated below. All of these fields can be updated and edited at any point during the lifecycle of the Non-Compliance. When the new record has been produced, a unique ID number will be assigned to the Non-Compliance with the prefix “ESC” followed by a sequential number.



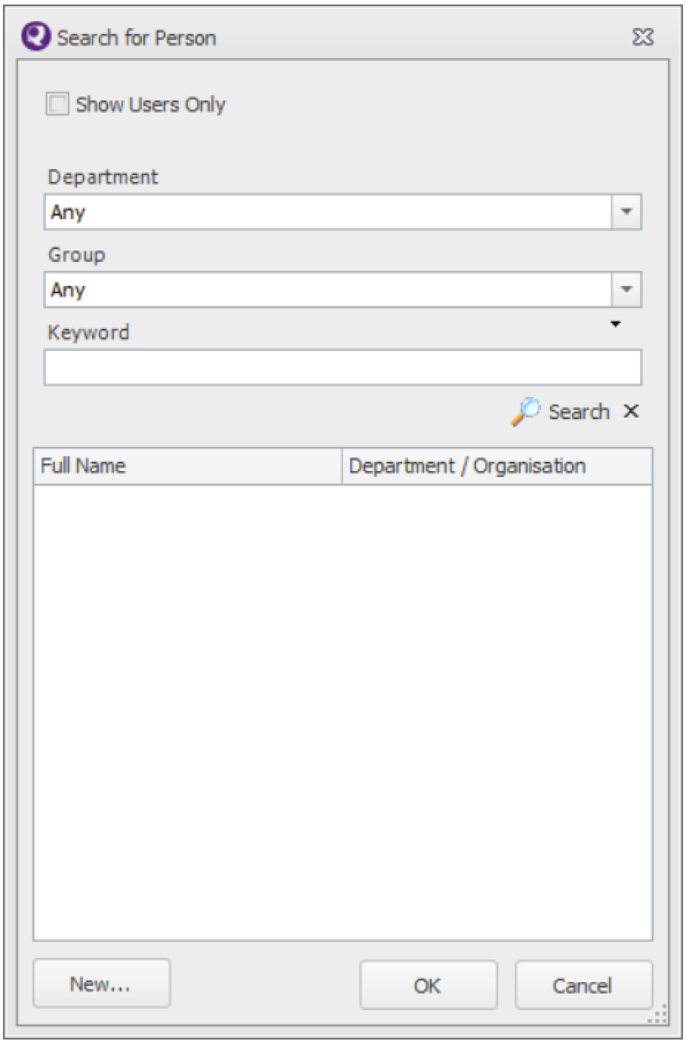
The Non-Compliance will be given an overall Target Date which can be adjusted based on the individual circumstances of the Non-Compliances, again, this can be adjusted throughout the lifecycle of the Non-Compliance. The target date which is generated upon initial creation of the record is a default set for the Non-Compliance template, which is 60 days from the raised date.

Appendix A

Adding a new User to Q-Pulse

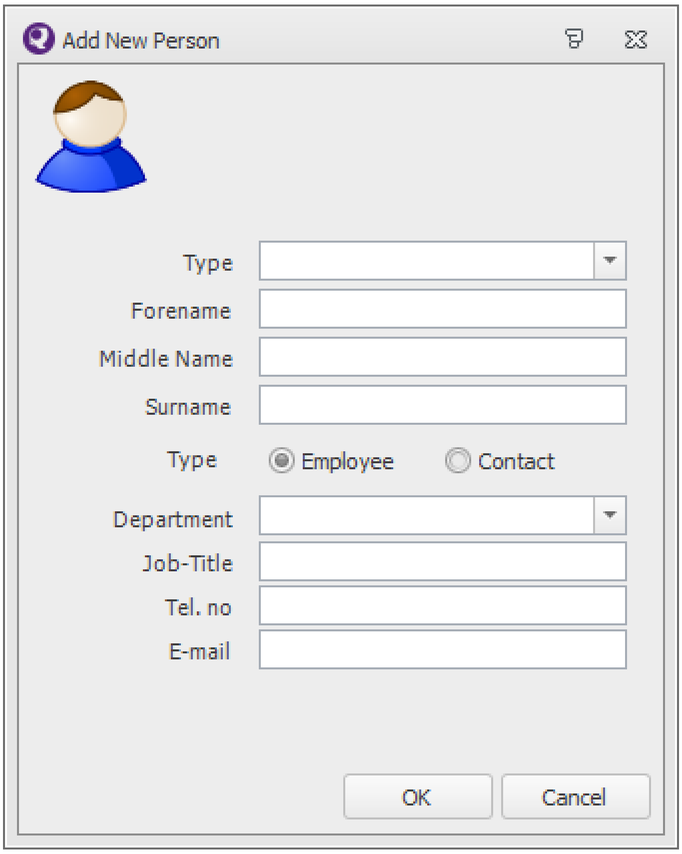
On occasions it may be required to add a new user to Q-Pulse, in order to complete this activity you must have the appropriate permissions assigned to your account. If you do not have the permissions you can contact an appropriate individual with the permissions.

There are several locations from which a new user can be added to Q-Pulse, the most common point of access is when you are search for a user to assign them to an action or a field in a record from the window shown below.



In this window there is an option for “New”, this will only appear for those with permission to add new users. If this option is not available your account does not have permission to add new users.

After pressing this button, a new window will open which allows for the entry of user details.



This form must be completed to create a new user record, completing as many of the fields as are applicable.

The only mandatory fields are a Forename, Surname and Organisation if you select "Contact".

