



External Guidance - FPP Post-prequalification Change Application Wizard guidance

Document Version Number: 1.2

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2. Scope

This guidance covers the submission of an application for FPP Post-prequalification Change/Variation Application via the ePQS Portal Wizard. The guidance provides step-by-step instructions on how to use the ePQS Portal Application Wizard to create, submit, receive feedback, and respond to queries on the WHO ePQS portal regarding FPP Post-prequalification Change application.

3. Prerequisites

Applications wizards are accessed via the ePQS Portal –<https://who.my.site.com/ePQS/s/login/>. Therefore, access to the ePQS portal must be granted first. To seek registration, apply via the form on the Portal landing page above.

Post-prequalification change application can only be created if there exists in the ePQS system at least one accepted or prequalified product for the applicant account.

Many wizards include steps that require the applicant to select an account from within the ePQS database. For instance, when an applicant wishes to create a product site for a product or nominate a reference authority. Users can verify these accounts exist before commencing an application by referring to the spreadsheet available from the “View ePQS Registered Accounts” tile, as indicated in figure 1.

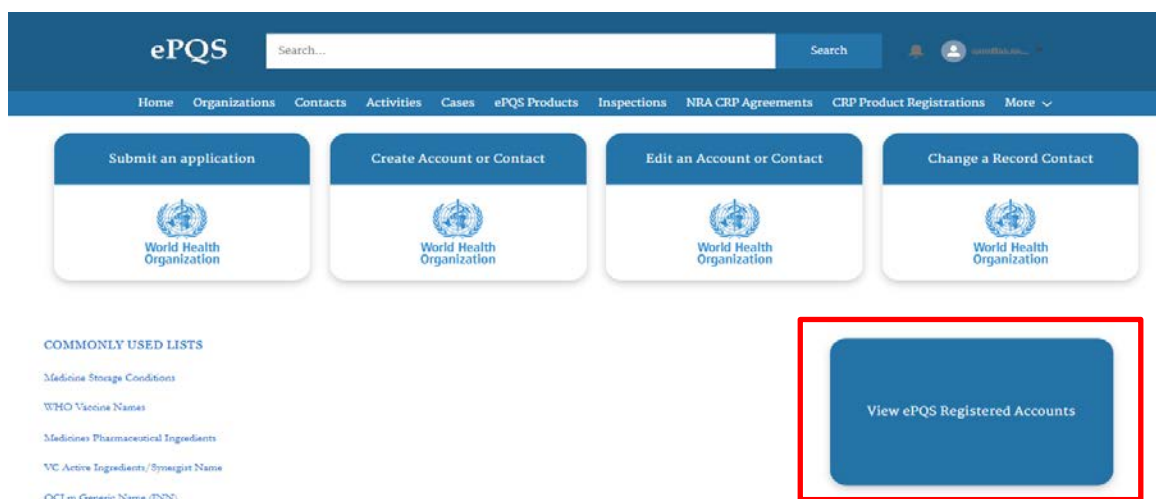


Figure 1: The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts.”

4. Accessing the Portal

Applications wizards are accessed via the ePQS Portal – <https://who.my.site.com/ePQS/s/login/>.

