Management of SOPs through Q-Pulse Guide

Contents

1. Introduction

A large number of the functions detailed within the document will be completed centrally by the relevant Quality Assurance representative. For R&I in general this will be the Quality Assurance Manager with delegated authorities within the GCRF and Bio-Repository as an example. For those functions carried out centrally (QA) will appear in the title of the section, however interaction with staff will still take place to complete the functions within Q-Pulse.

Specific work instructions will be presented to staff in any instructions they receive from Q-Pulse as well as any Q-Pulse training they may receive.

## 2. Creating a new SOP record (QA)

When there is a requirement to create a new document in Q-Pulse which must be signed by the relevant approvers, this is achieved through the actions detailed within this section. This functionality is carried out by the Quality Assurance Manage or appropriate designee. Firstly, to begin the process of creating the relevant document record you must open the documents module from Q-Pulse. This is achieved by selecting the documents ribbon in the home screen which will in turn open a new window for the documents module.
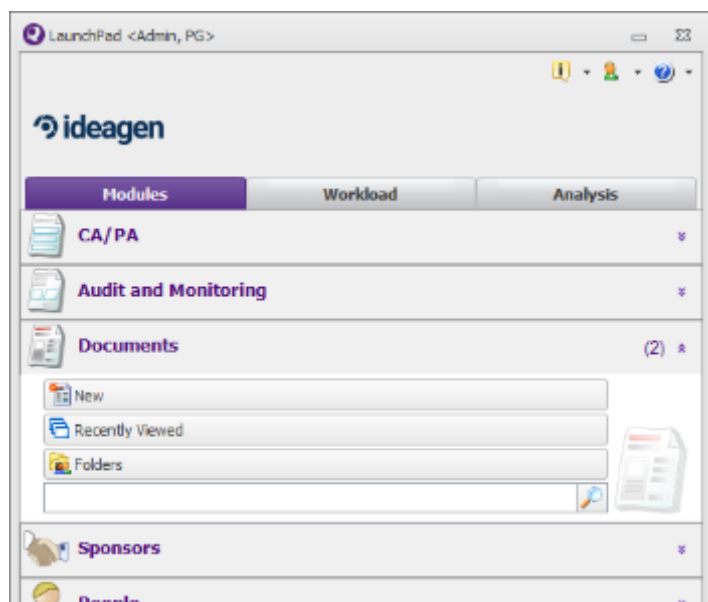

From within the documents module in Q-Pulse, select "File > New > Document > Draft Document"
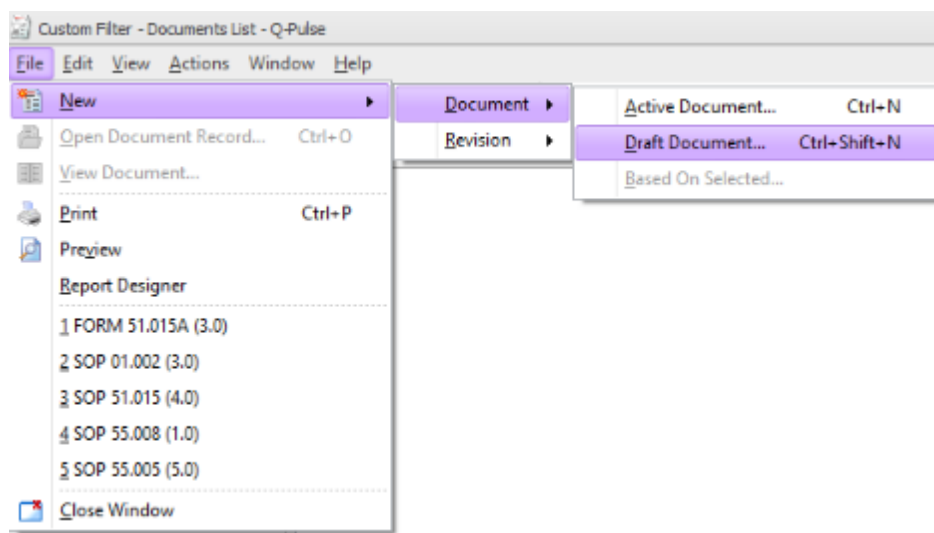
This will in turn open a new window which is an individual record for a draft document, this will not be an active document until appropriate signatures are in place and the document is then made active.
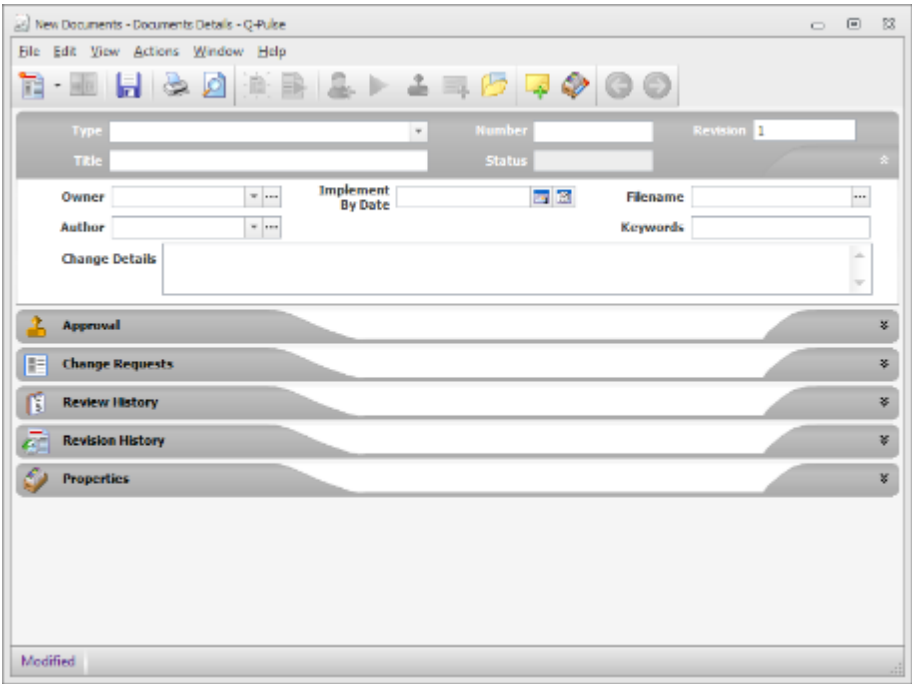

There are multiple fields to be completed within this document record, the first selection is to make an appropriate selection from the available options on the type of document. From the image below it is shown that numerous document types are available, SOPs, Forms and Guidelines are contained within the "Chapter" drop down option.
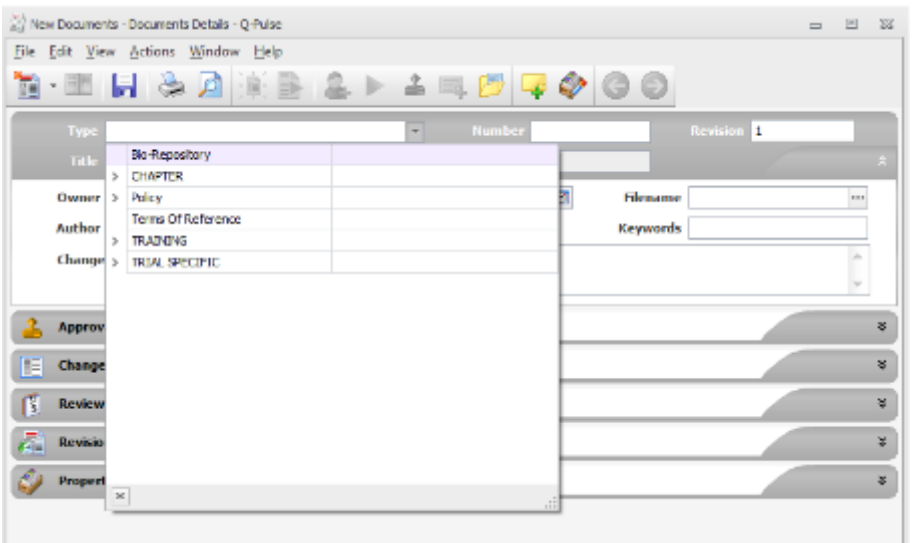
The chapter option can then be expanded to give the option of all the available Chapter numbers and from this select whether it is an SOP, Form or Guideline.
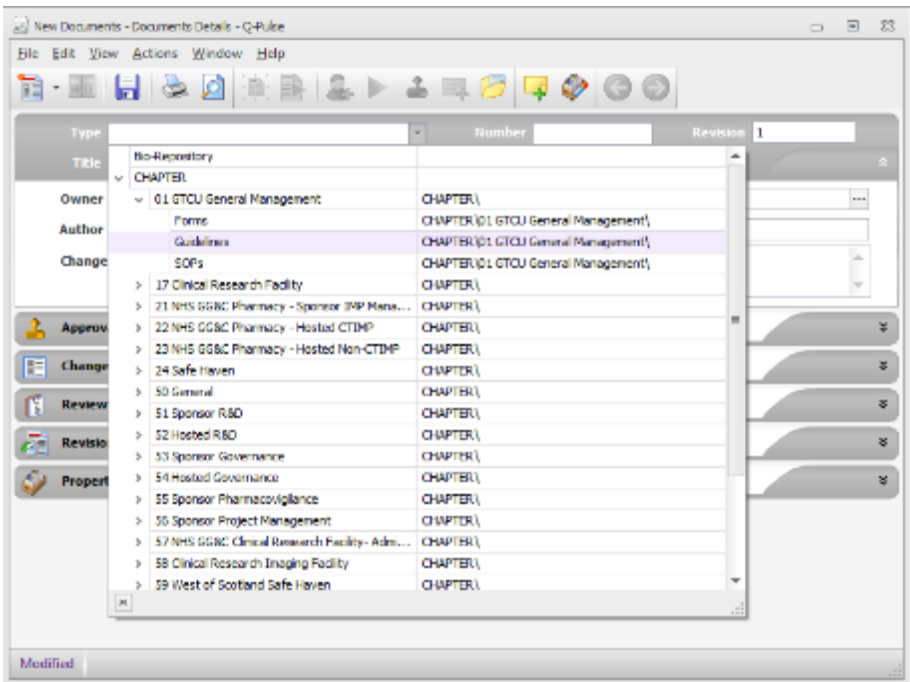

When the appropriate selection has been made, the "Number" field will auto-populate with the appropriate prefix and select the next number available in the stack. This may not be the next number available and this must be confirmed and agreed with the RCB who manage the administration of SOP numbers. If this number is to be changed, it can be overtyped.
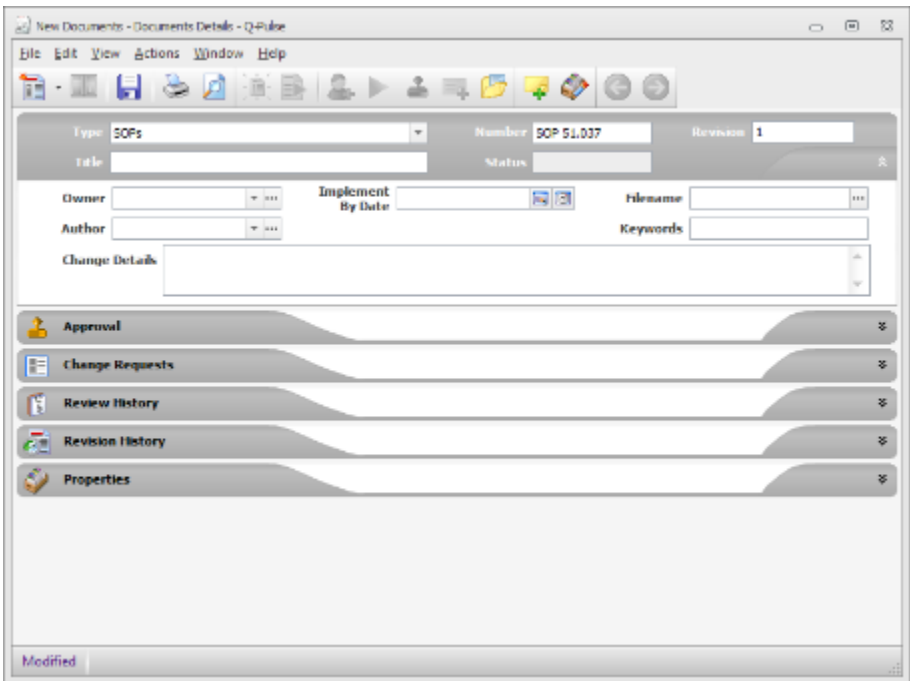
The next fields are the revision number which will default to 1, this must be expanded to include the decimal point and may not always begin at 1.0. This can be changed if required. The next field is the Title, this is the name given to the document in question and must be typed in.

Following this, both the "Owner" and "Author" fields can be populated. Generally these names will be the same and will be reflective of the individual responsible for writing and updating the document in question. In some instances further into the lifecycle of a document these names may diverge to capture a change of ownership in the event the assigned author is no longer in post for example. The names for both fields can be selected from the list of all names entered into Q-Pulse.
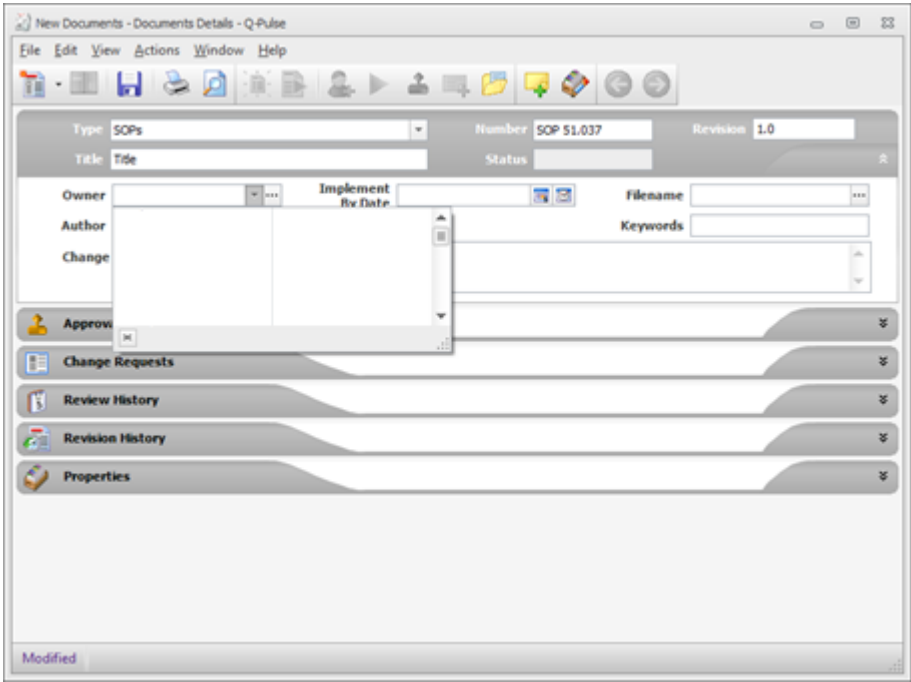
The next field which can be populated is the "Implement By Date", in the event it is a requirement to meet a deadline for the release of a document this field can be used to track progress. This is not a mandatory field and if approval and release of the SOP is not time sensitive then this can be left blank.


The next field "Filename" is where the document itself is attached to the record, to achieve this select the button with 3 dots beside the field to open the document selection window.

This will open the following window which can be used to navigate through your local machines file structure and select the appropriate document. When this has been attached, select OK to add the document to the record.
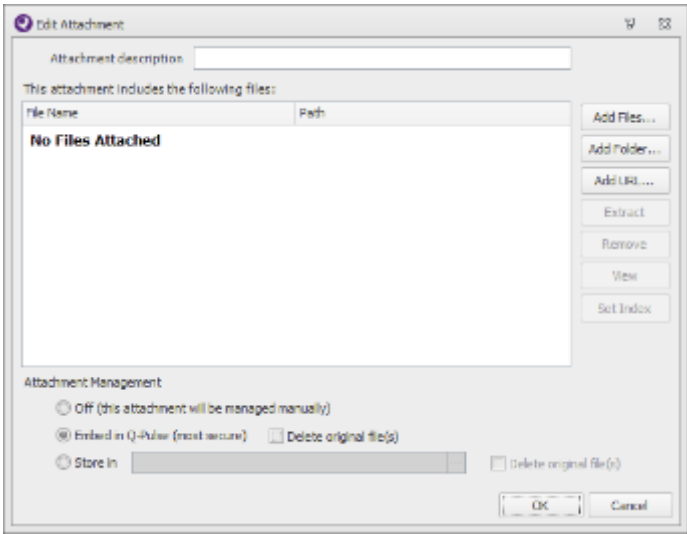

The final field for completion in this section is "Change Details", this will become more relevant through the life cycle of the document and can be used to explain how this document differs from previous versions. In the event of a first release, used the words "First Release" for example.
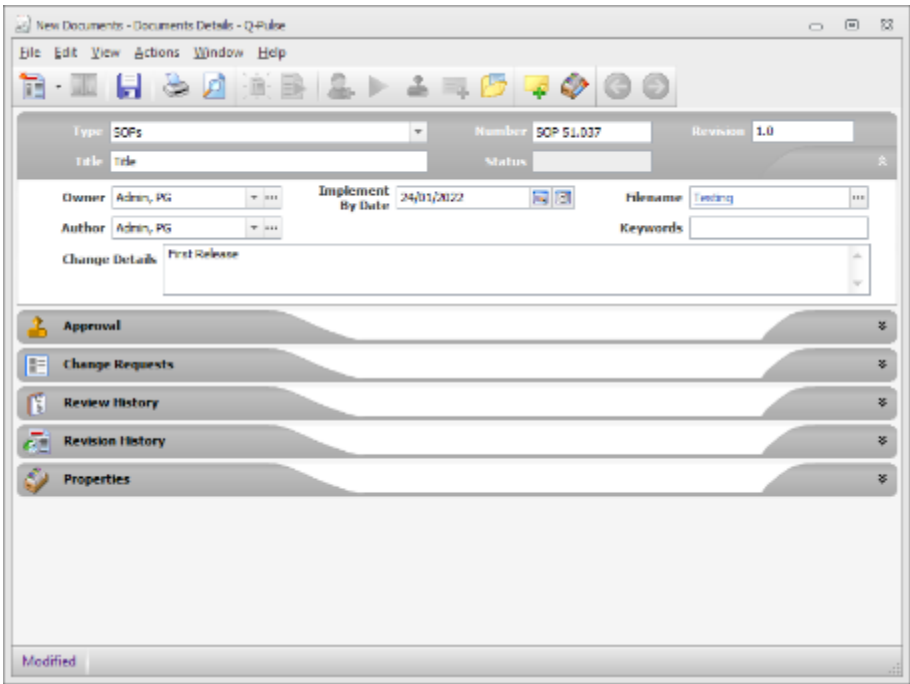
The next section is to then set up the approvals and sign off of the document, before this is achieved you must save the document record as completed so far. To do this select the save button at the top of the record.