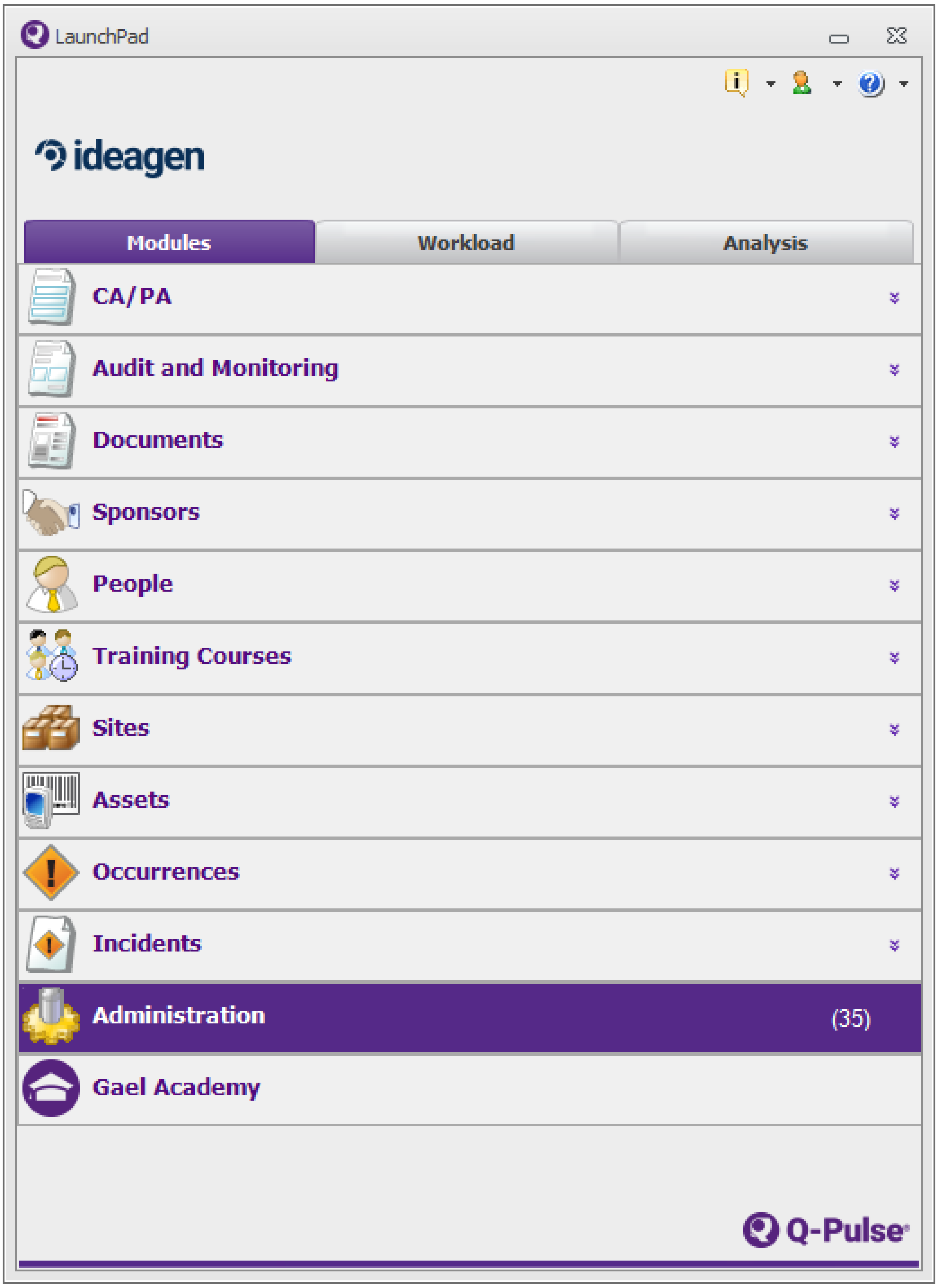
The appropriate title may be selected from the "Type" drop down, the relevant name details in each field and then make a selection of user Type as either "Employee" or "Contact".

The Employee type is for an individual within R&I and a Contact type is for an individual at a site location. This selection will then determine if the next field is "Department" or "Organisation". The remaining fields of Job Title, Tel No. and E-Mail are optional and may be completed if the information is available.