5. Wizard steps

4.1 Wizard commencement

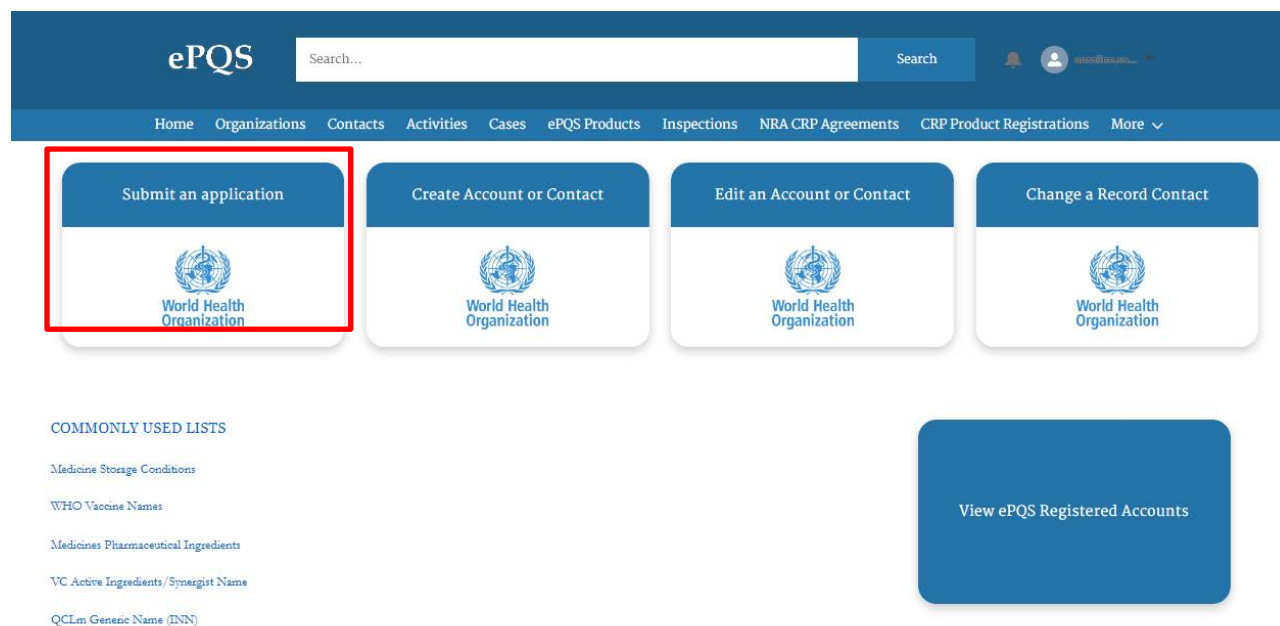


Figure 2: Commence the application process by selecting the Submit an Application tile

An application can be initiated by selecting the Submit an application tile from the portal as indicated in Figure 2.

4.2 Wizard Selection

Having passed the initial “Create a New Application screen”, the system may prompt you to confirm the Applicant organization that is making the application. This occurs if you are a registered user that is associated with more than one Account.

More commonly, you will arrive on a screen requesting the nomination of the contacts for this application, as shown in Figure 3. The system will present any contact associated with this account for selection. Please note that, the contacts do not need to be ePQS portal users, although it is likely they are.

ePQS Application Wizard

Organization & Contacts | Application Info | Product Details | Documents | Finalize

Choose Contact

Choose Applicant Primary Contact
Nominate a primary contact for this application who is an employee of ePQS Test Account 1 - NonStateActor, and also indicate if there are other secondary people involved.

* Primary Contact
ePQS External Applicant 1

Optionally Choose Secondary Contacts
If needed you can optionally choose a secondary and an alternative secondary contact, or leave the selection as "--None--".

Secondary Contact
--None--

Alternative Secondary Contact Choice
--None--

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Figure 3: As part of the preliminary application steps, Applicants will be asked to nominate contacts for the application, and if applicable the product.

You will then be prompted to select the product type for which you wish to submit an application, as shown in Figure 4.

ePQS Application Wizard

Organization & Contacts | Application Info | Product Details | Documents | Finalize

Choose Product Type

Select the product area to narrow down the list of application types.