When saved, expand the "Approval" ribbon in Q-Pulse and from here you can add the names of approvers as required. This is achieved by selecting the button to the right hand side with the picture of the person with the green plus symbol.
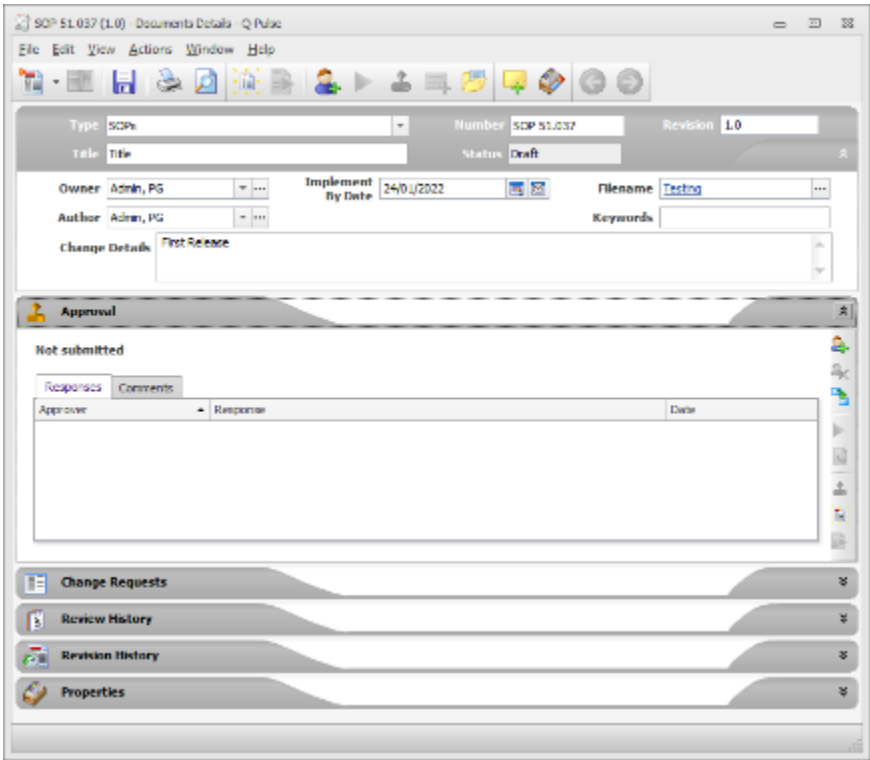
By selecting this, a new window will open from which you can search for users within Q-Pulse as shown below. Repeat this process until all required approvers have been added.
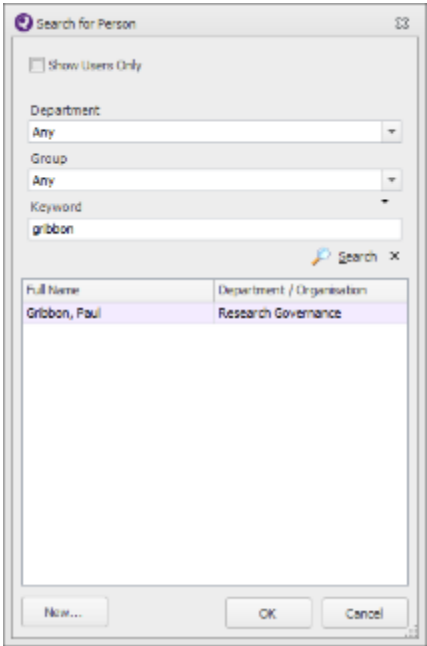
This will add all of the named approvers to the record as shown below, from here you must then select the order in which the approvals are conducted by select the workflow order button.

This will then open the following window, you can stagger the approval order for those assigned by selecting the name and using the side arrow as shown below to change the order of approvals.
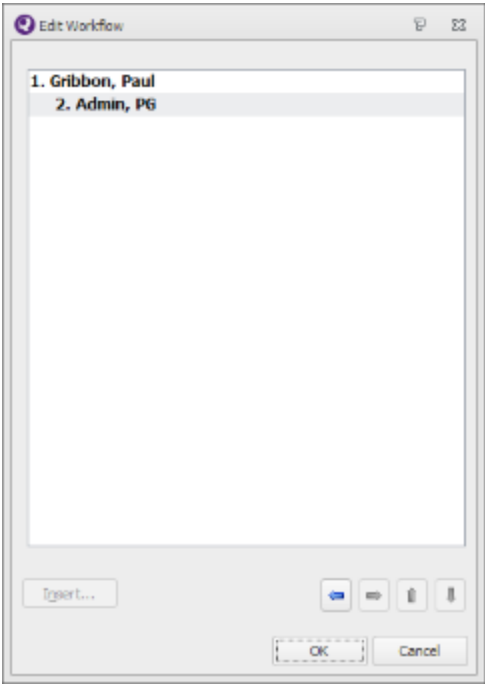
In the example shown, this has changed the 2nd approval to have a number 2 beside the name which means they will be the 2nd to sign after number 1 has completed their approval. This can be expanded as required to 3rd or 4th approvers also.

When the appropriate approvers and workflow have been assigned, you can then return to the document record and release the document for approvals. This is achieved by selecting the green play button to open the approval wizard. Once opened, select next to progress.
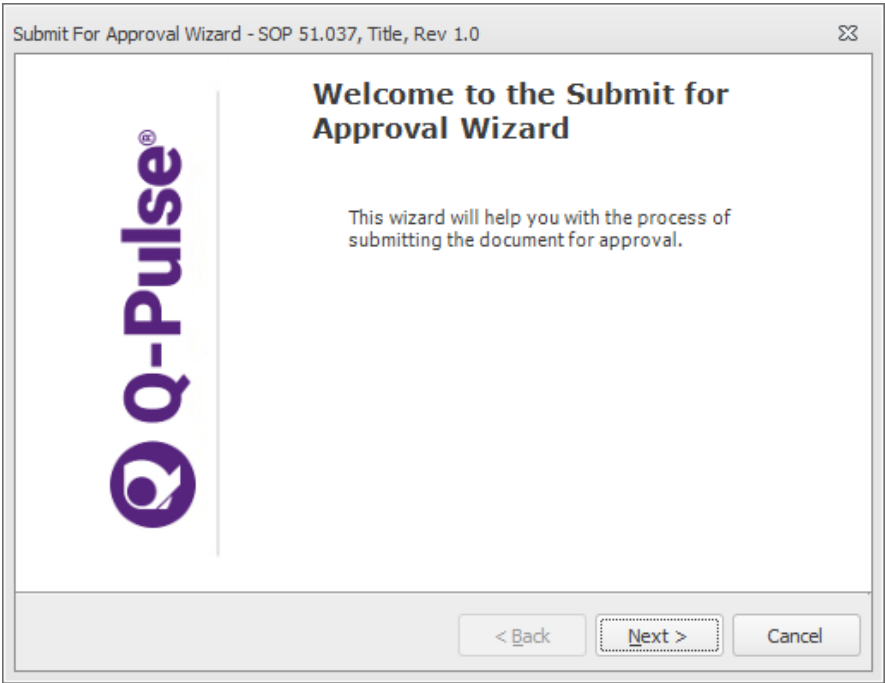
The next window then confirms the version number of the document and room for comment to the approvers, in this case you can add "first release" or any relevant details for the approvers. Select Next to continue.

The final page will provide a summary of what the actions will be in relation to the approvals, if this is all correct then select "Finish" to begin the approval process.

Once the approval process has begun, it shows as a statement that it has been submitted for approval and the approvers will be colour coded. Yellow shows that the approval action is with the individual, red shows it is pending and they have not yet been notified and green shows they have submitted their approval response. This can be misleading as it will appear as green even if the decision was to reject so must be reviewed.
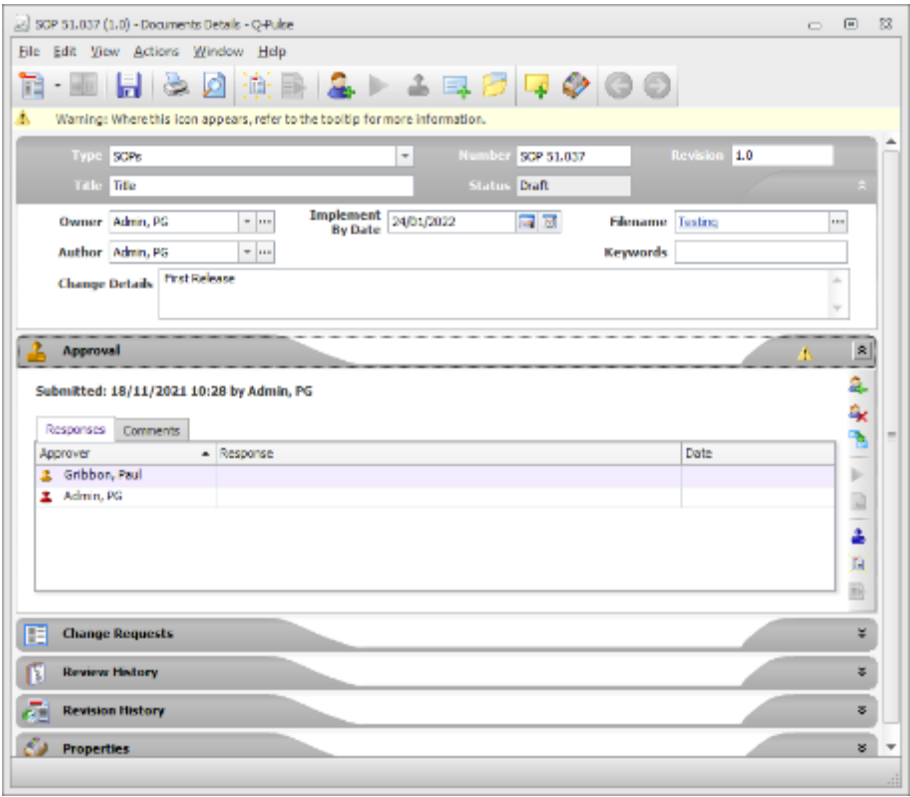
When an assigned approver has been notified of an approval action, Q-Pulse will send them an E-Mail to detail the required action. An example of this is detailed below.

This E-Mail will contain some basic instructions and a link to a how to guide to complete the required actions.
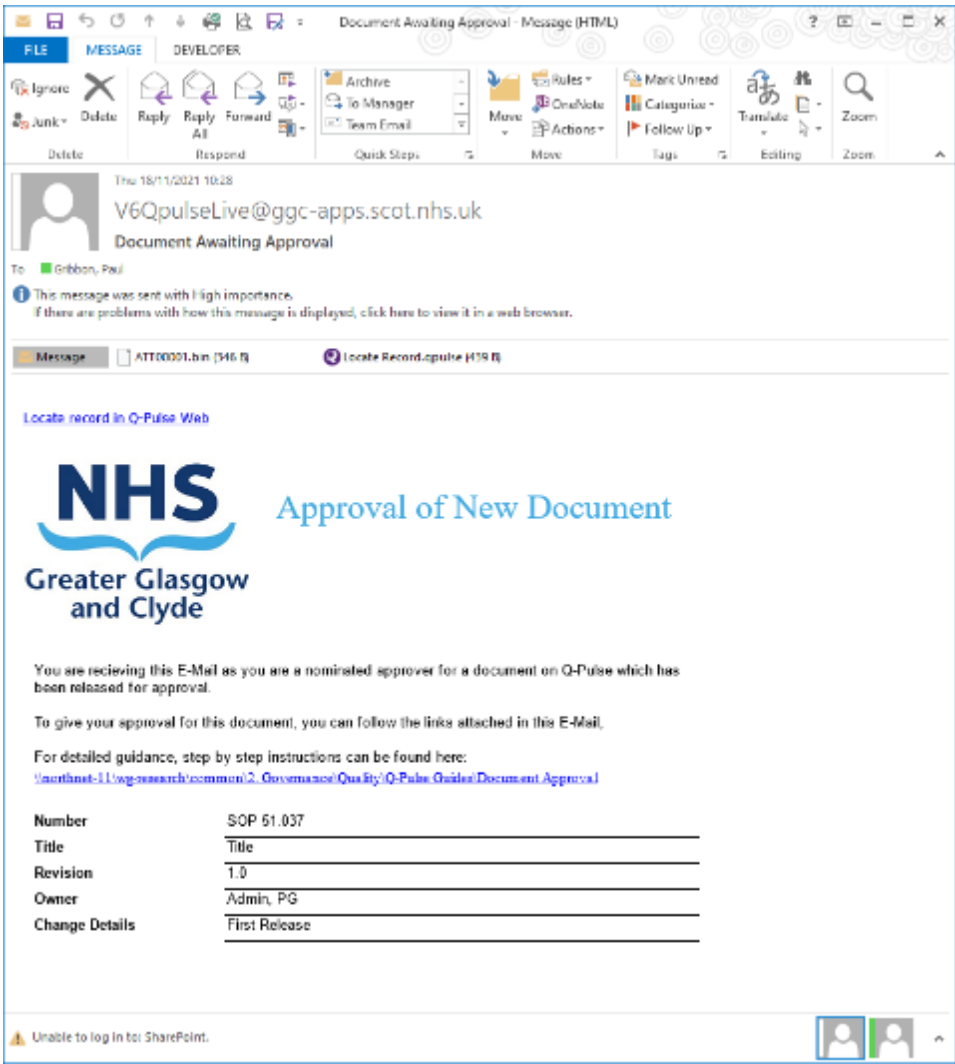
When a user logs in to complete an approval action in Q-Pulse they will be greeted with a window similar to the window shown below, from a drop down they can select "Accept" or "Reject" and make a comment in line with their decision if required.
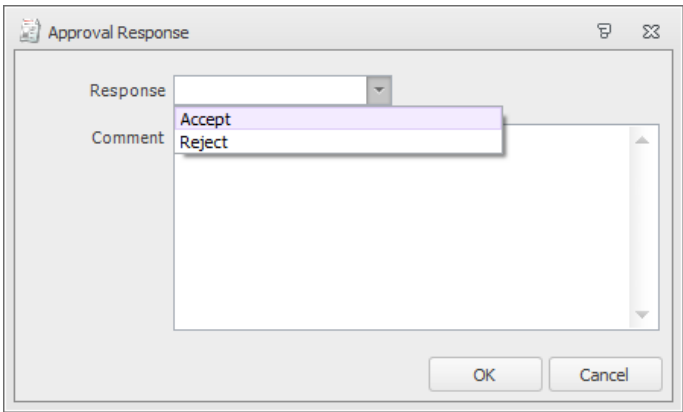

When all approvers have responded, the record will update to show all have responded and their icon will appear as green.

Guideline 50.023A - Version 1.0
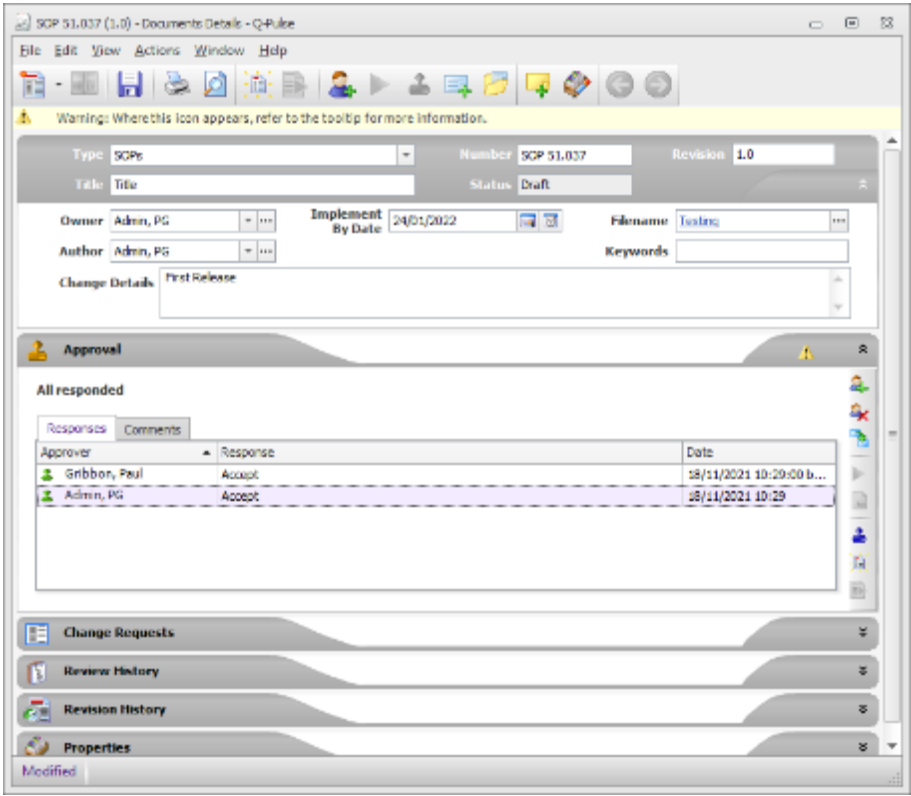
When all approvals have been returned, the document will then be made active by selecting the "Activate Document" button

Guideline50.023A_v1.0.docx

This will then open the following wizard to make the document active, to continue select the "Next" button.
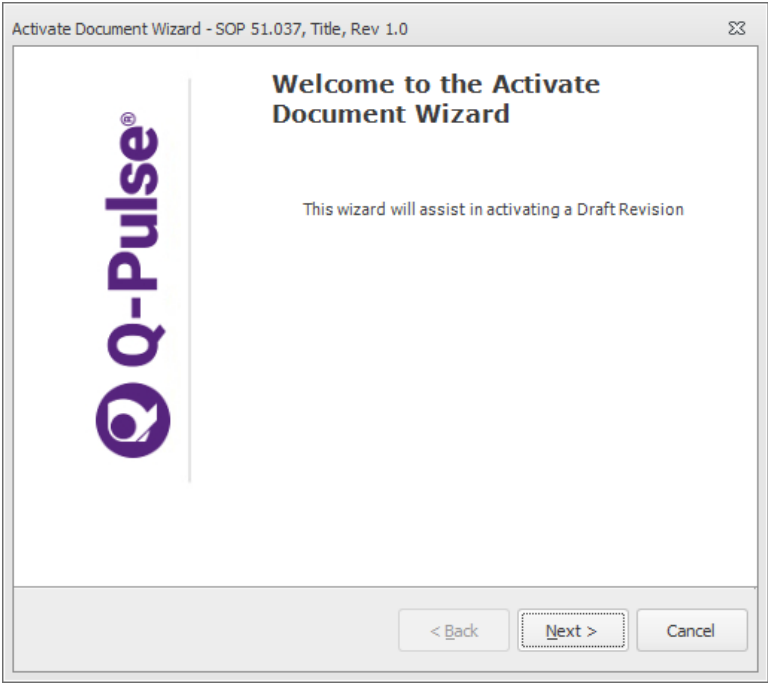
The next window will then confirm several details, the "Active Date" field will default to the current date but can be overtyped to reflect a different date if required, when completed, select "Next".
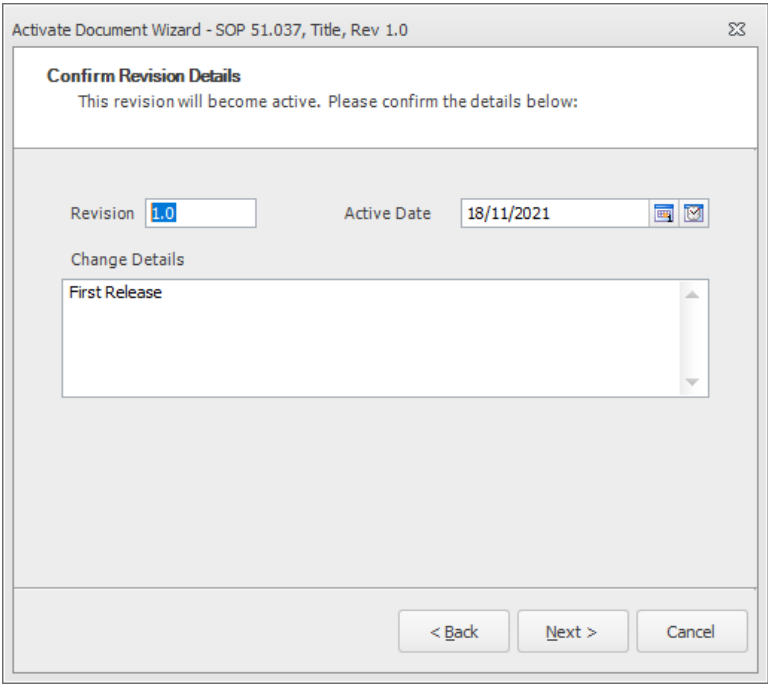
The next section is to then assign the appropriate names for the "Read and Comprehend" and "Notification" process for documents detailed in section 7. The option to automatically distribute is not selected so this action must be completed manually after, select "Next" to continue.