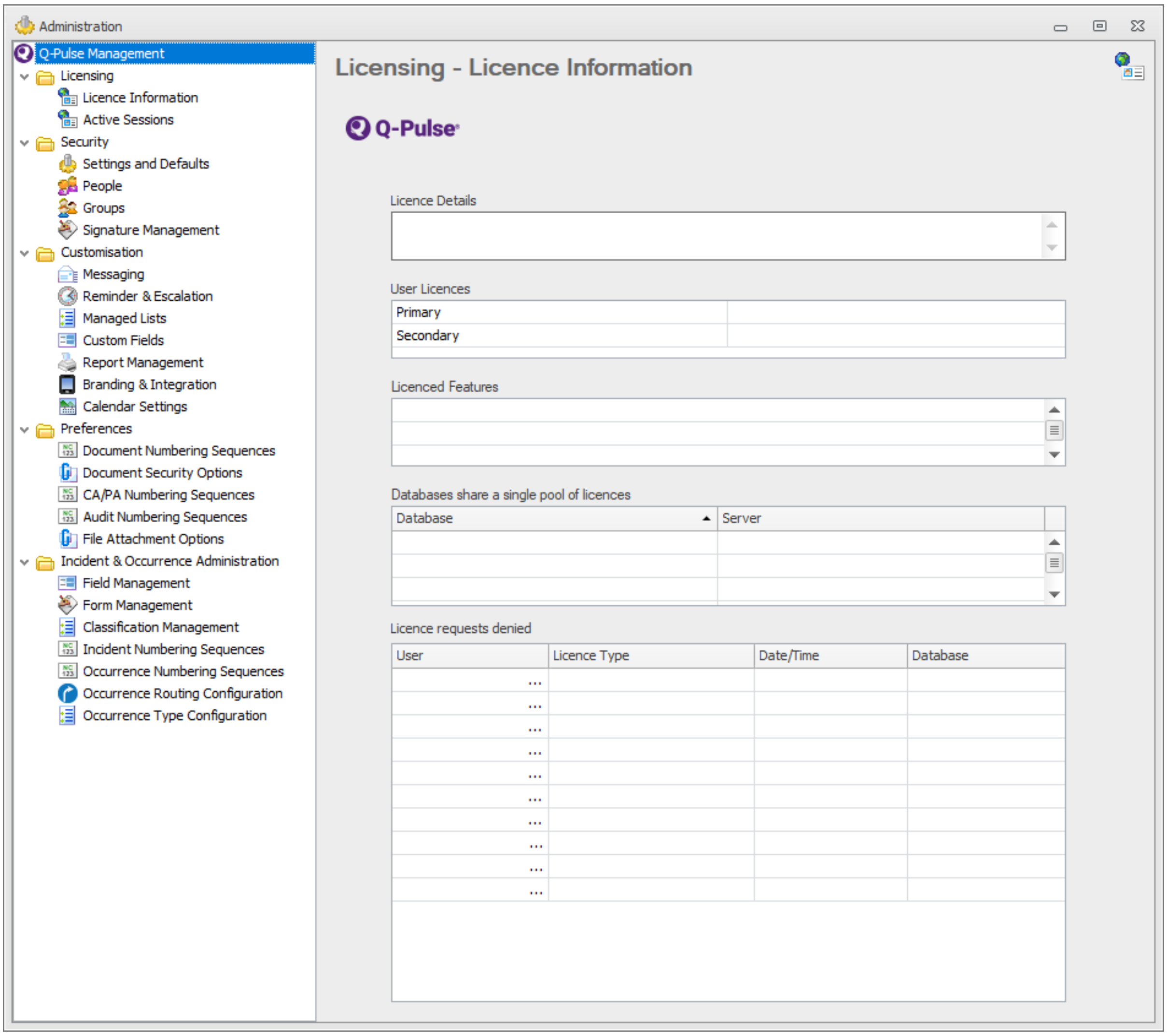
When all appropriate fields are completed, select OK to create the user record, this will then result in this user being a selectable option.

If an organisation is not available in the list, see the next section for how to add.

Alternatively, a user can be added to Q-Pulse from the "Administration" module for users with appropriate access. This is available from the front launch pad.



By selecting this, a new window will open with a number of options.