The final page will be a confirmation of the actions to be taken, if correct select "Finish".

This will then result in an active copy of the document being available on Q-Pulse, the "Implement By" date will now have changed to an "Active Date" and "Review Date".

Once this is complete, a copy of the document will be sent to RCB for release on the CTU website.

3.   Creating a new Version of SOP record (QA)

To create a new revision of a document in Q-Pulse, the first step is to locate the record of the document in question. If it is a known or specific document, it can be searched for under the document tab from the front launch screen. To achieve this, expand the document tab and search for the document using either its number or title.
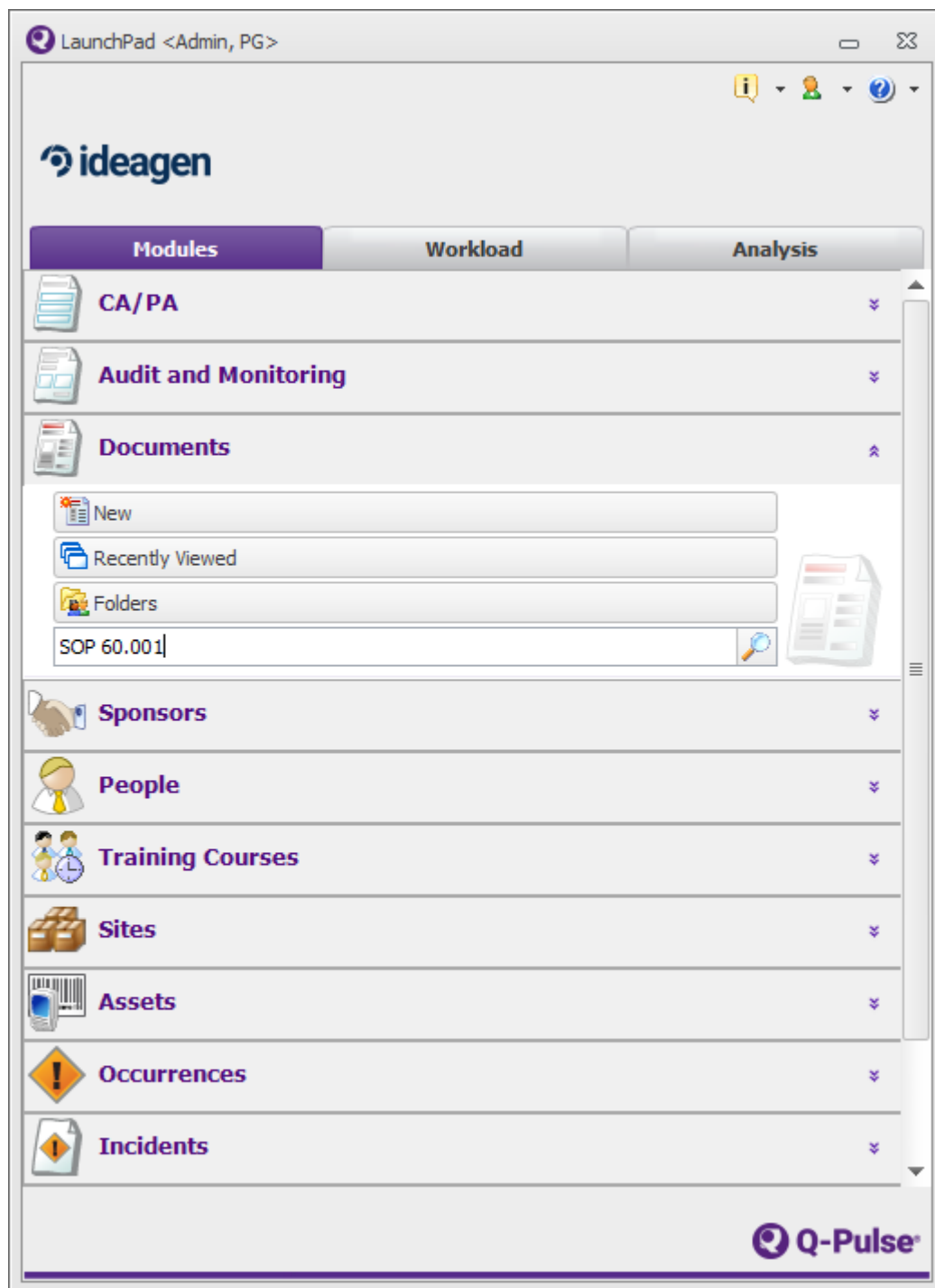
This will open a new window with a list of the returned documents. When the document record has been located, there are a number of ways to then create a new revision of the document.
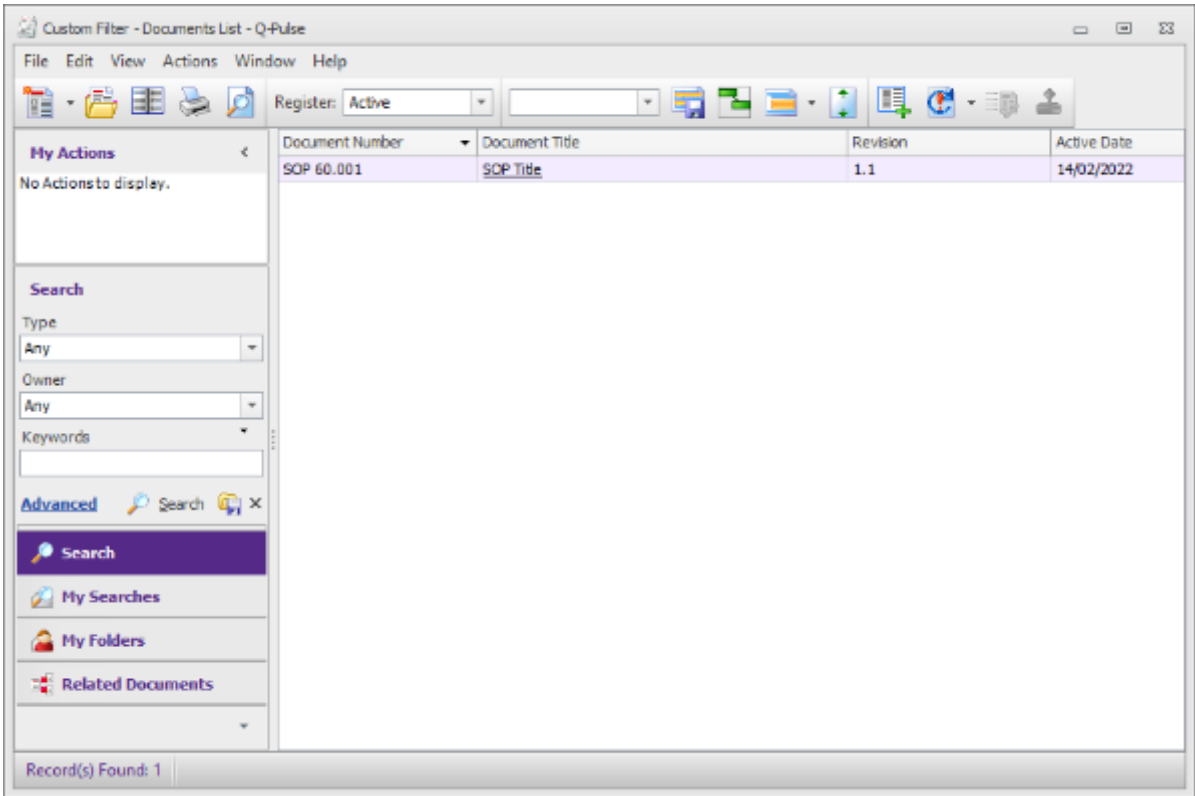

The first option, when the record has been located you can right click on the line listing and select "Revise Document >Draft (Using Approval)"
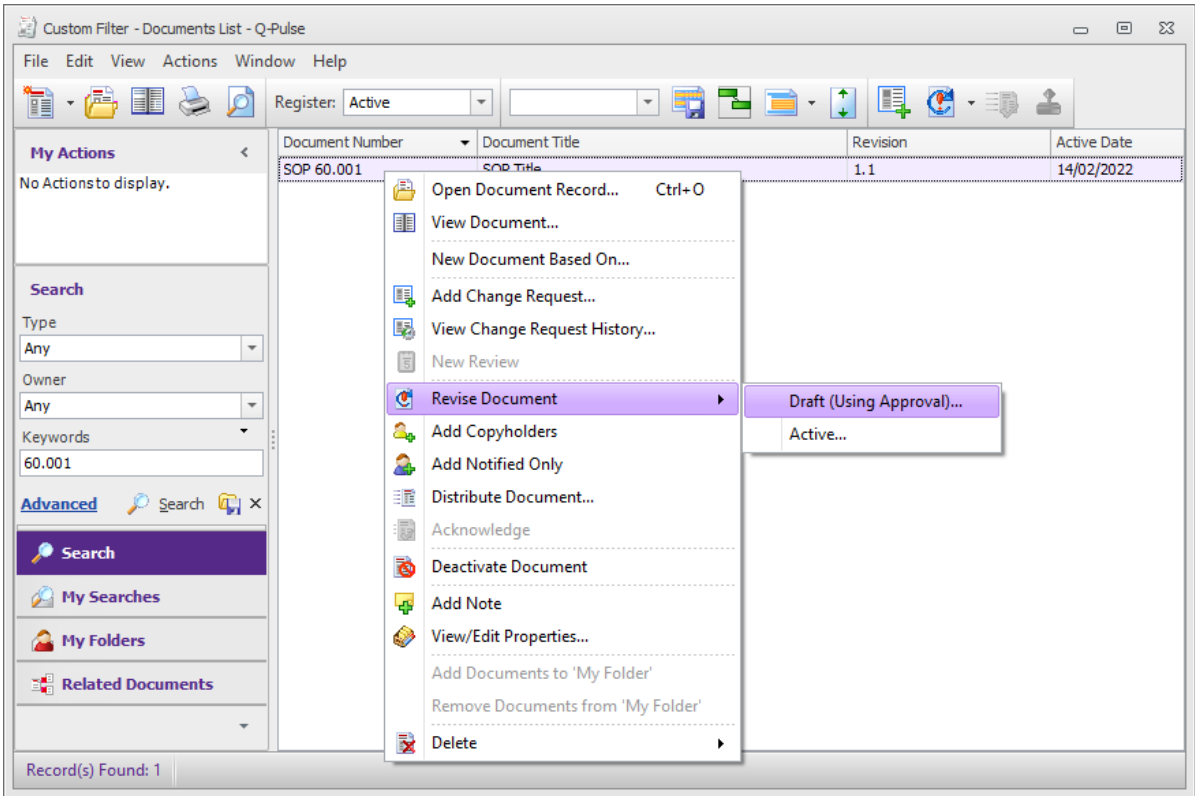
Alternatively, from the same location when the document in question is highlighted you can select "File > New > Revision > Draft (Using Approval)
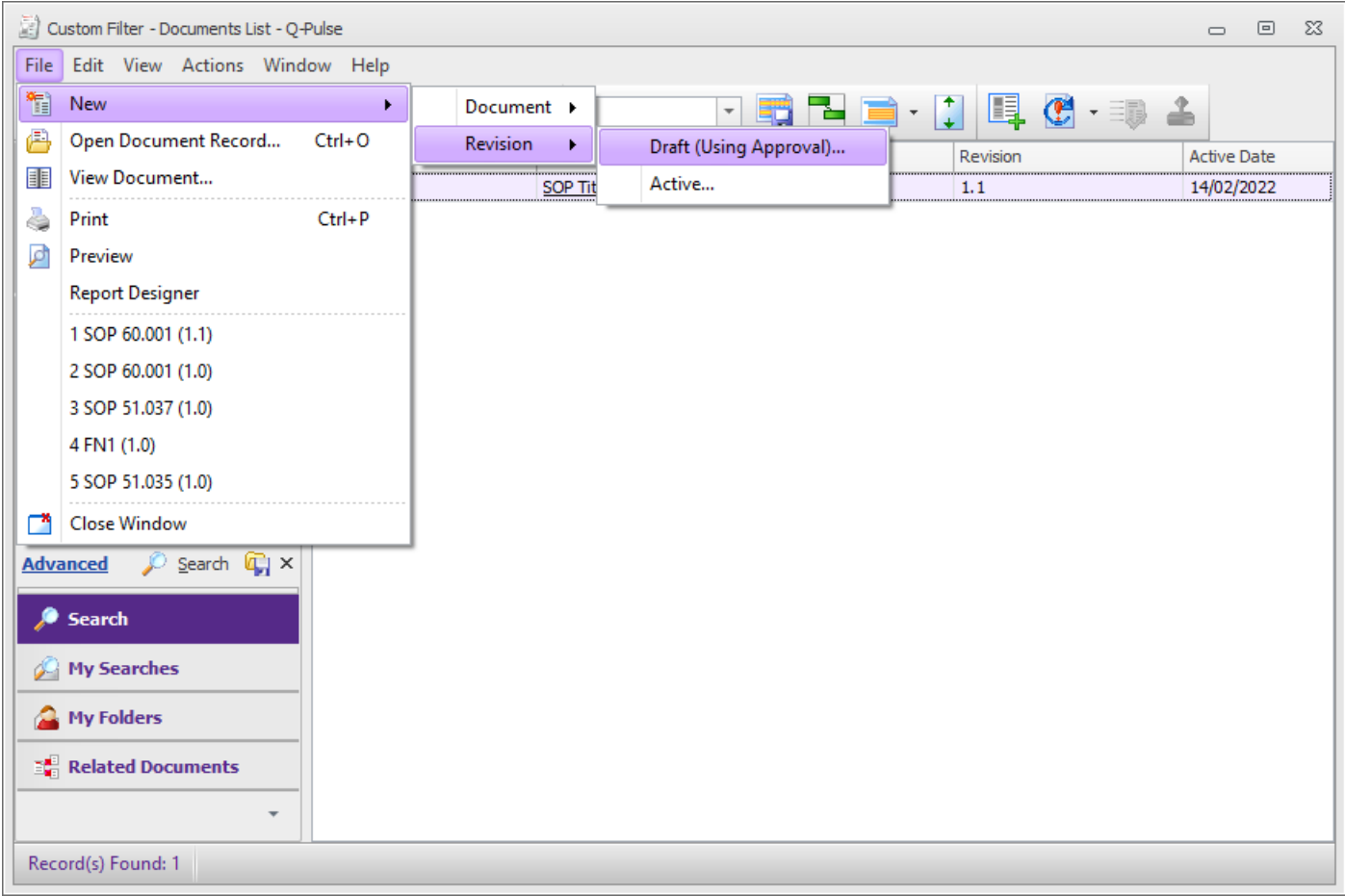
The final option is to first open the record for the document question, from here select "File > New> Revision > Draft (Using Approval)
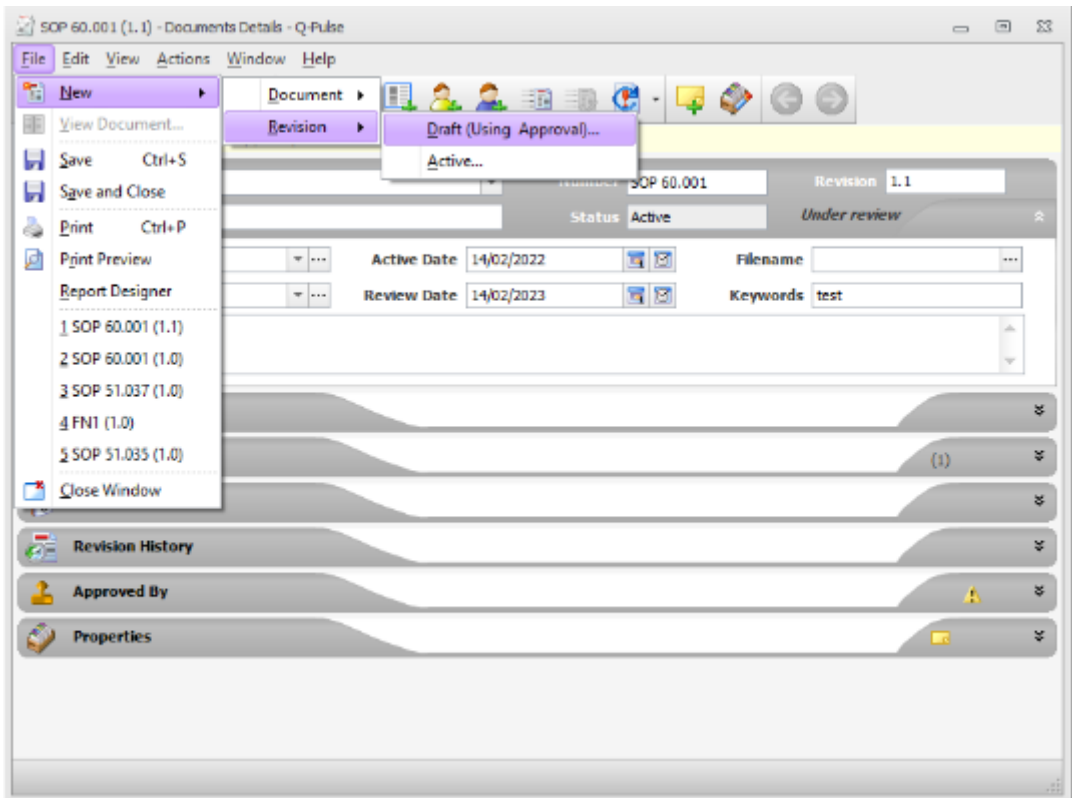
All of these options will result in the following window being opened to start the wizard which will guide you through the process. Select Next to continue.
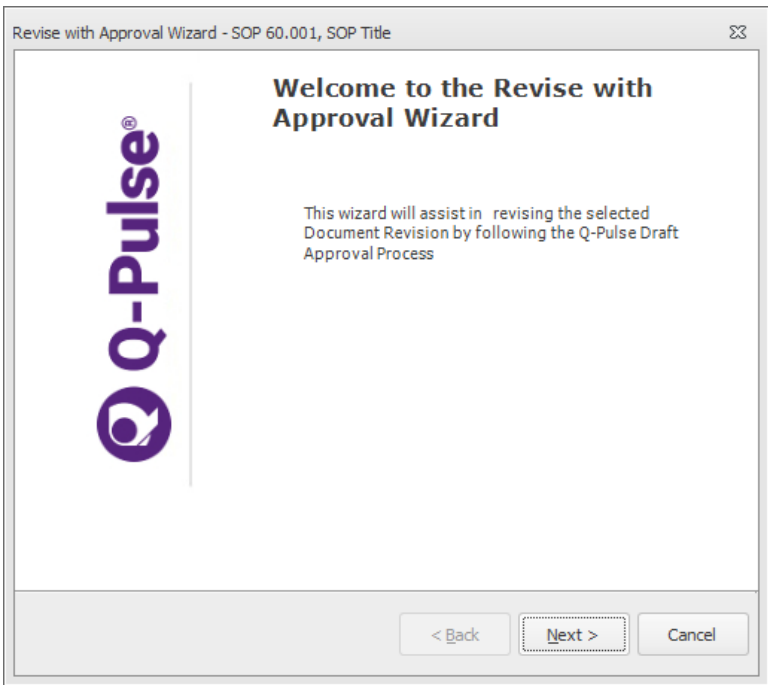
The next page will present you with a new window in which the details for the document can be updated, this includes the revision number and the title. Revision numbers can only be increased in full number increments, increase this number to the next in sequence. Select Next to continue.

Revise with Approval Wizard - SOP 60.001, SOP Title

Confirm Draft Document Details
Confirm the details of the new draft document:

Type   SOPs   Number   SOP 60.001

Revision   1.2

Title   SOP Title

< Back   Next >   Cancel

If any change requests are raised against the document which are still pending implementation a window will appear asking if you wish to implement them in this revision. Select any that are appropriate at this stage and select Next, this is covered in more detail in Section 5.

Revise with Approval Wizard - SOP 60.001, SOP Title

Identify Change Requests to Implement
Check those change requests which you intend to implement in this new draft:

Number	Details	Implement
CR115	Enter the details of the change request here	☐

< Back   Next >   Cancel

The next page will contain the list of assigned approvers for the document, if no change requests were present this would have appeared previously. If approvers have already been assigned to the existing version of the document they will be carried forward.

The list of approvers can be updated by using the add and remove approver buttons on the right hand side. The workflow must be set appropriately to ensure the approvals happen in sequence. The left and right arrows can be used when a name is highlighted to ensure they are stacked appropriately.
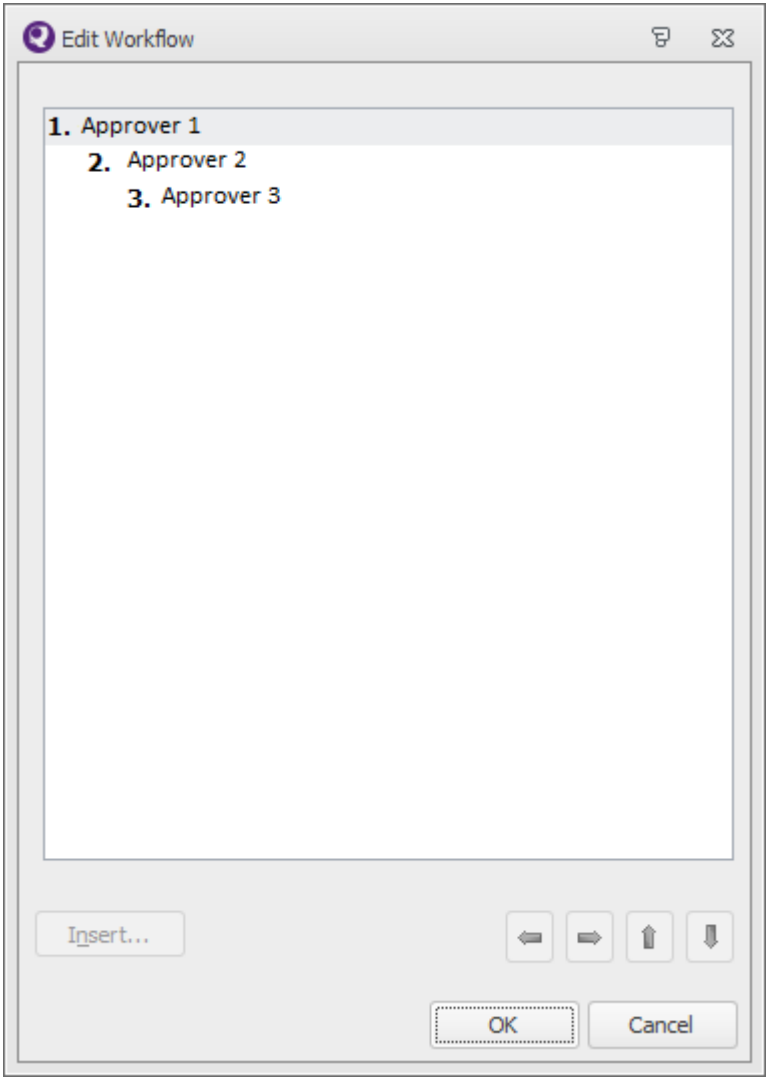
When the approvers have been appropriately assigned, select Next to continue the process. At the bottom of the page there is an option to automatically submitted for approval when created, if this is selected the approvers will be contacted as soon as the document is created to approve.

The next page will allow you to upload the appropriate updated document, this is achieved by selecting the button with the 3 dots to the right of the field. This will open a standard document selection window, locate the document and attach.

When the document is attached, select "Next" to continue.

The final page will act as a confirmation of all the details entered, if all correct then select "Finish"

This will open a new window with updated document record.

When the new revision window is opened, enter the appropriate "Change Details" with an explanation of the difference from the previous version.

When an updated document has been created, the previous version history is visible from the "Revision History" tab.

If the box to automatically submit the document for approvals was not selected during set up, it may be submitted at this stage. To submit a document for approval, expand the approval tab from within the document record and select the submit for approval button on the right hand side.

When submitted for approvals, the icon beside the names will change colour as it moves through the process. The first user will appear as yellow to show the action is with them, the other will remain red as they cannot yet complete an action. Once an approver completes their approval action the icon will change to green.

When a user has been requested to complete an approval action they will get an E-Mail notification which contains a how to guide on completing.
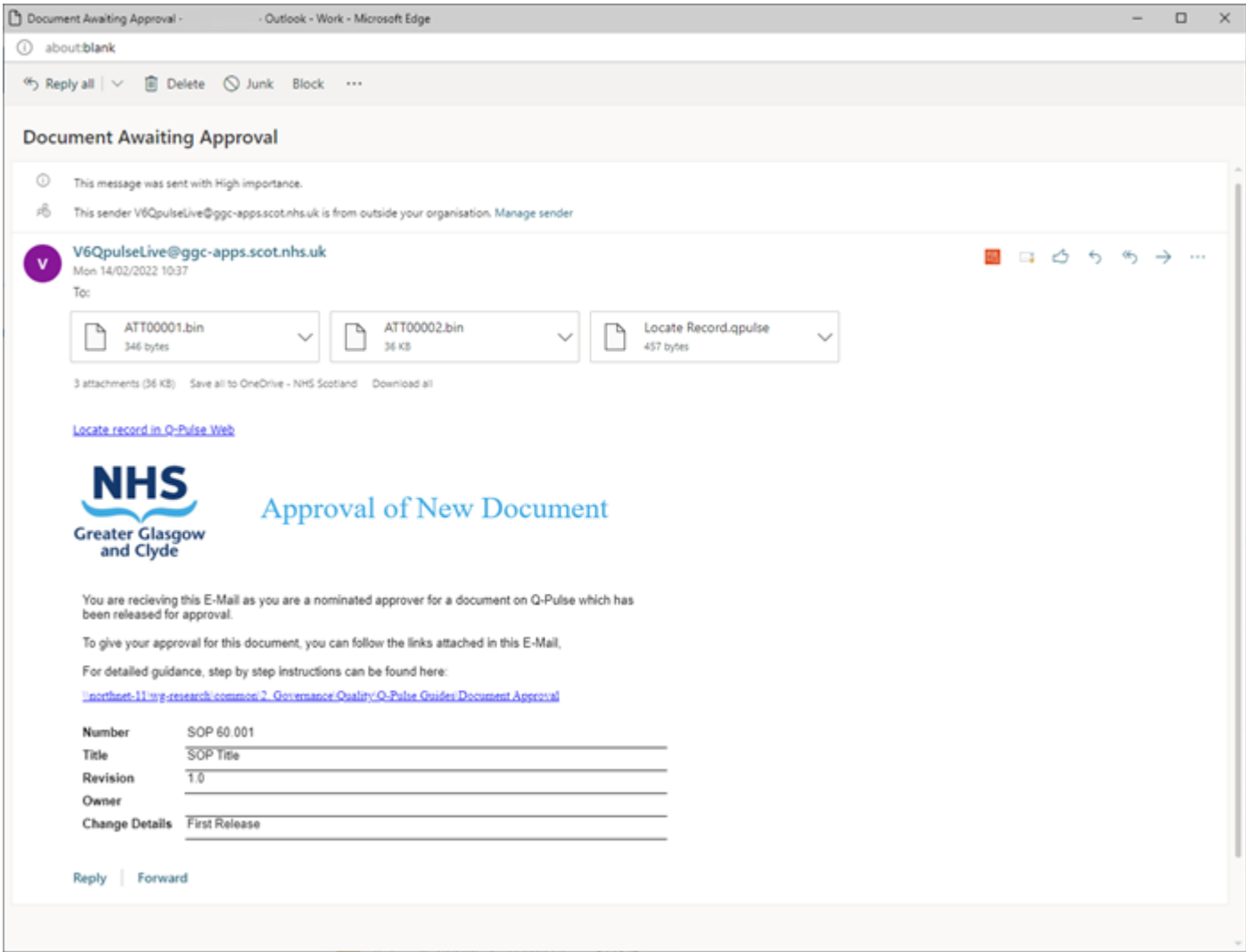

When all approvals have been completed, follow the same process as detailed in Section 2, page 14 onwards, to make the document active.

4. Make Document Obsolete (QA)

During the review of documents it may be required to remove a document from Active status as it is no longer required. This is achieved by completing Form 01.006C and actioned by the Quality Assurance Manager or appropriate designee. To carry out this action, navigate to the record in question and select "Actions >Deactivate Document", this will then launch a wizard to guide you through this process.
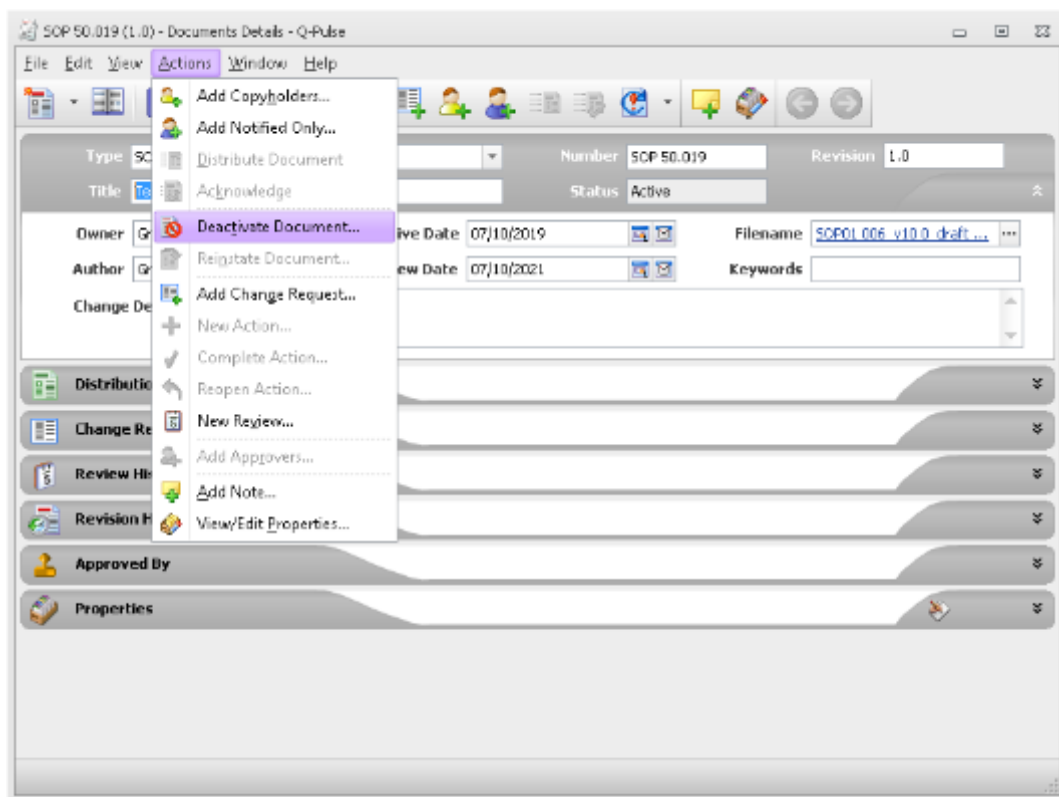
The first page of the wizard is a confirmation of the action to be taken, to proceed with this process select "Next".
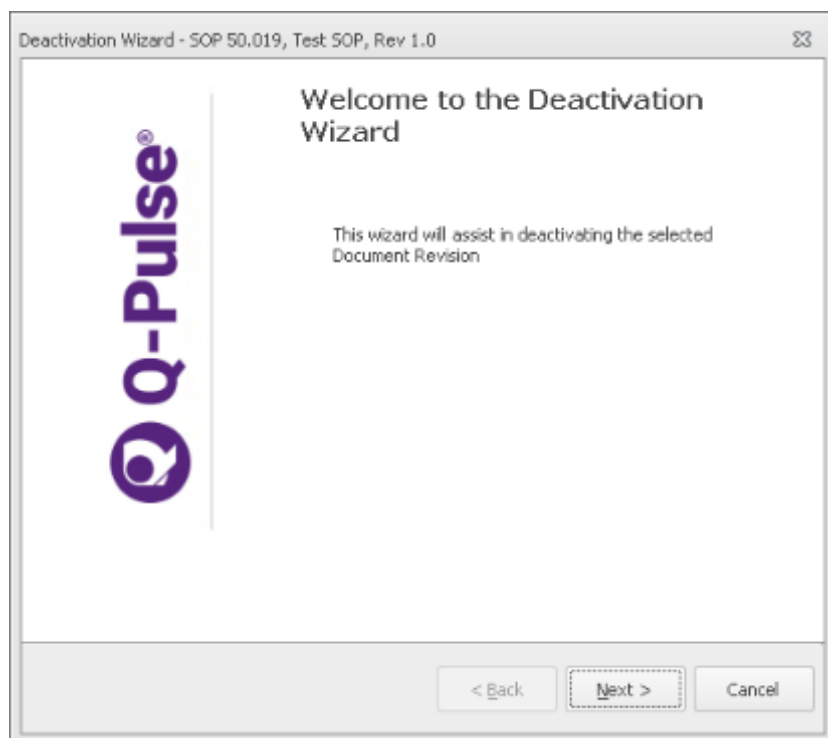
The next page is to select whether the document is to become Obsolete or Inactive and state the reasons for this. Either option will remove the document from Active status and can be selected dependent on the circumstances. Once this is completed, select Next.

The final page is a confirmation of the action to be taken, if this is correct then select Finish to confirm.