New users can be added under the “People”option on the top left hand side

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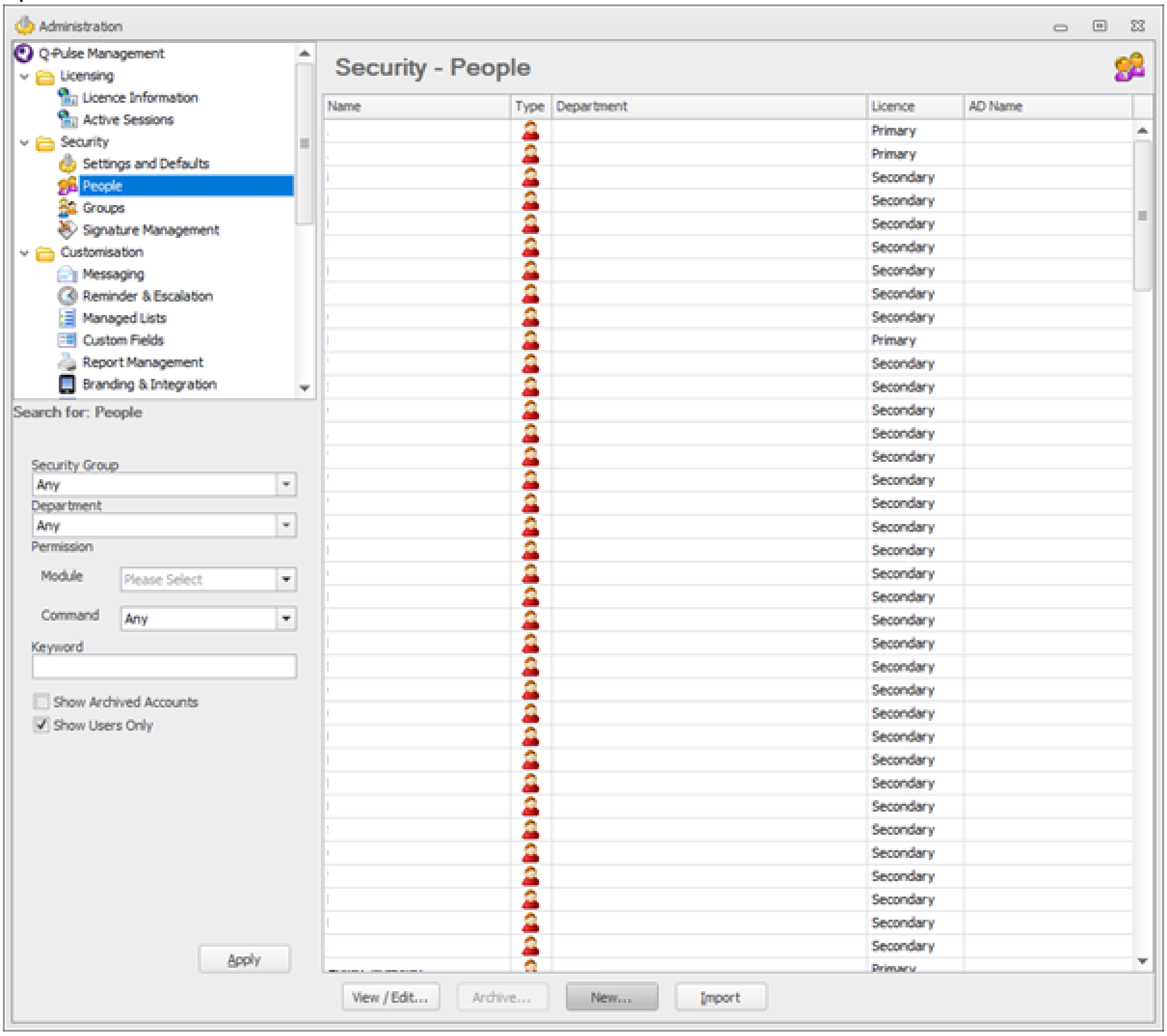
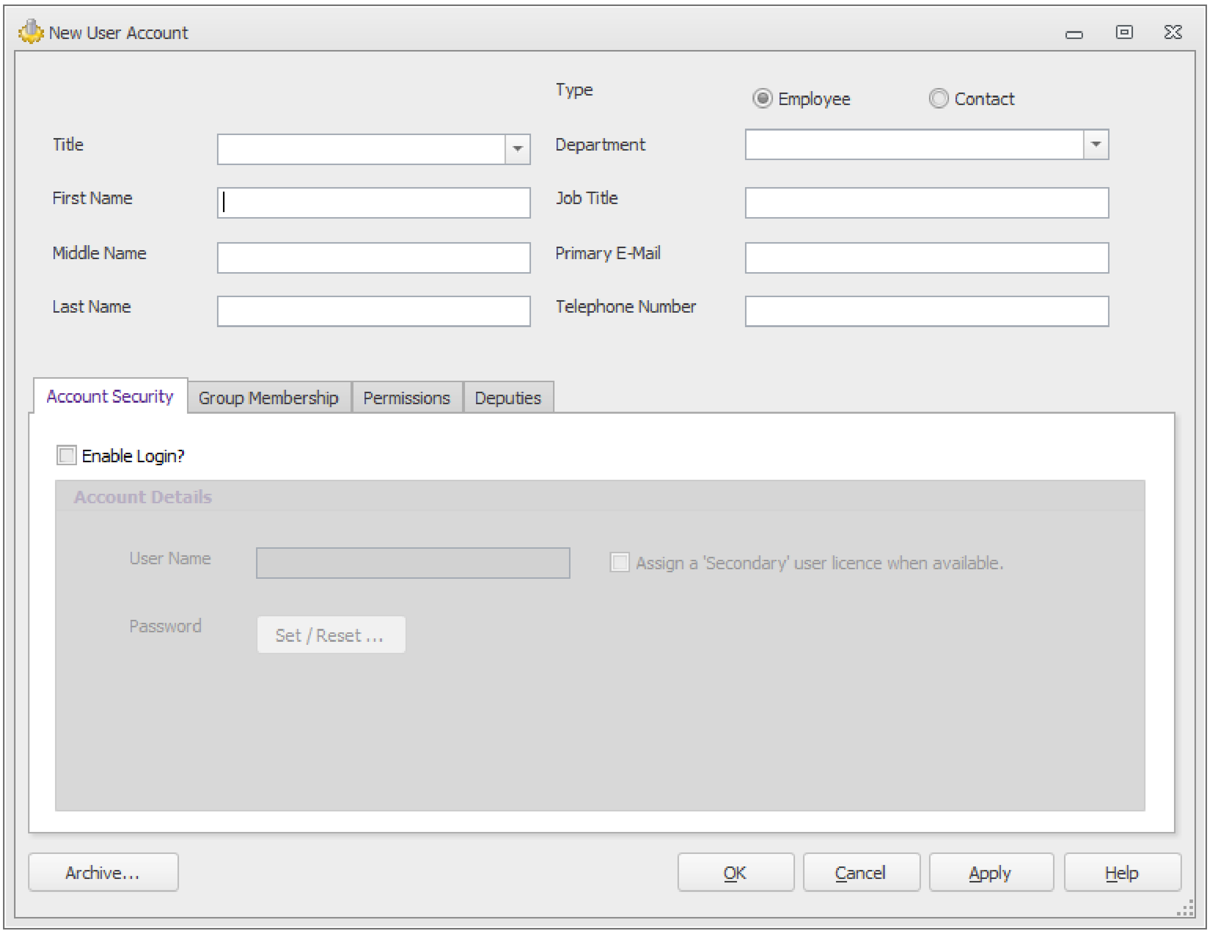
Selecting this will open a new window with a range of options associated with user accounts, an option for “New” will be available at the bottom.



When the “New” button is selected, a window will appear where the details can be entered similar to the one before.