Once this has been completed, the status of the document will be changed to reflect. The record itself will still be accessible to act as evidence if ever required.
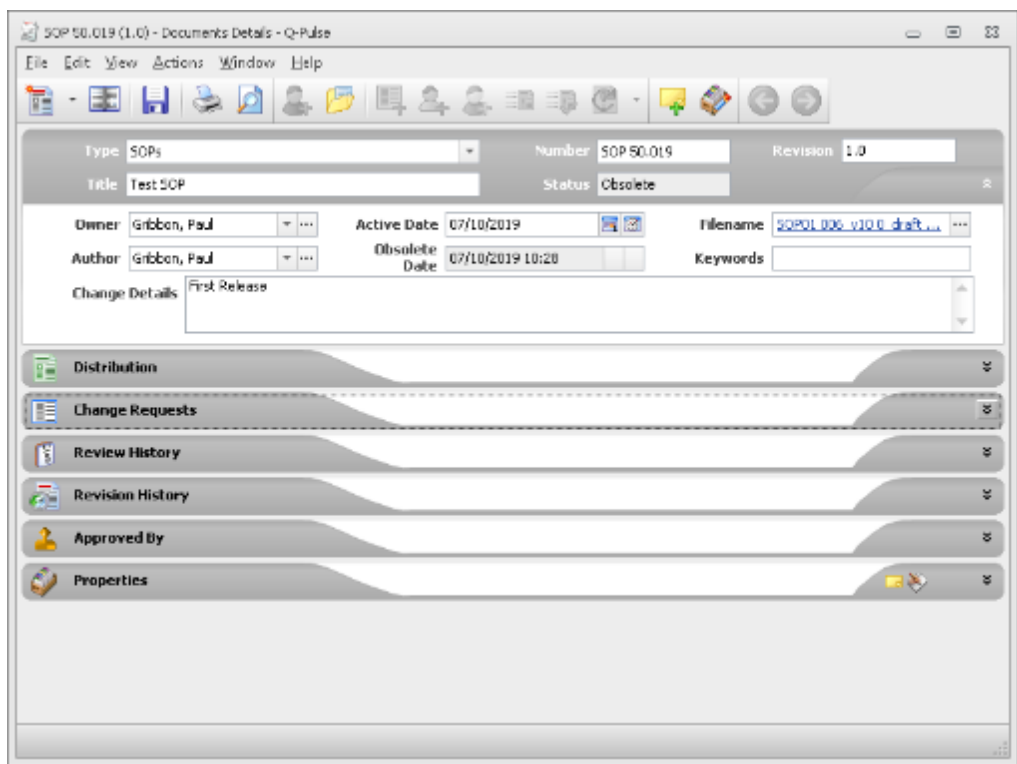
Once a document is deactivated in this way, an automated message will be sent to the Author, Owner and Copyholders of the document to inform them of this.
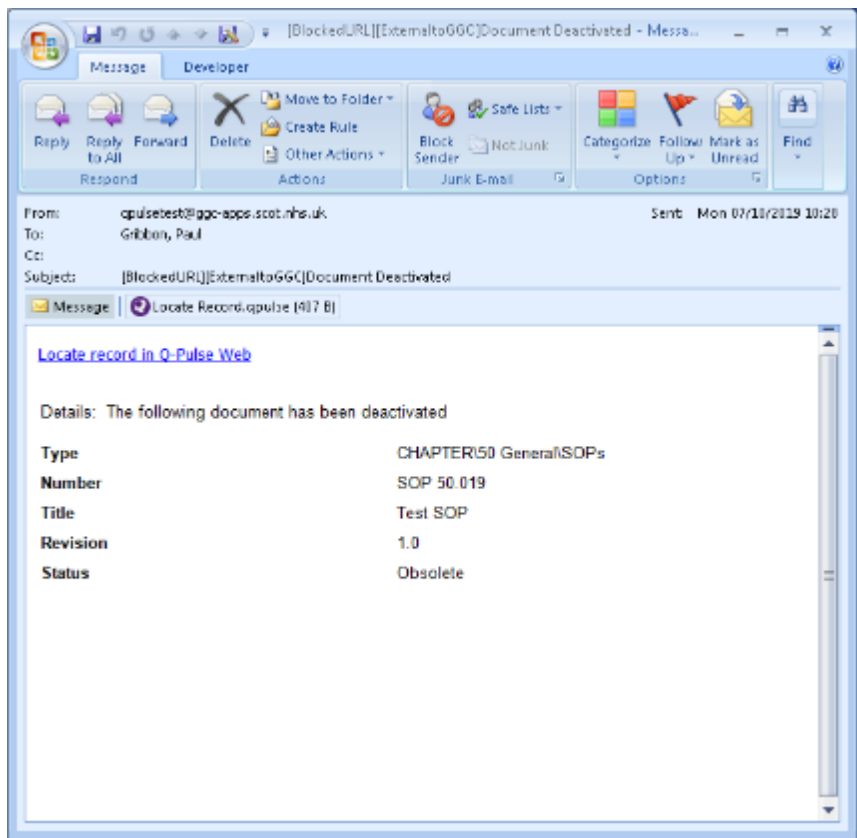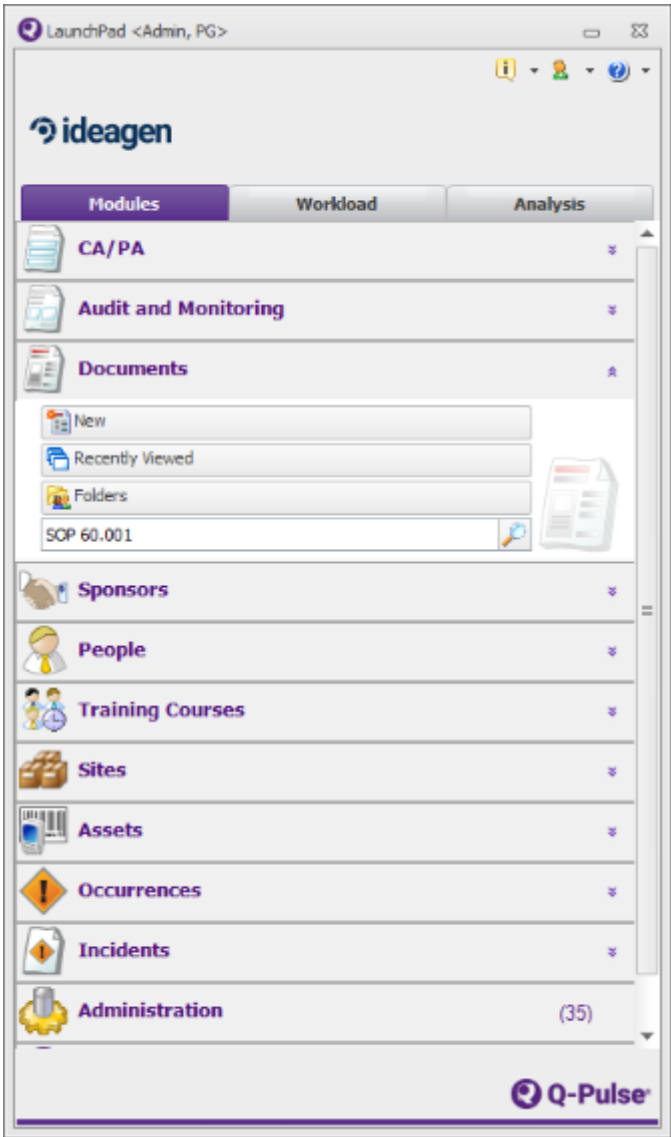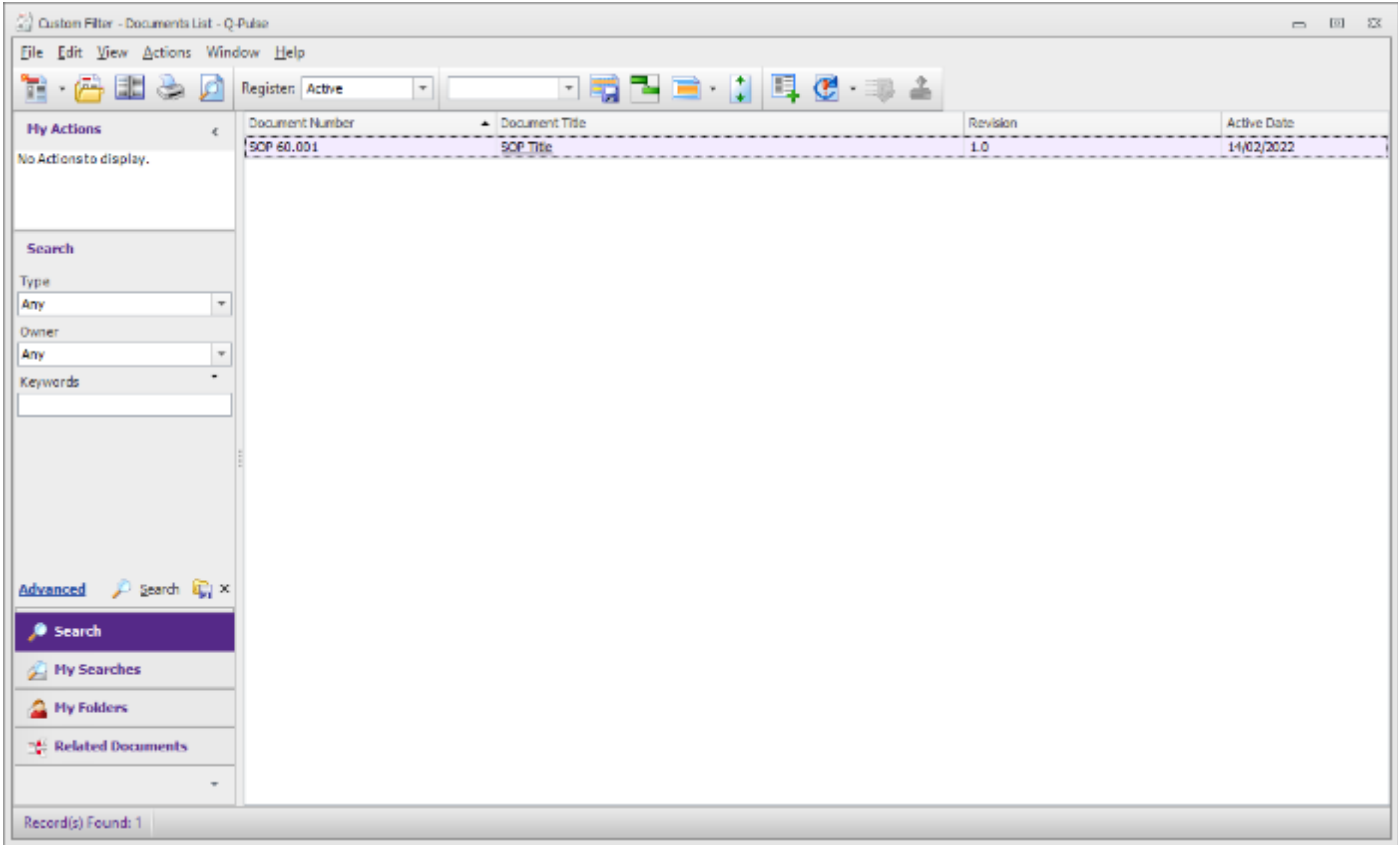
5. Change Requests

A Change Request is a record held against a document within Q-Pulse to act as a reminder for actions to be taken during its review, as a notification process for issues with a document by a stakeholder or for the purpose of seeking clarification. All Q-Pulse users with access to the document module will have the ability to raise Change Requests against a document.

5.1. Raising a Change Request

A change request can be raised against an SOP, Form or Guideline by any Q-Pulse user with access to that document. In order to raise a Change Request, the document record must first be located and opened. This can be achieved by expanding the document tab from the front launch pad and using the search bar to search for it by its number or title.

This will open the document window with a list of documents that match the criteria entered.

There are 3 different ways in which a change request can be added to a record, the first option is to right click on the line listing for the document in the returned search results and then selecting "Add Change Request".
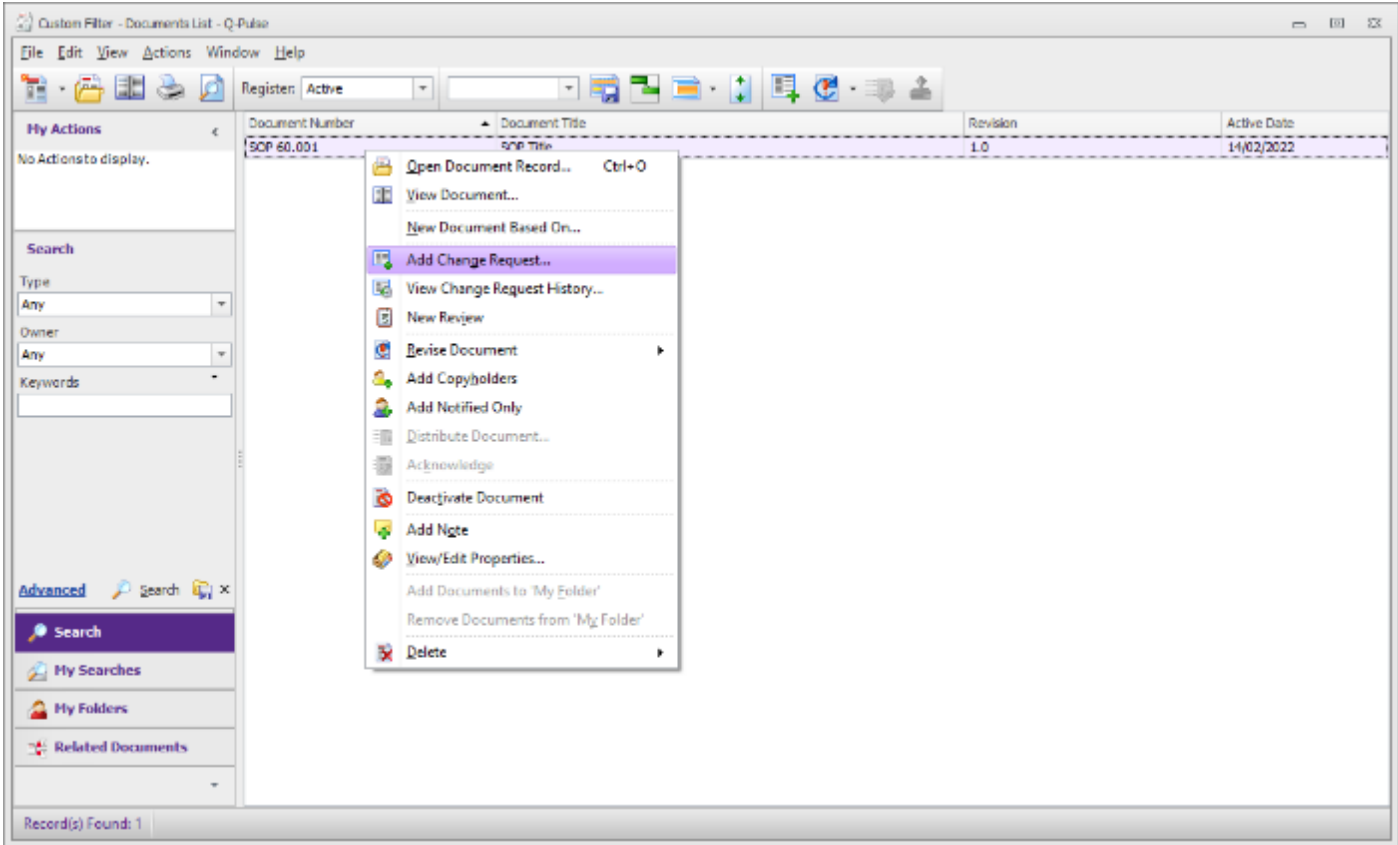
Alternatively, you can open the document record and from this window select "Actions > Add Change Request"
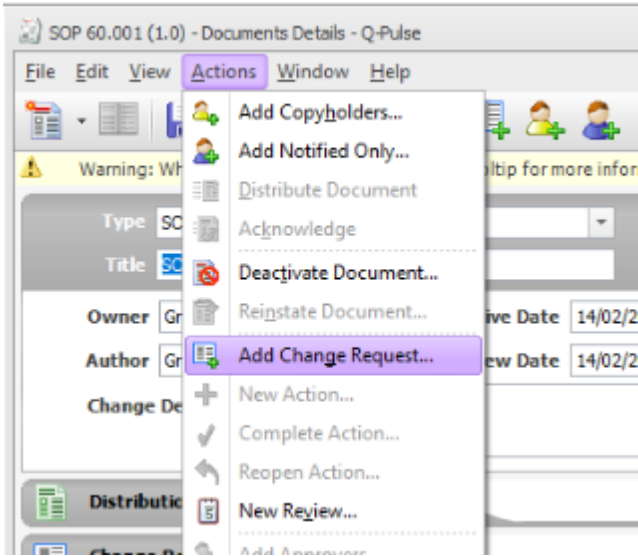
The final option is also within the document record window, expand the Change Request tab and click the add change request button.

All of these options will result in a new window being opened, from this you can record details of the change request you wish to create.

Several fields will be pre-populated, the name of the account you are logged in with and the current date as well as a default severity rating. Each field can be updated.

The first step is to use the "Details" field to record a description of the issue, clarification, suggestion or question as required. This should be of sufficient detail that the owner of the document is able to understand the full detail.

If appropriate, supporting documents can be attached. For example, a track change copy of an updated version of the document, a report or form produced as an output of the SOP, email correspondence etc. Raised by and Raised date can be changed if being completed on behalf of someone else and the appropriate severity can be selected. For example, if it is a note to correct typos is can be Low, a suggested improvement which may impact on outputs may be medium or a critical issue which will immediately impact on a process would be High.

To add a document in the supporting information field, select the button to the right with 3 dots to open the following window, from here files can be added using the "Add Files" button. This will open a standard Window document explorer window where the appropriate document(s) can be selected and added. This process can be repeated for multiple documents in this field. This will add the documents to the Change Request for review by the document owner.

When all fields have been satisfactorily entered, press the OK button to add this change request to the document record. As can be seen below, a new line has been added to the change request tab to show the details. The Change Request will be assigned a unique ID number when you press save on the document record, you will be prompted to save before you can close the document record. If you do not save, the change request will not save to the document record and be discarded.

As can be seen below, when saved an ID number will be assigned.

5.2.   Review a Change Request

When a change request has been created, the document owner will get a notification with a basic overview of the details as seen below.

A document owner is then able to log in to Q-Pulse, navigate to the document record in question and open the change request record. This will produce a new window with more options than the one shown before.

From here, all fields not greyed out can be edited, the original details can be expanded if required, more attachments added, owner change, severity changed and a response provided.

When the owner has reviewed the details and made a determination they are able to either "Accept" or "Reject" the change request by updating the status field. If they decide to reject, the change request will no longer be active and not play a further role in future actions but be retained as a record. If the decision is made to accept, it will remain for future document reviews and updates. An optional implementation date can be entered to track and manage a timescale for implementation.

As can be seen in the example below, 3 change requests have been added with 3 different statuses.

When the document is to be updated, a prompt will appear asking if any change requests are to be implemented, if not selected for implementation they will be retained on the record until future updates. This field will not show any change requests which have been rejected.

If a change request is marked as having been implemented, the record will be updated in the "Implemented In Revision" field to show when the fix to the change request was implemented.

6.   Document Review

### 6.1.   Creating a Document Review (QA)

To create a document review record in Q-Pulse, the first step is to locate the record of the document in question. If it is a known or specific document, it can be searched for under the document tab from the front launch screen. To achieve this, expand the document tab and search for the document using either its number or title.