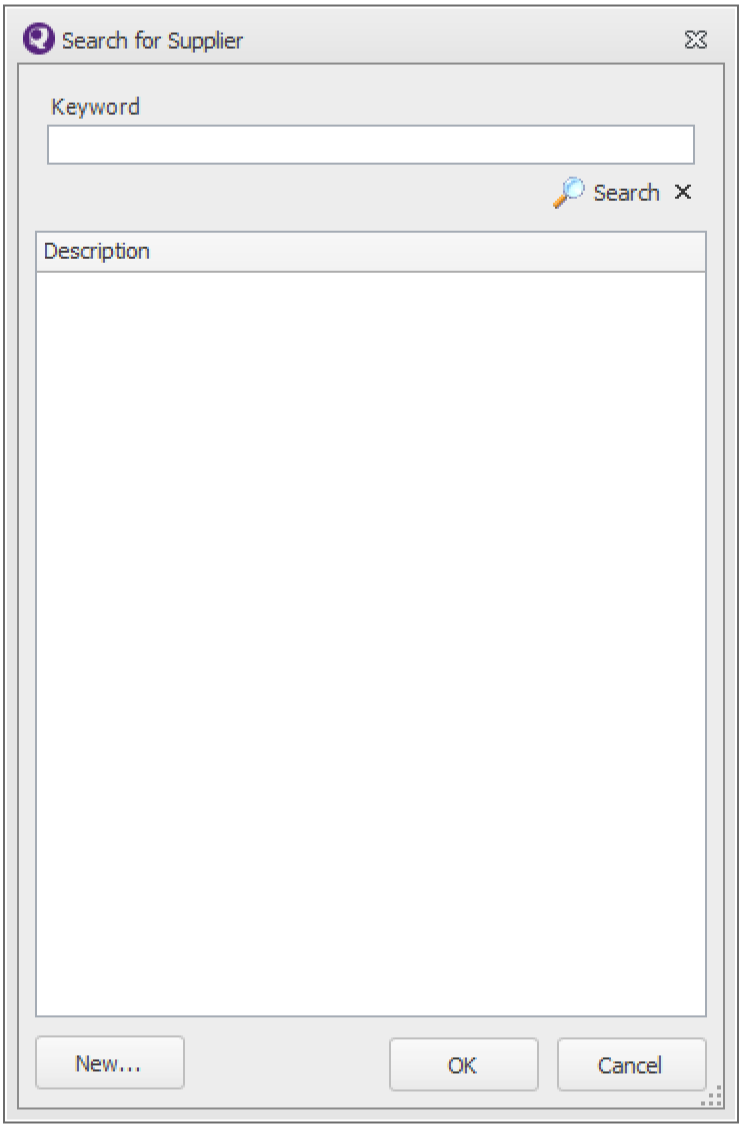


As before, complete the relevant details to create a user. The additional options will only be required for users who need to log in to Q-Pulse and this will be the responsibility of System administrators to create.

Adding a Site

As with adding a user, only accounts with sufficient access rights can complete this action. If your account does not have the appropriate access rights you may request this of someone who does.

As with adding a user, there are several locations from which a Site can be added, the most common access point again will be when searching for a site to assign to a field in a record.



If your account has sufficient access rights the option for "New" will appear in the bottom right, to add a new Site select this button.

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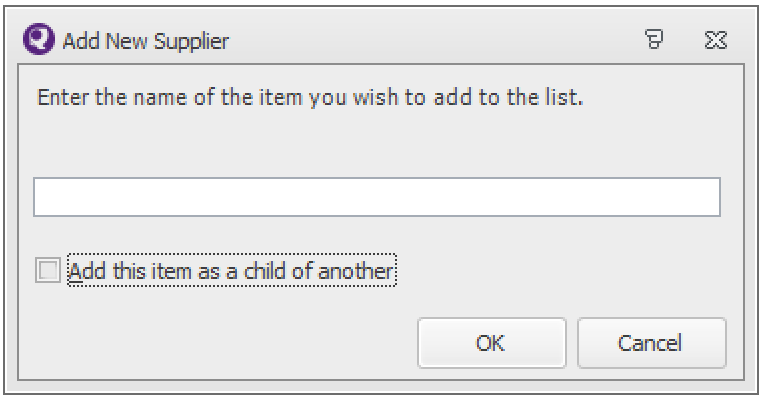
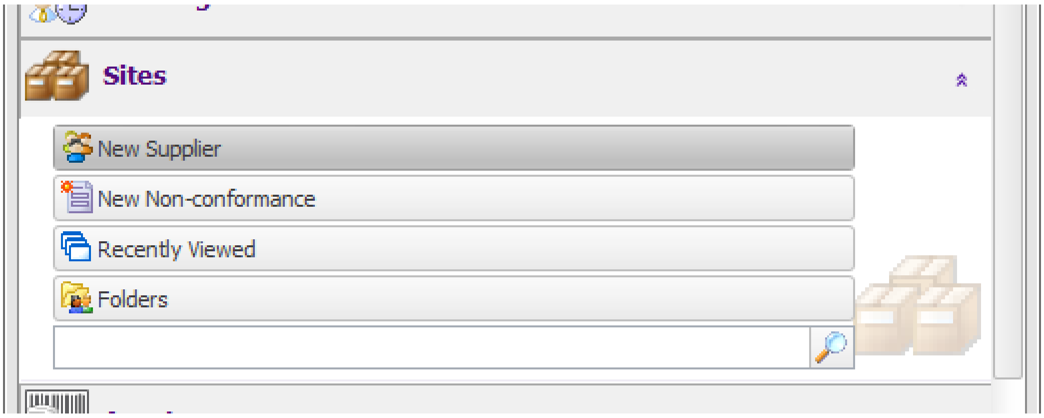
This will open a new window in which the name of the site can be entered.

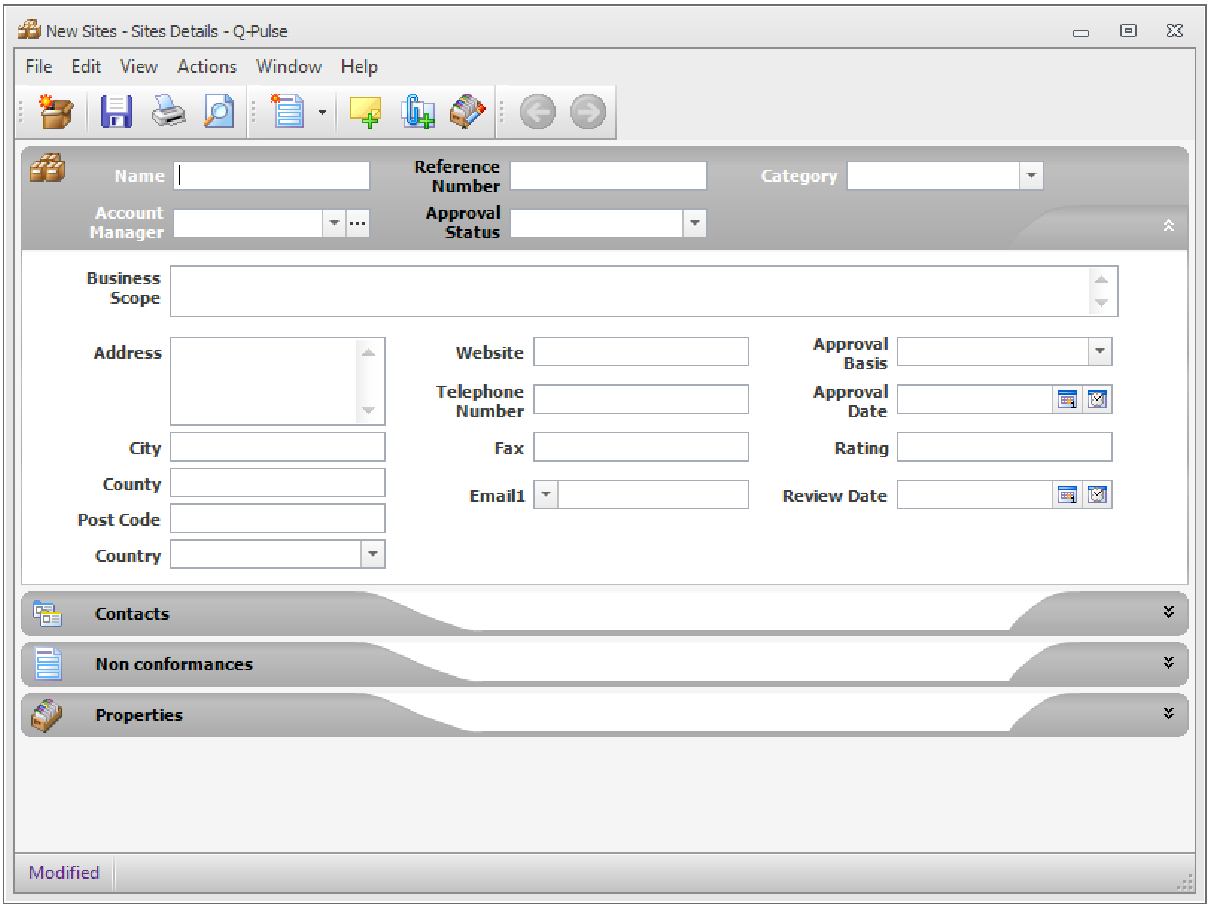


Simply enter the site name and select OK, there is an option to add as a child of another site which is not relevant in this instance. After you have added a site, they can be selected from the list and have contacts associated with them as an organisation when creating new users.

Alternatively, a new site can be added if you have access to the “Sites” tab on the front launch pad. By expanding this tab you will see an option for “New Supplier”.



Select this to open a new window in which details of a site can be added.



As can be seen, a number of details are available to be recorded against a location. The minimum requirement for information to be entered is a name only, further details can be populated against a record as the need arises.