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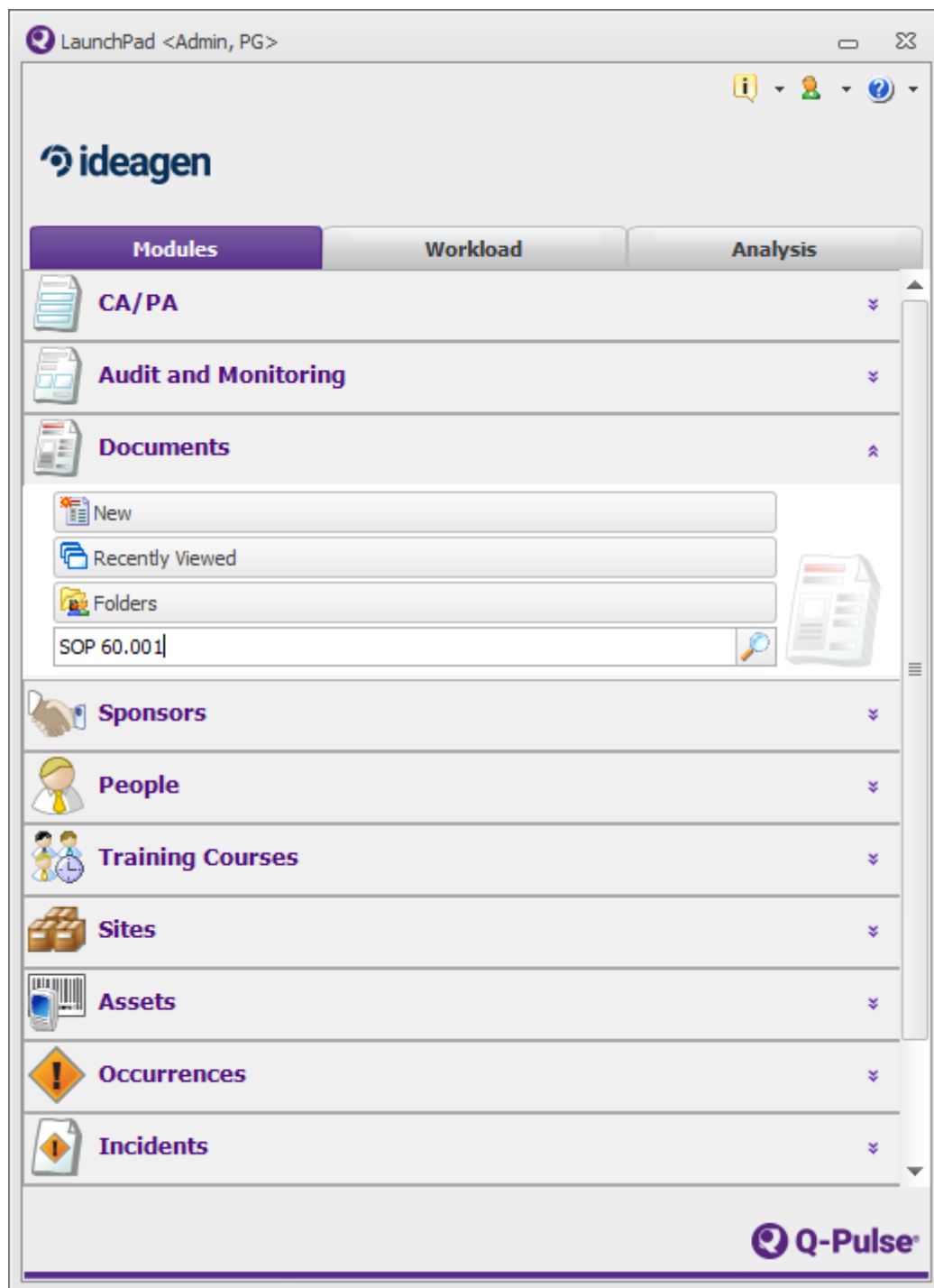
This will open a new window with the document listed. If it is a list of documents who are approaching their review period, the advanced search feature can be used. In the document window shown below, on the left hand side select the "Advanced" button with highlighted blue text to open a query window.
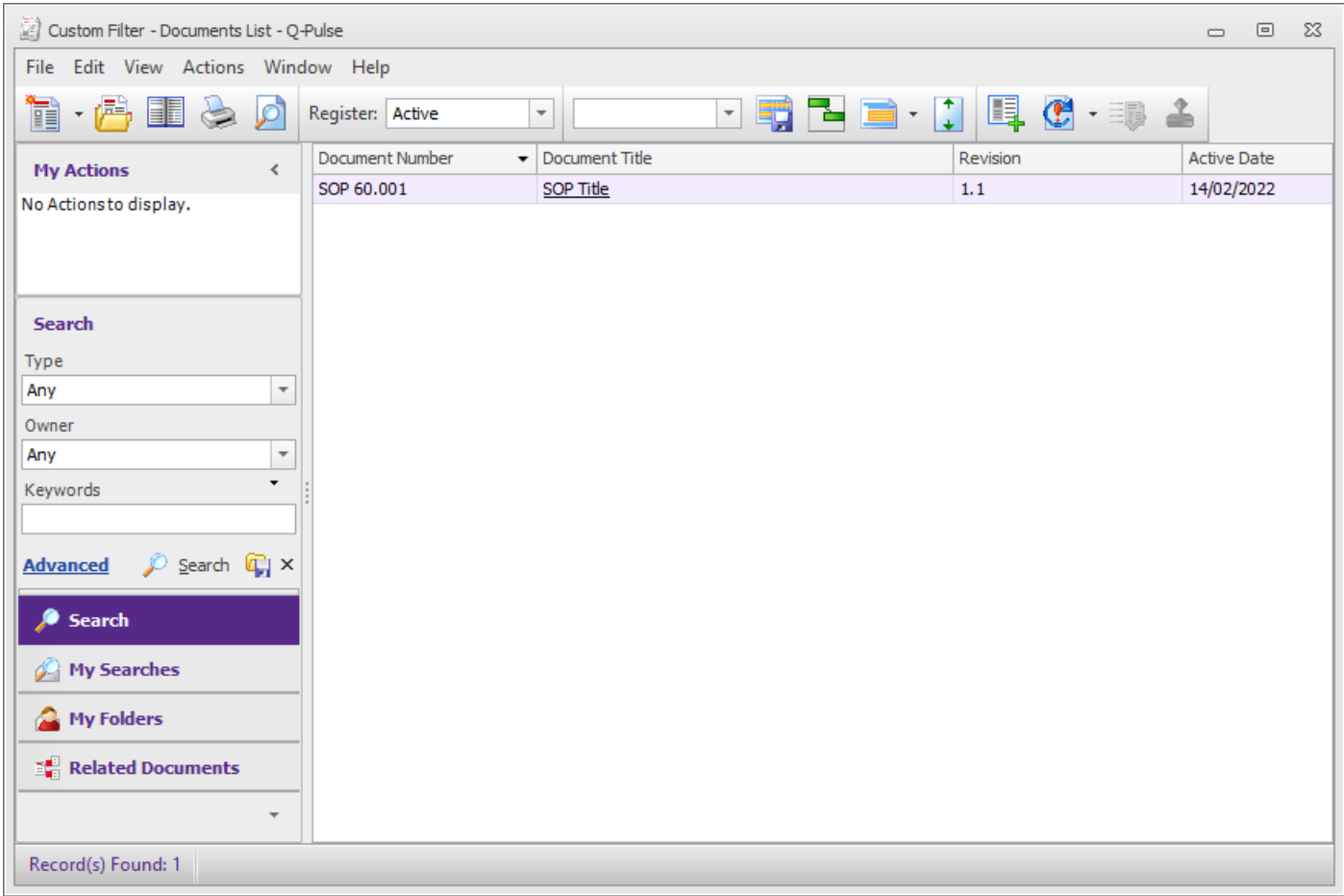
This will open a window, clear any existing content by pressing the "X" buttons beside any existing lines to have a blank record as shown below. New conditions of the search can be added by selecting the "And" "Or" options.
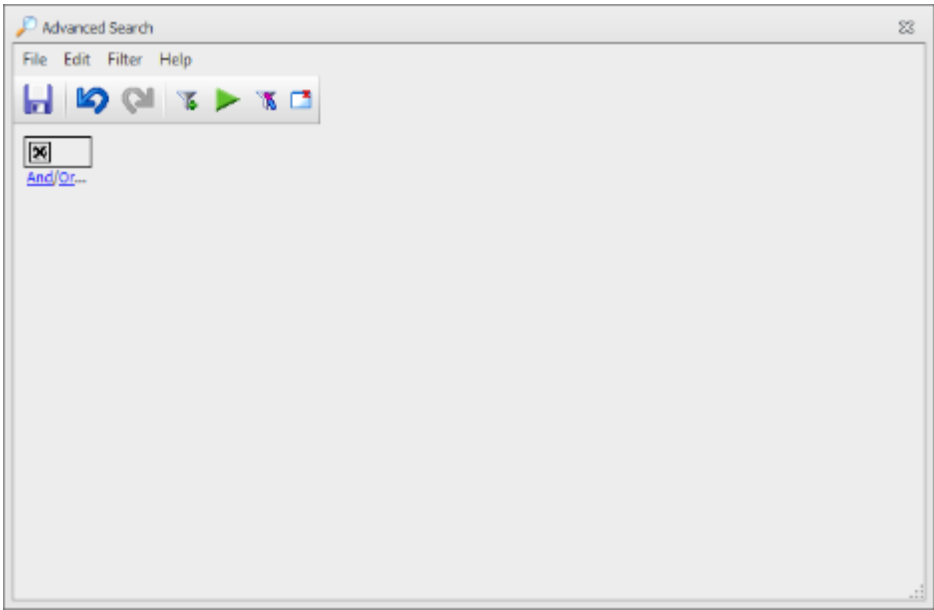
When you select "And" a new line will appear with blank fields.
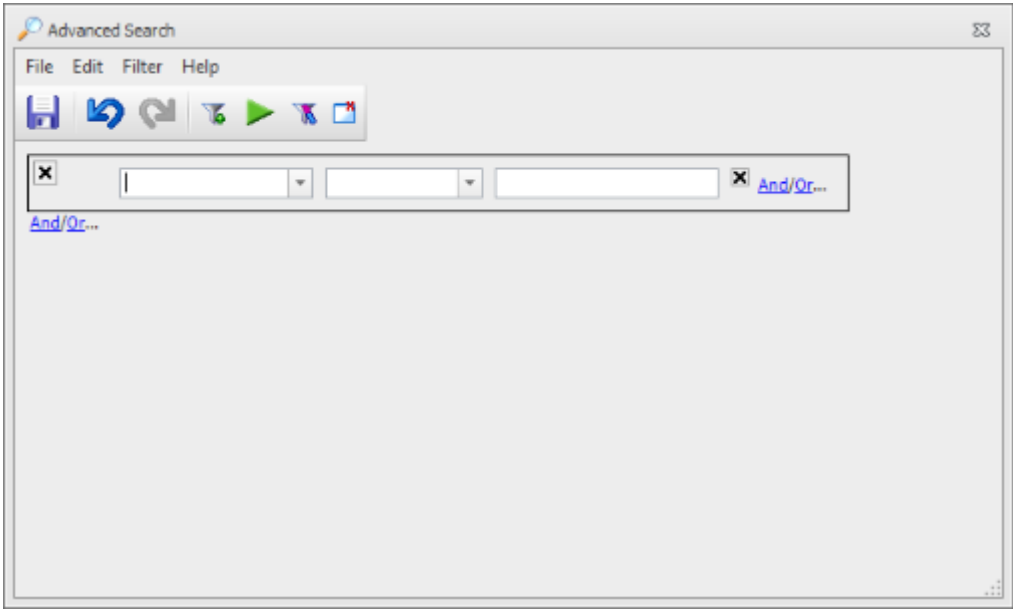
A list of options will be available which will change depending on the selections where a drop down list is available, all fields within Q-Pulse can be searched. The first field will give a list of all the fields associated with all documents in Q-Pulse. Expand the "Document Details" option to see a list of associated fields, in this list scroll down to select "Revision Review Date".

With this selected, appropriate options will then be available in the 2nd field, in this instance select "on or before"

The final field will then allow you to enter a date, from here you can search for all documents slated as requiring a review within a given window, this can be a forward view of 6 months for example.

From here, you are then able to add extra search criteria by selecting "and" "or", select "And" beside the existing line and this will allow you to set a 2nd criteria search results must meet. The example below shows that only documents with an ID number starting with "SOP" will be returned.
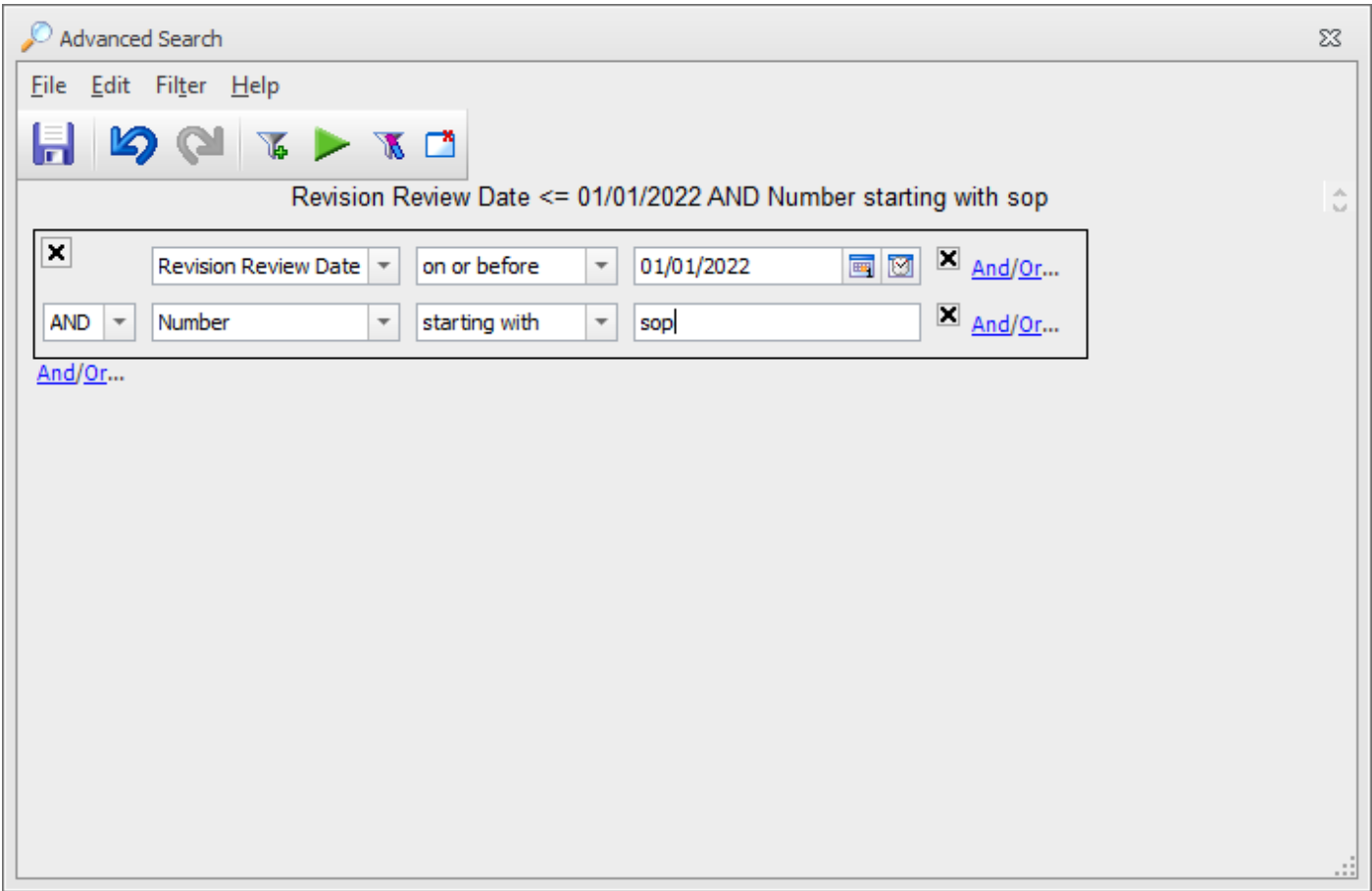
When the required documents have been identified there are 3 different options for creating a new review. The first is to right click on the document record from the search list and select "New Review".
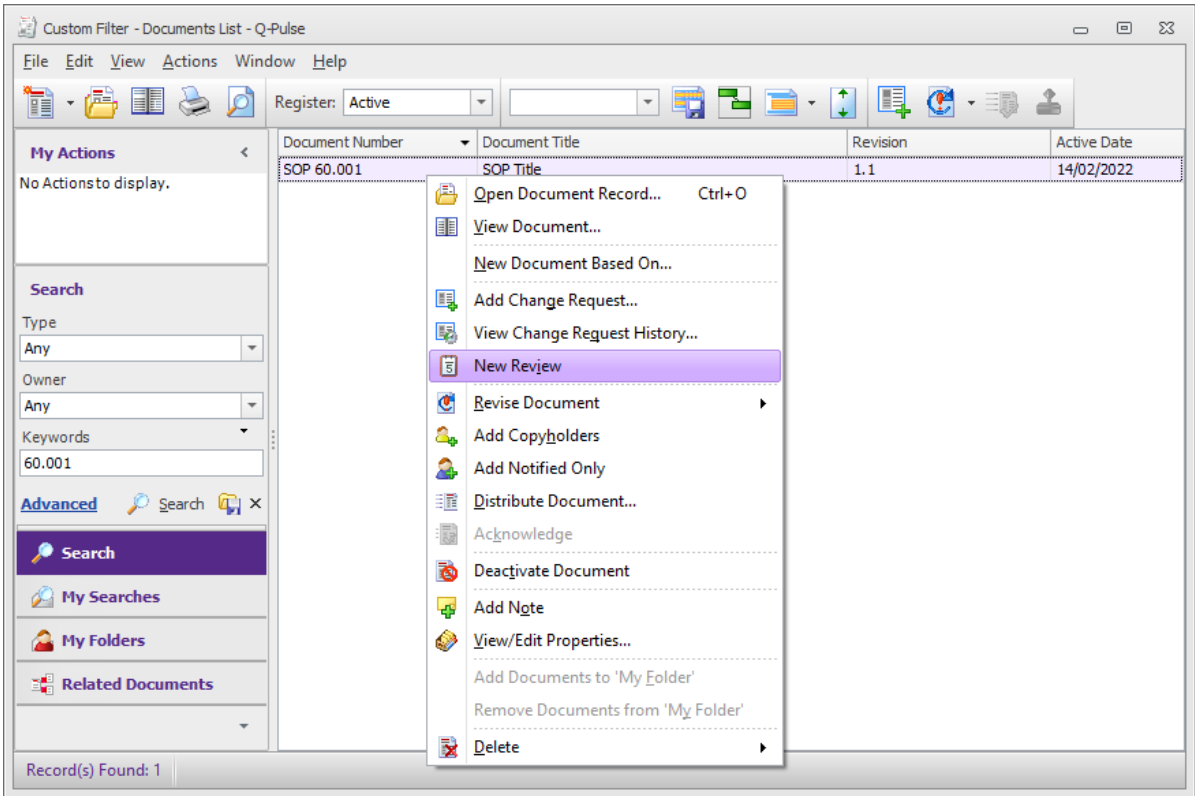
The 2nd option is to open the document record and select "Actions > New Review"
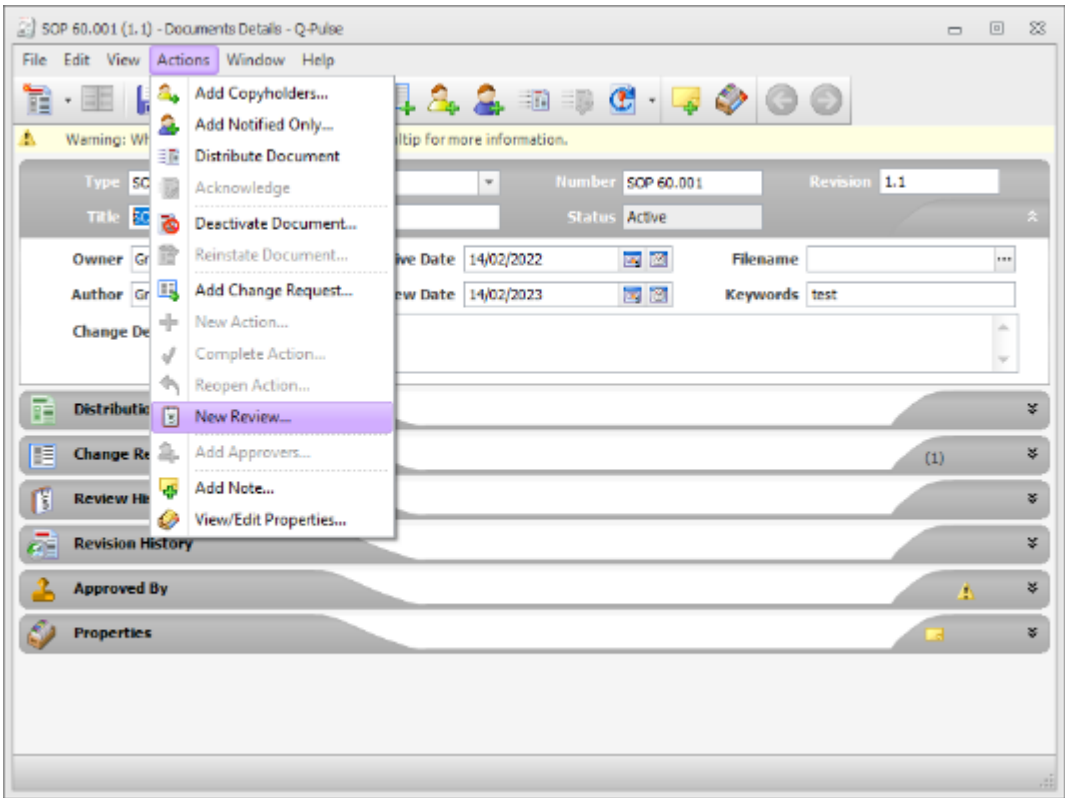
The 3rd option is to expand the "Review History" tab in the document record and select the "New Review" button on the right hand side.

All of these options will result in a new window being opened from which users can be tasked with reviewing the document. The review owner tab will be prepopulated based on the account creating the review, this can be changed and should be the document owner. The bottom of this window will have details of all existing change requests which can be considered by all the reviewers when conducting the review, the review owner should update the Change Request status as appropriate if this has not already been completed.

6.2.   Adding Reviewers

Named individuals can be added to the review to act as a record that they have fed in to the process, the actual method for conducting this review may vary for each scenario. A group meeting to review the SOP may work best, or users to feed in remotely and individually can also be used. Each individual involved should be recorded in this review record to act as evidence of their involvement. To add a new reviewer, click the "add new reviewer" button on the right.

This action can be completed by the Quality Assurance Manager or designated Authority if they are informed of the required names, or by the individual responsible for the review.

This will open a new window in which the details of a reviewer can be added. A target date can be set in the top field which is the required date for any responses by the reviewer. The reviewers name can be selected from the "Reviewer" tab by either typing and selecting from the drop down or searching by pressing the button with 3 dots to open a search window. The text in the "Action Required" field is default but can be updated with specifics of what is required from the reviewer. The remaining fields should be left blank and are for the Reviewer to complete.

When you have entered the details for the reviewer, select Ok on this window and repeat this process as required to add the relevant reviewers. Once this is complete, select Ok to close the review window and save the document record.