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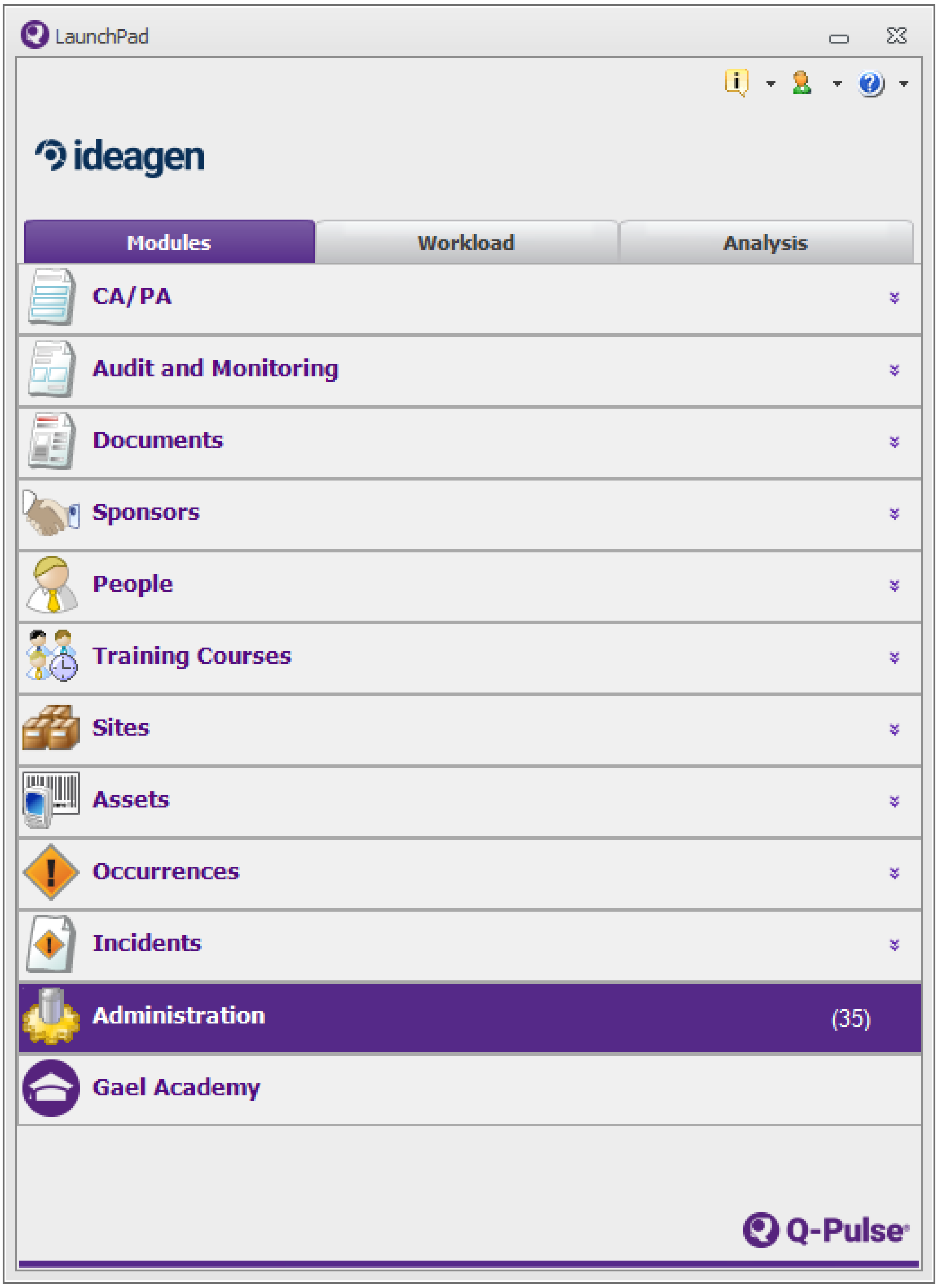
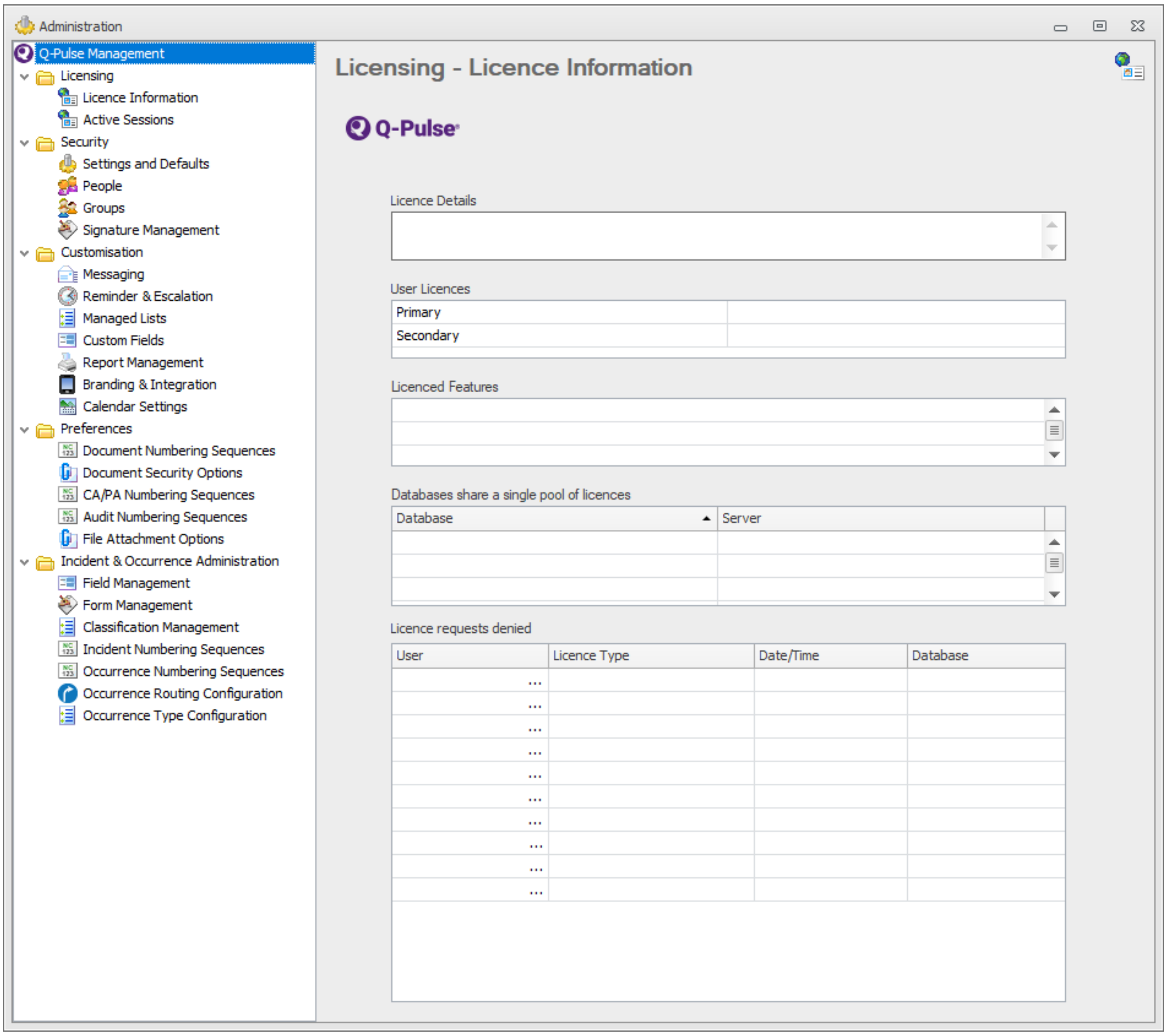
Adding a New Trial

A new trial can only be added by an account with administrator privileges, this must be completed from the Administrator page which is accessed from the front launch pad.