All reviewers named will then receive an automated e-mail message to notify them that they have been added as a reviewer.
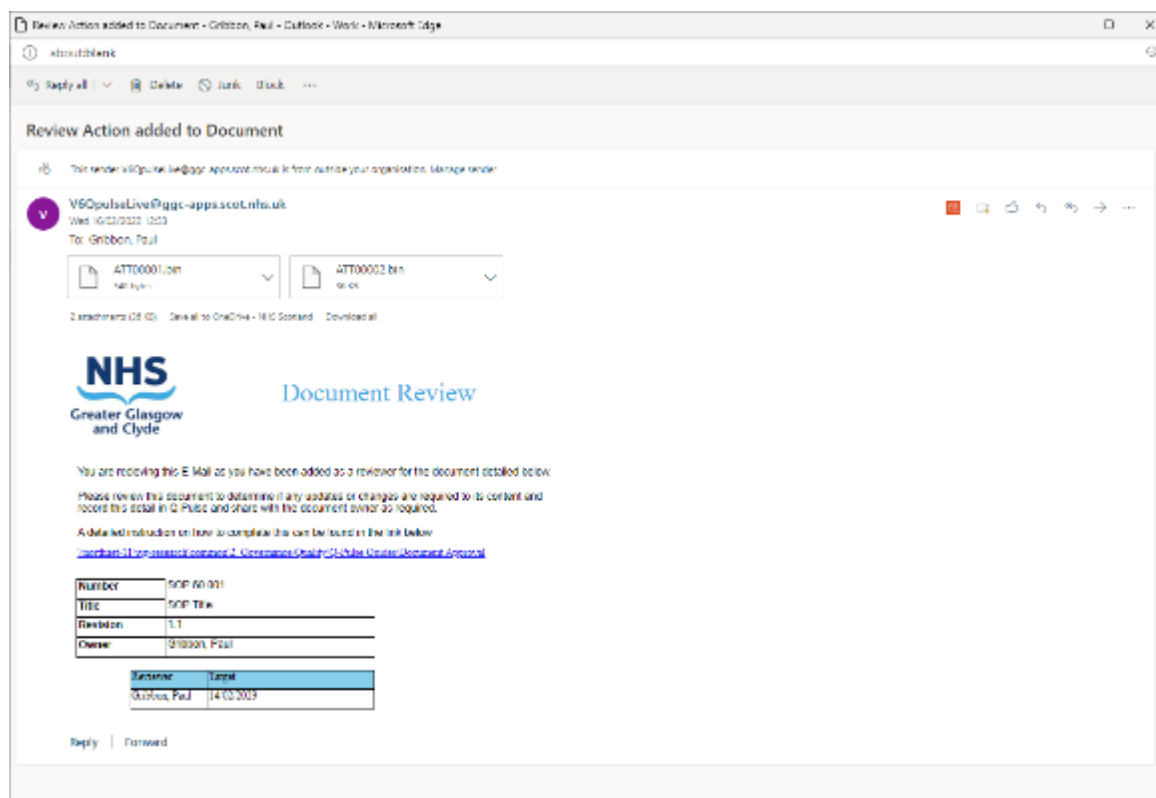
6.3.   Responding to a Document Review

When the reviewer navigates to the review record, they will see the same screen as before but with several areas greyed out as they can only respond to their own review line. They have visibility of the Change Requests to consider during their review as well as the document itself from the document record.

They may open their review line by double clicking on it, selecting the "edit review" or "complete review" buttons on the right. This will open the following window.

The reviewer must then carry out the review, either as a group or individually and update the record in Q-Pulse with any comments they may have and a decision on whether or not an update to the document is needed. When the review has been completed, enter the appropriate date in the "Reviewed on" field to close the review. Select ok to complete.

Once this field has been completed, the output of this will be displayed on the main document review screen.

Once all of the reviews have been completed by the assigned reviewers or a designated deadline has passed, the document/review owner is then able to consider all the returned information from the reviewers and make an overall decision on the update to the document. At this stage, all that needs to be completed is a decision on whether or not to update the document. The review owner will complete the remaining fields, completing a reviewed on date, outcome of "Change Required" or "Change Not Required" and comments on the final outcome of the review.

If a change to the document is required, the Document owner will update the master copy of the document and go through the usual processes of engaging relevant stakeholders before releasing a new draft for approval. If the outcome is that no change is required, this will be recorded in the record and this will then extend the review date of the document to the standard review increment for the document type. The default is 3 years, however this can be updated as required.

6.4.   Scheduled Review

The process described above will be used for both Schedule and Unscheduled Reviews, the only difference will be that Scheduled reviews will be managed and alerted in advance by the Quality Assurance Manager or the appropriate designee.

6.5.   Unscheduled Review

In the event of an unscheduled review, this will be managed on a case by case basis and may be prompted as a result of external audits or the raising of a Change Request. The same process of creating a review record will be followed.

## 7.	Read and Comprehend

As described in SOP 50.023, the requirement for Staff to Read and Comprehend certain SOPs associated to their Staff Category is detailed within each SOP. This is reflected and recorded in Q-Pulse as each staff member will be issued with the relevant SOPs to Read and acknowledge they comprehend its contents through Q-Pulse.

This has been mentioned previously in Section 2 and 3 and only appears as an option for Active documents or when documents are being made active. The records relating to this for Active documents can be found under the "Distribution" tab.
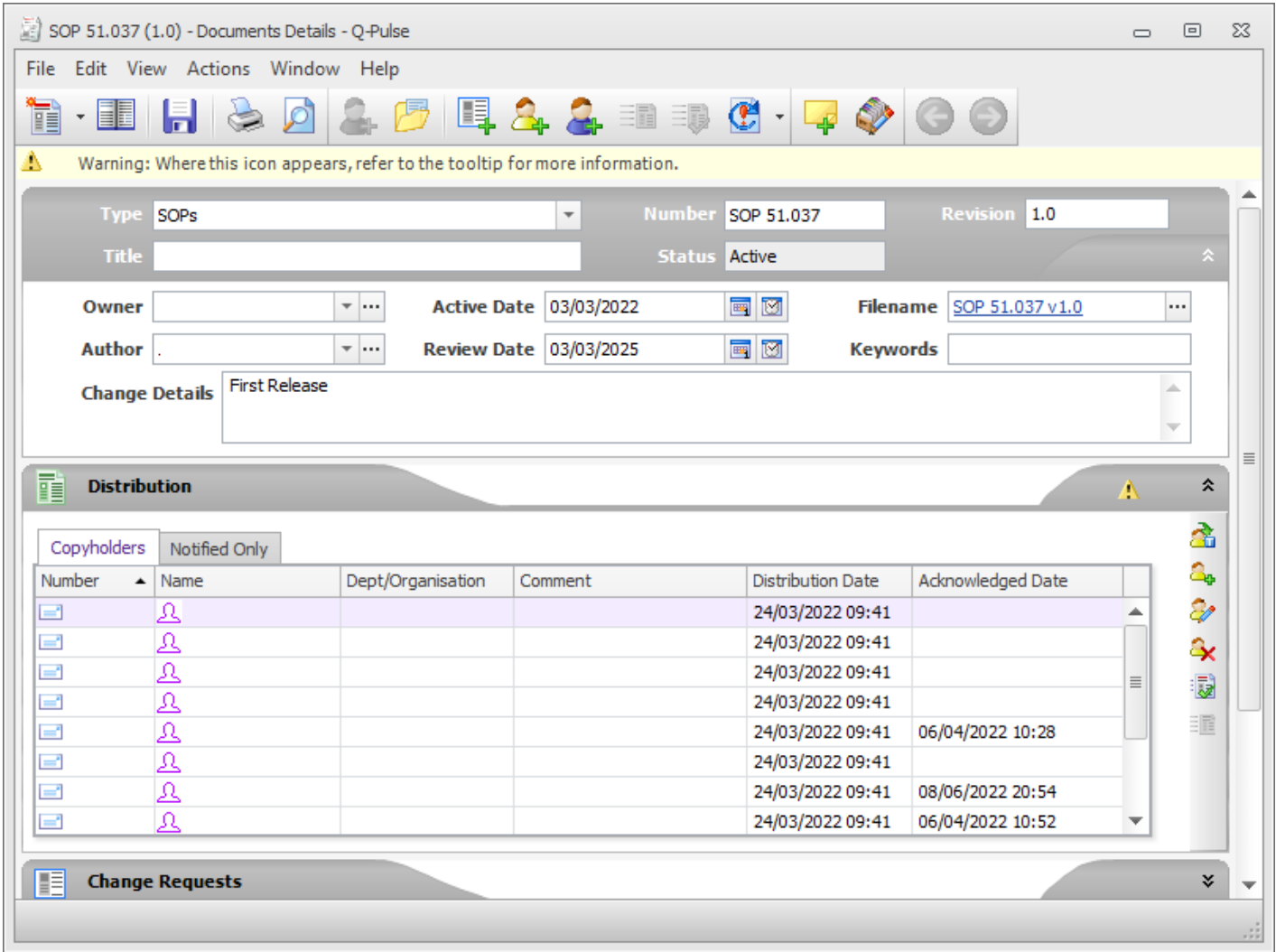
As can be seen in the example above, a list of staff will have a record of the document having been distributed to them and a record of when they have acknowledged they have read this document.

Reports are run centrally by the Quality Assurance Manager or the appropriate designated authority to ensure staff are responding in a timely manner as well as automated reminders being sent by Q-Pulse.

In the event a document is to be added as new or update which changes the staff groups associated to the SOP, this will be reflected in the records by the Quality Assurance Manager or the appropriate designee at this time which is detailed in Section 2 and 3.

In the event new members of staff join R&I or change role within, the Quality Assurance Manager or the appropriate designee must be notified to ensure they are set up with the appropriate Q-Pulse account and the correct documents distributed.

7.1.   Responding to Read and Comprehend Action

When a document is distributed, an E-Mail will be sent to all Copyholders and Notified individuals. This will include a file to locate the record in the desktop application and a link to open the record in the web version.

Documents which require acknowledgement can also be identified without receiving an E-Mail by opening the Q-Pulse application and then opening the Documents Module from the front Launch Pad.
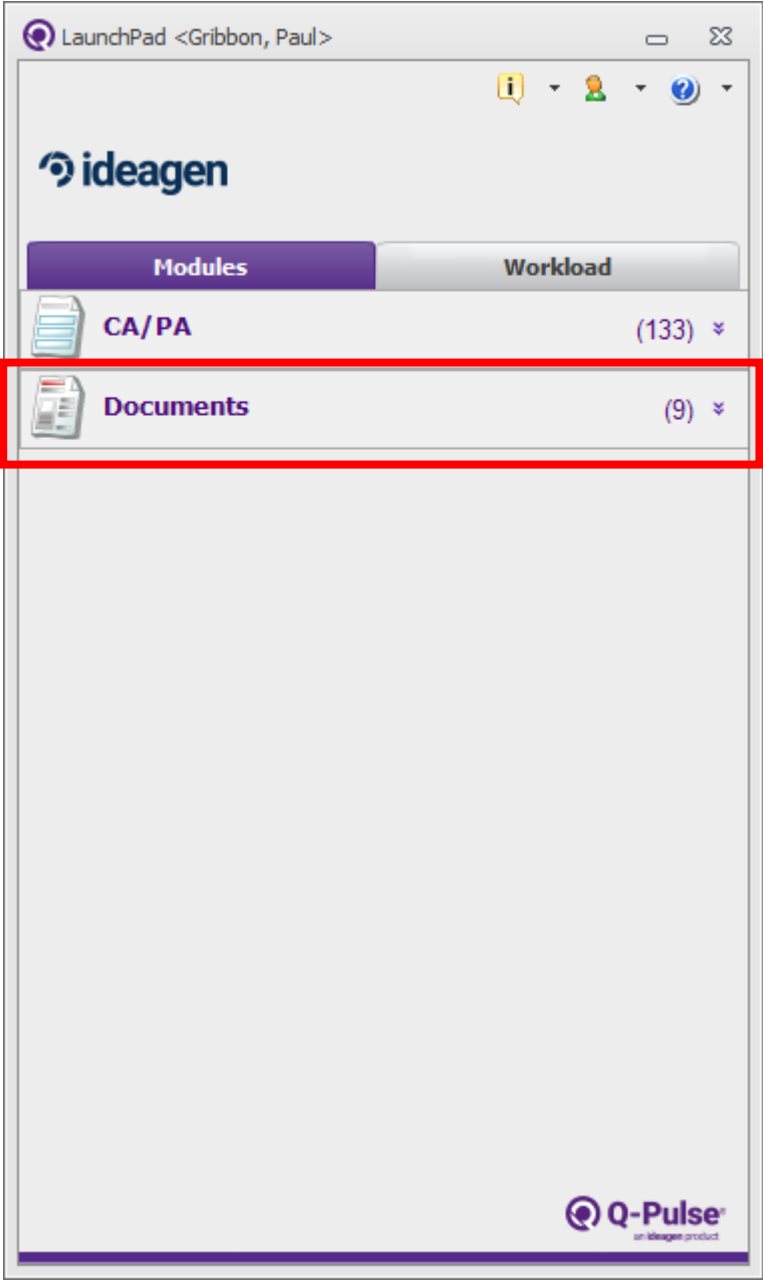
This will then open a new window for the documents module, in the top left hand corner of this window the actions associated with your account will be listed.
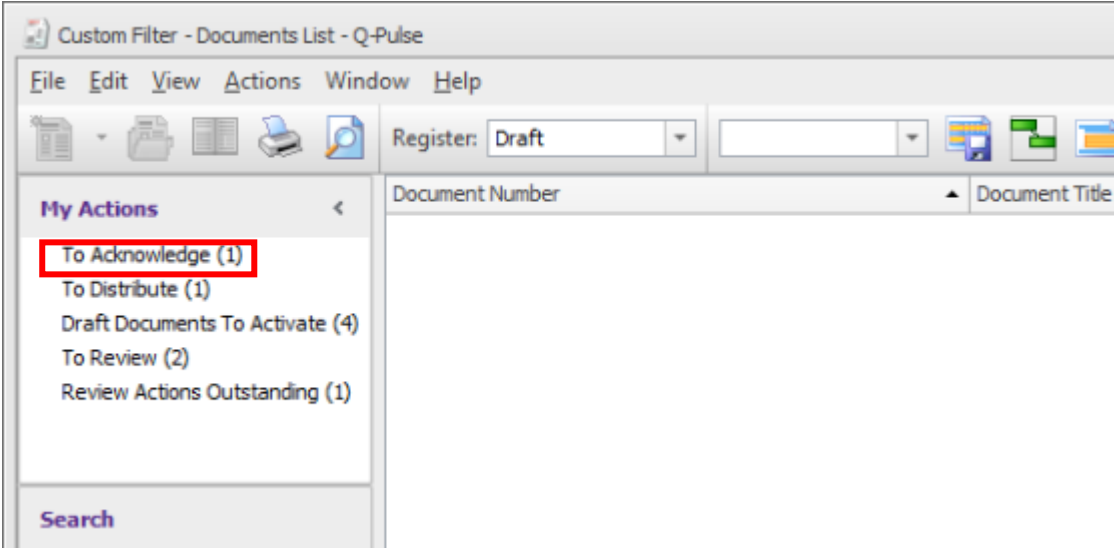
A number of different actions may be displayed and the numbers to complete for each will appear in brackets beside, in this instance it is the "To Acknowledge" action which is of interest. Double click on this to perform a search which will return a list of all documents to acknowledge.
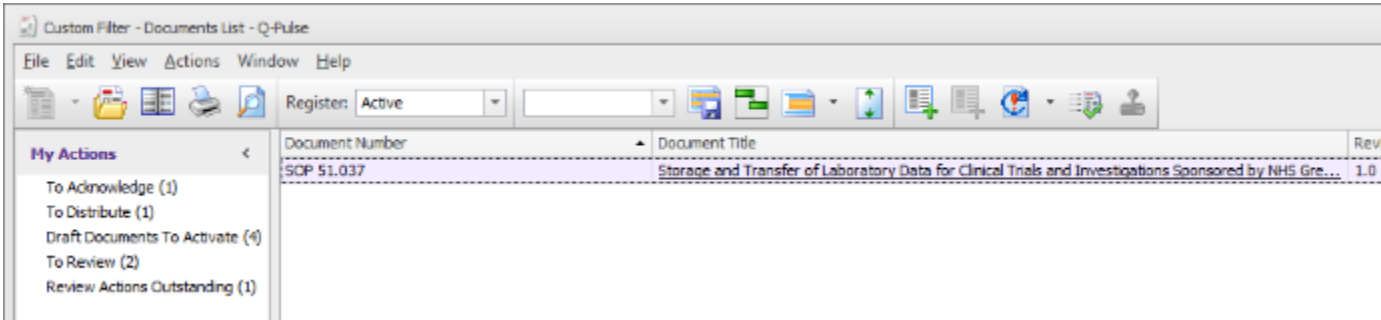
When the search completes and the documents are listed, each record can be opened by double clicking on the line or the document itself can be downloaded and opened by clicking on the title which will appear in blue underlined text.

You will then need to acknowledge receipt of the document, when you open the record for the document in Q-Pulse you then expand the "Distribution" tab, highlight your name and on the right hand side there will be a button to acknowledge receipt.

Once this has been clicked, an acknowledgement date will appear beside your name.
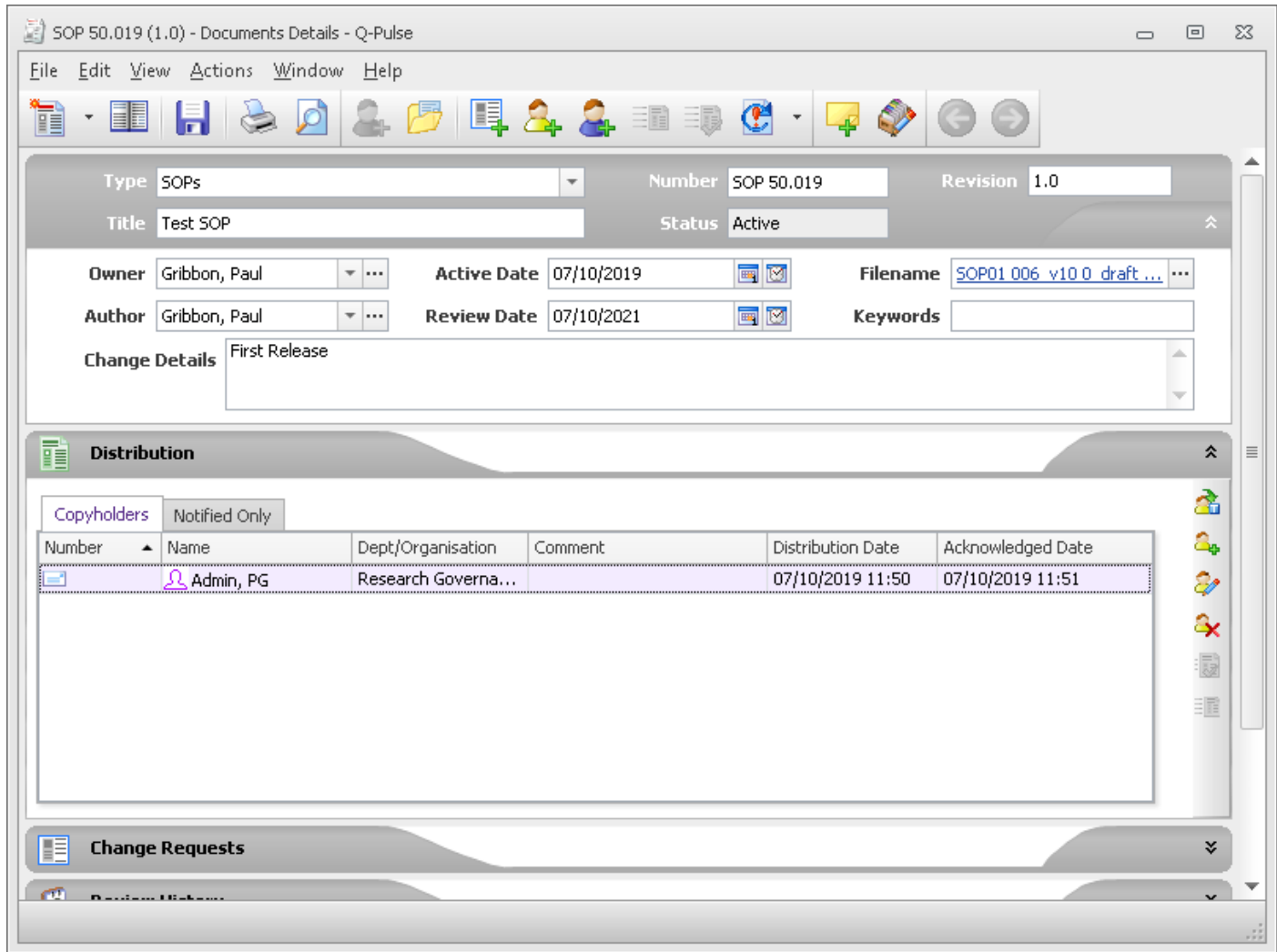
Alternatively, if you wish to acknowledge a document through the web portal it can be done by following the web link in the email notification. This will open the document record which will look similar to that shown below.