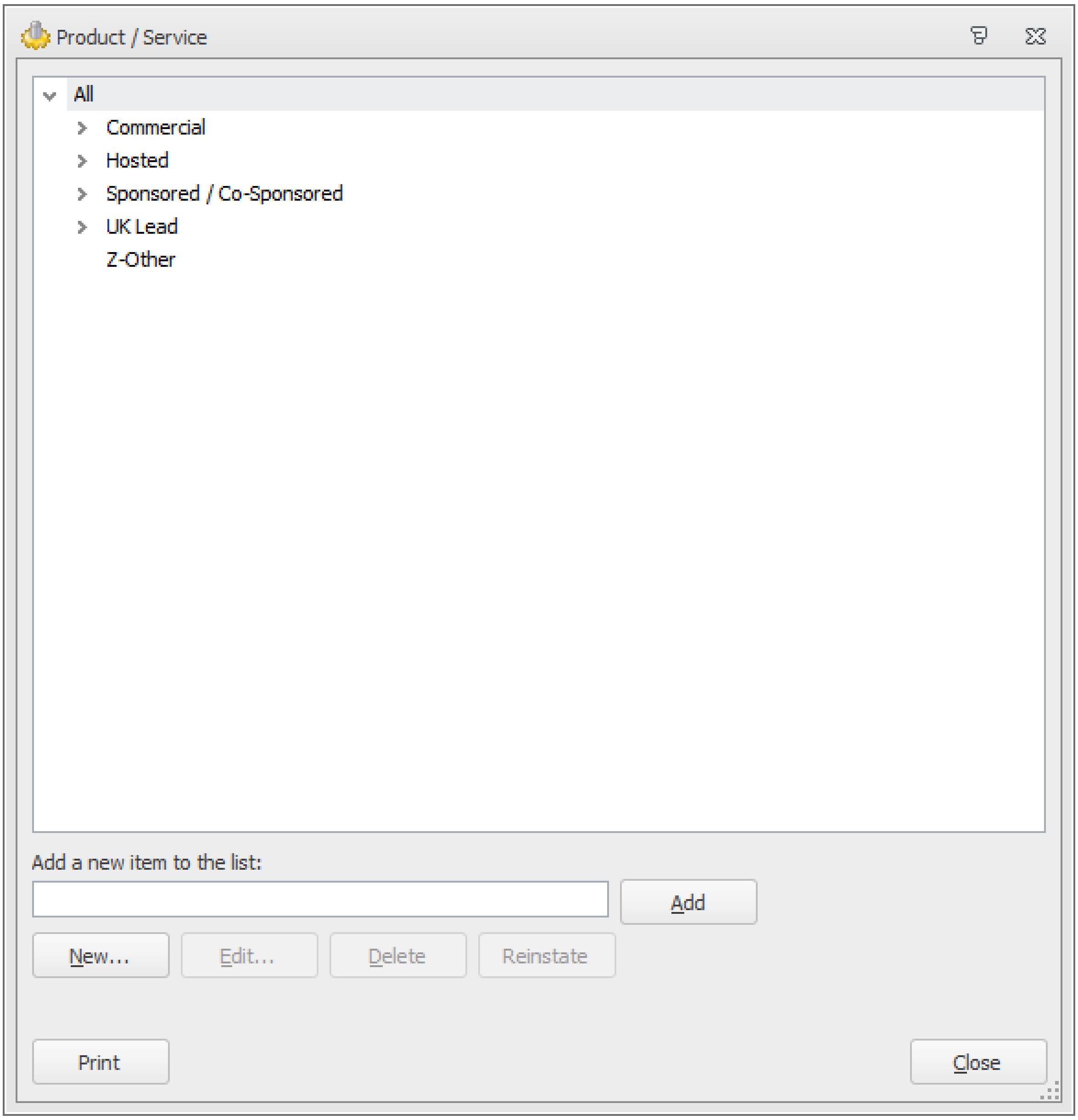


By selecting this, a new window will open with a number of options.

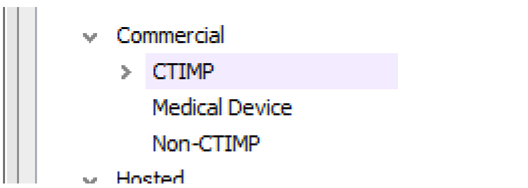


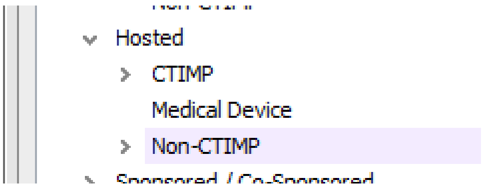
New trials can be added under the “Managed Lists”option on the top left hand side

This will display a range of lists within Q-Pulse, specifically it is is the “Product/Service” list.



Expand the options in the formatted list to add the trial to the relevant area, i.e. Commercial > CTIMP or Hosted > Non-CTIMP for example





With the appropriate area selected, type the short title of the trial into the field at the bottom in the format of “Short Title” followed by “R&I ID” and then select “Add”.

This will add the trial as a child of the appropriate structure.

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Prepared by: Paul Gribbon Signed Date

Approved by: Caroline Watson Signed Date

Document History

Version	Date	Description
1.0	19/04/2022	First Release