If you do not have the email as a reference, by opening the web portal version the front screen should display the actions associated to your account in the way shown below.

To open the list of documents to acknowledge, click on the number which appears in brackets beside the action to open a new window.
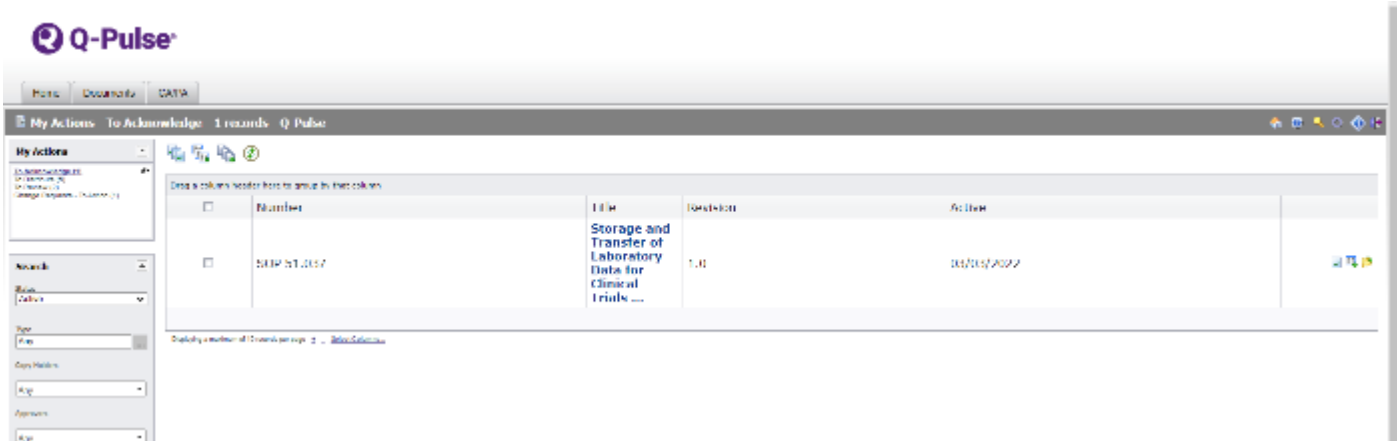
This will then return a list of documents, from here you can download and open the document by clicking on the title which appears in blue underlined text and when you have read and understood the content select the button to acknowledge on the right hand side.

This will open a window to confirm acknowledgement of the document.
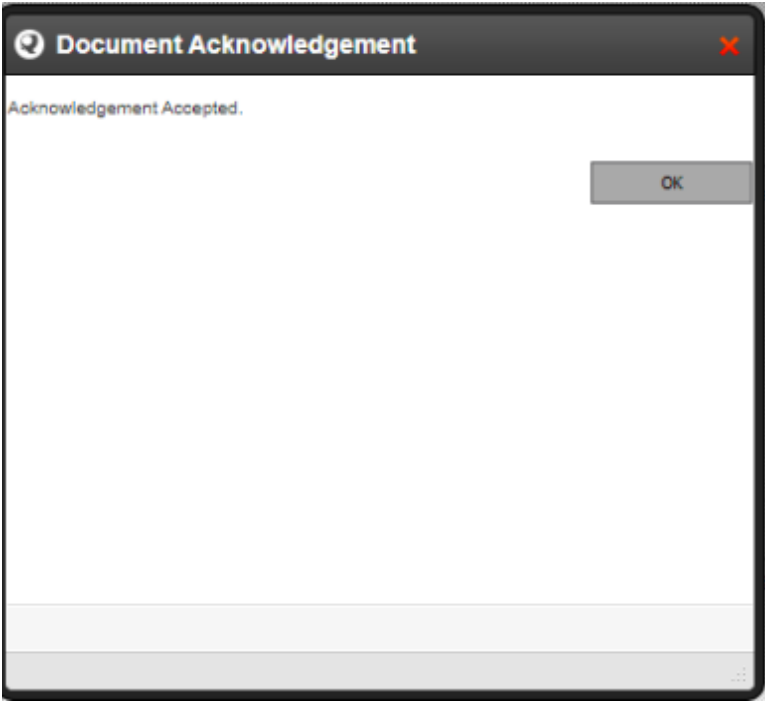
Alternatively, the individual document record can be opened by selecting the open button on the right hand side of the listing. This would be the process if you have followed the link from an email.
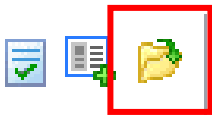
When the document record is open, on the top right hand side there is a button which allows you to acknowledge receipt, press this once the document has been reviewed and understood.

 - Acknowledge

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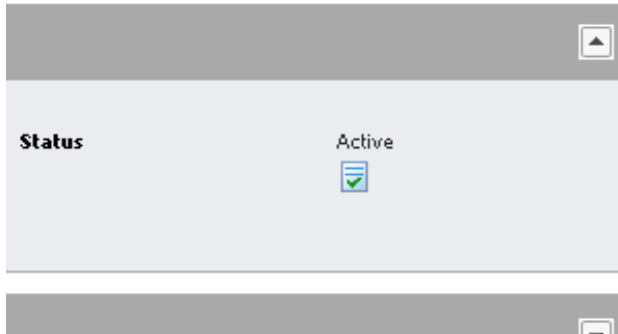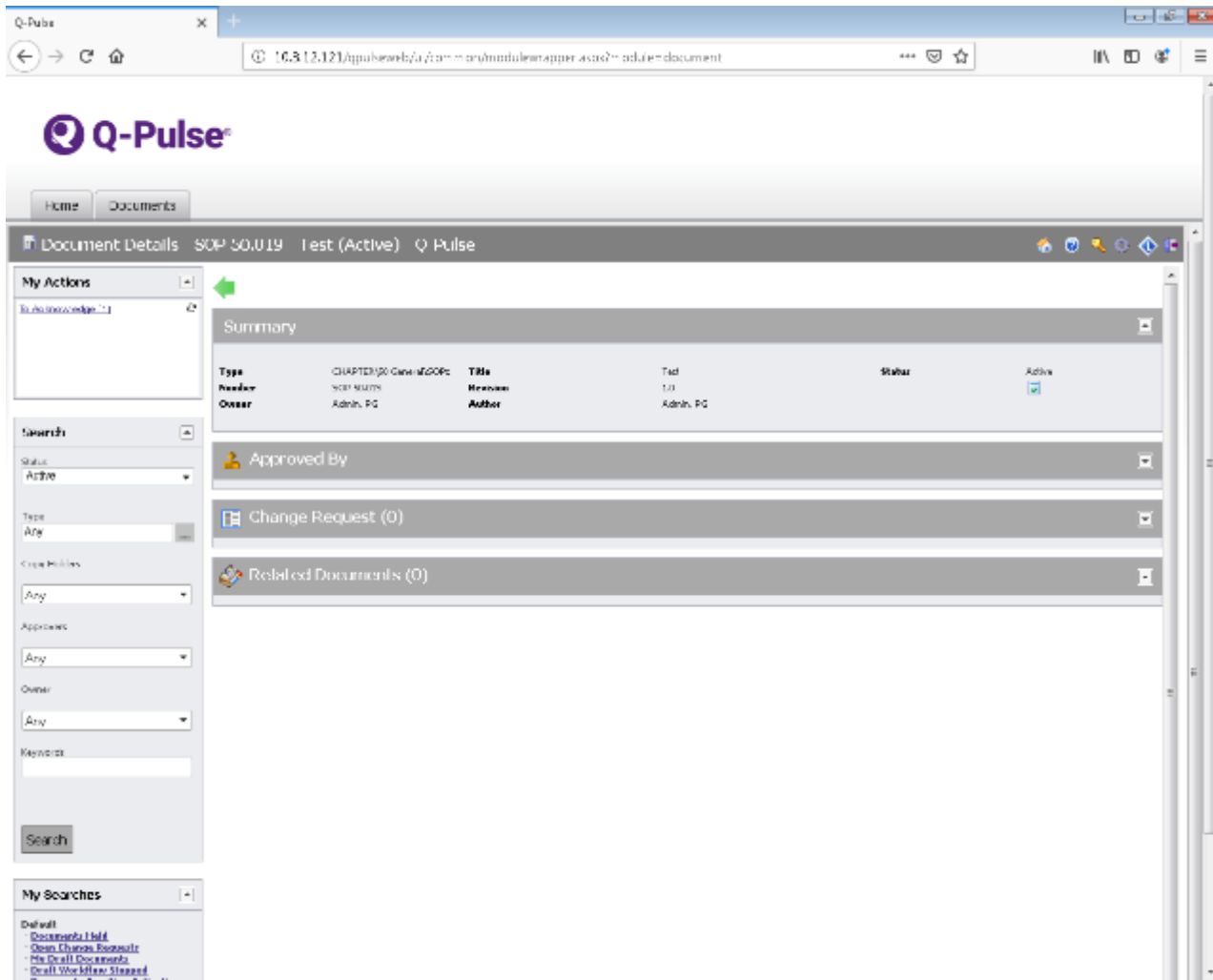
Once you press this button, a window will display to confirm you have acknowledged the document.

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8.   Related Documents (QA)

SOPs, Forms and Guidelines can be interconnected in their nature and reference other processes. This relationship which is detailed in SOP section 6,.Referenced Documents, can then be represented within Q-Pulse by forming these links.

This action will be taken by the Quality Assurange Manager or the appropriate designee, to achieve this, during the release of a new SOP or update of an existing SOP detailed in section 2. and 3, the properties tab of the document can be expanded and the document properties option selected.
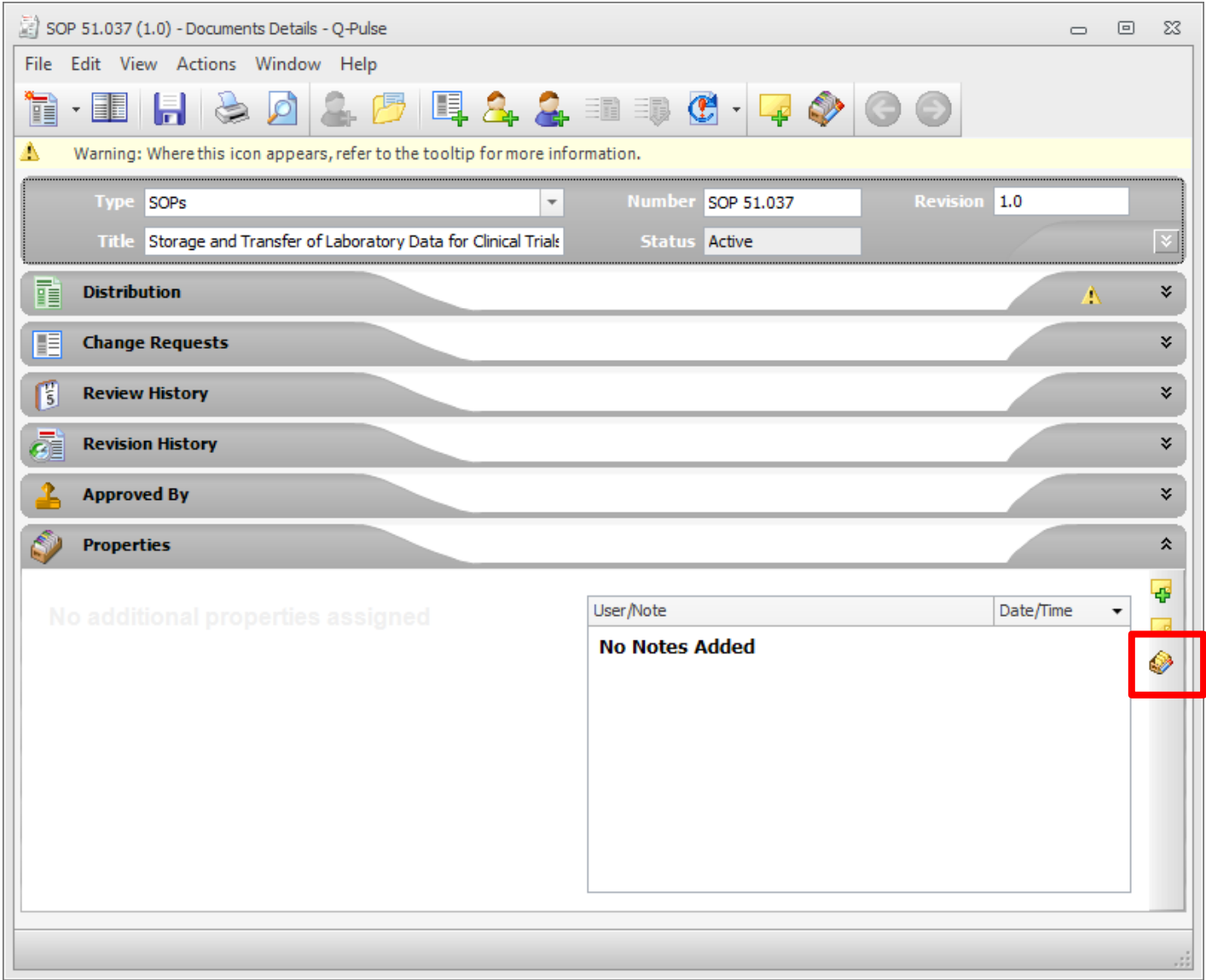
This will open a new window which has a number of different options in which associations can be formed to the document. In this instance it is the "Related Documents" option which is of interest, select this option to change the displayed screen.
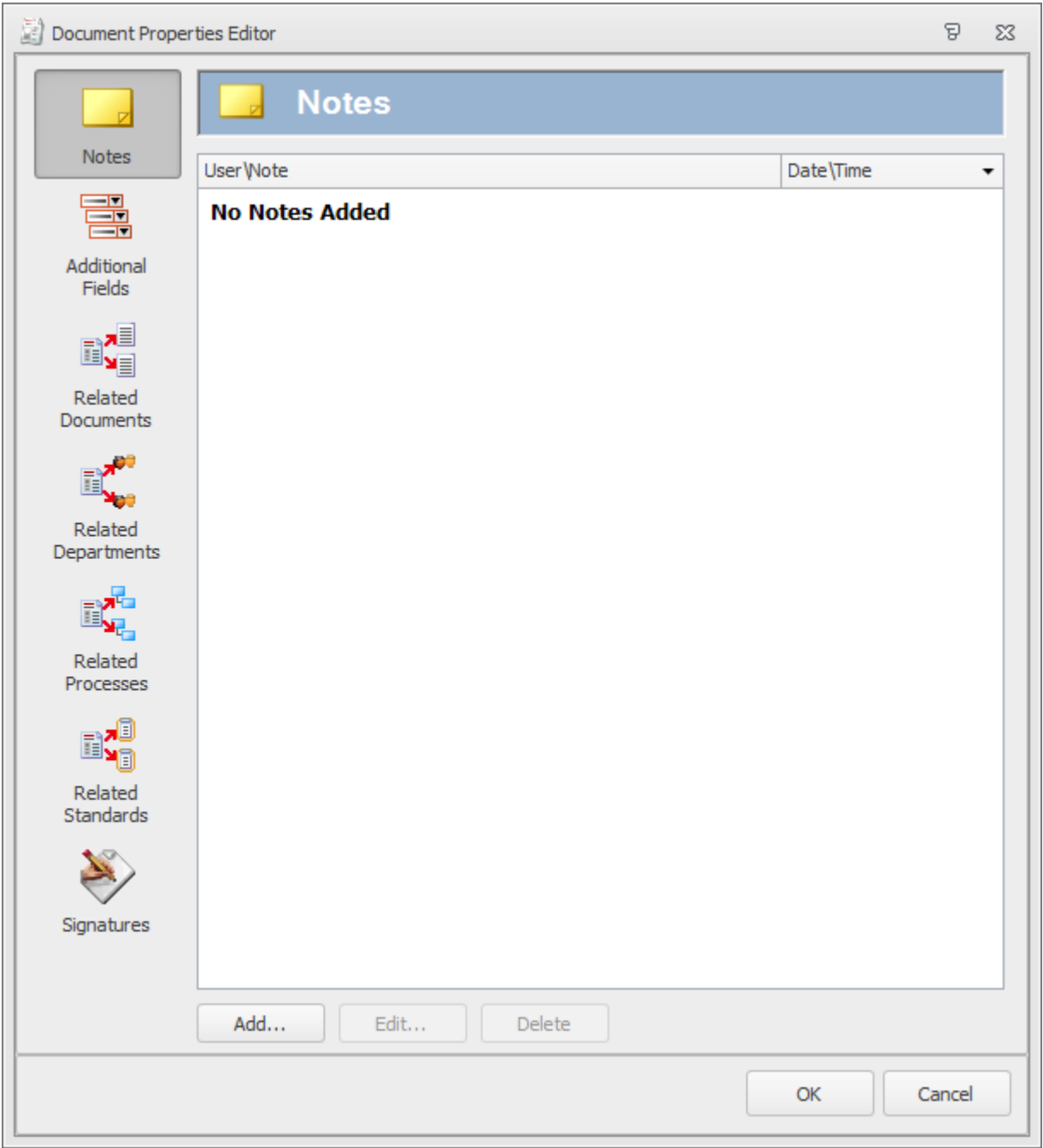
In this screen there is the ability to "Add" a link to another document, this allows to link any document held in Q-Pulse to this document record.

By selecting Add, a new window will open and allow you to search based on a keyword which can be the document number or title.

Search for Document	☒

Type
Any ▼

Keyword ▼

🔍 Search ✕

Number	Title	Type

OK Cancel

Search for Document	☒

Type
Any ▼

Keyword ▼
SOP 50

🔍 Search ✕

Number	Title	Type
SOP 50.010	Project Data Entry...	CHAPTER\50 Gene...
SOP 50.009	Project Numbering	CHAPTER\50 Gene...
SOP 50.011	Setting up Researc...	CHAPTER\50 Gene...
SOP 50.016	Development of ne...	CHAPTER\50 Gene...
SOP 50.001	NHS Greater Glasg...	CHAPTER\50 Gene...
SOP 50.013	Setup and mainten...	CHAPTER\50 Gene...
SOP 50.017	Clinical Research &...	CHAPTER\50 Gene...
SOP 50.018	Clinical Research &...	CHAPTER\50 Gene...
SOP 50.006	Registration of Bio ...	CHAPTER\50 Gene...
SOP 22.050	Recording Pharma...	CHAPTER\22 NHS ...
SOP 50.019	Independent Stak...	CHAPTER\50 Gene...
SOP 50.020	eCRF User Accept...	CHAPTER\50 Gene...
SOP 50.022	Preparation of Ter...	CHAPTER\50 Gene...
SOP 50.021	Participant recruit...	CHAPTER\50 Gene...

OK Cancel

From the presented list of options, select the relevant SOP, Form or Guideline to add this link.

This process can be repeated as many times as is required to form all the appropriate links. With these links in place, it will allow you to view all the associated documents to an SOP when it is undergoing review and help to manage the potential ripple through impact of any changes.

9.   Change of Ownership (QA)

There may from time to time be the requirement to change the ownership of a document if this happens outside of the normal review period of the document the record can be updated to simply change the "Owner" field over to the new name based on the rules set out in SOP 51.023. This must be completed by the Quality Assurance Manager or an Appropriate Designee.

In the event that the Author and Ownership are to be changed, these fields will be updated during the review process of the document as detailed in Section 3. by the Quality Assurance Manager of the appropriate designee.

Document Details

Prepared by: Paul Gribbon   Signed   Date

Approved by: Caroline Watson   Signed   Date

Document History

Version	Date	Description
1.0	25/08/2022	First Release

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