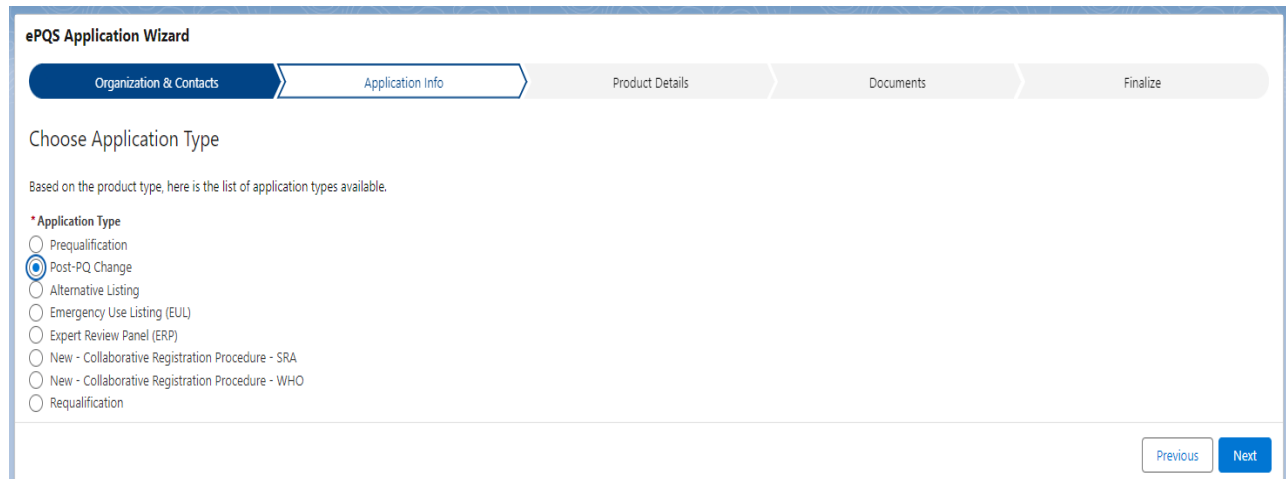
* Product Type

- ☐ Active Pharmaceutical Ingredient
- ☐ Active Pharmaceutical Ingredient Master File
- ☒ Finished Pharmaceutical Product
- ☐ Finished Vaccine Product
- ☐ IMD Evaluating Laboratory
- ☐ Immunisation Device
- ☐ In Vitro Diagnostic
- ☐ Male Circumcision Device
- ☐ Quality Control Laboratory
- ☐ Vector Control Active Ingredient
- ☐ Vector Control Product
- ☐ WHO Prequalification Evaluating Laboratory

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Figure 4: You must first select the associated product type, before selecting the application type.

On the next screen you will be offered a list of the specific application type and then application subtype relevant to the product type.



ePQS Application Wizard

Organization & Contacts | **Application Info** | Product Details | Documents | Finalize

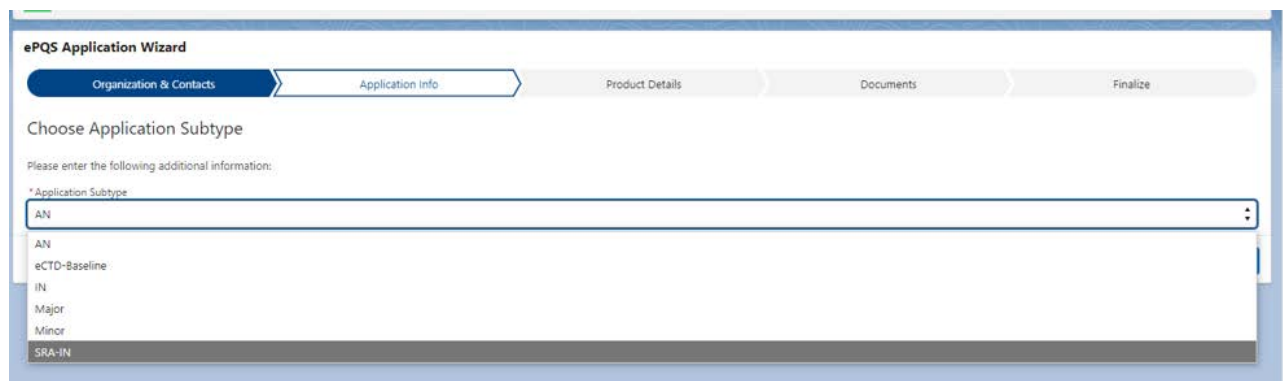
Choose Application Type

Based on the product type, here is the list of application types available.

* Application Type

- ☐ Prequalification
- ☒ Post-PQ Change
- ☐ Alternative Listing
- ☐ Emergency Use Listing (EUL)
- ☐ Expert Review Panel (ERP)
- ☐ New - Collaborative Registration Procedure - SRA
- ☐ New - Collaborative Registration Procedure - WHO
- ☐ Requalification

Figure 5: Then you will be offered the application type to select.



ePQS Application Wizard

Organization & Contacts | **Application Info** | Product Details | Documents | Finalize

Choose Application Subtype

Please enter the following additional information:

* Application Subtype

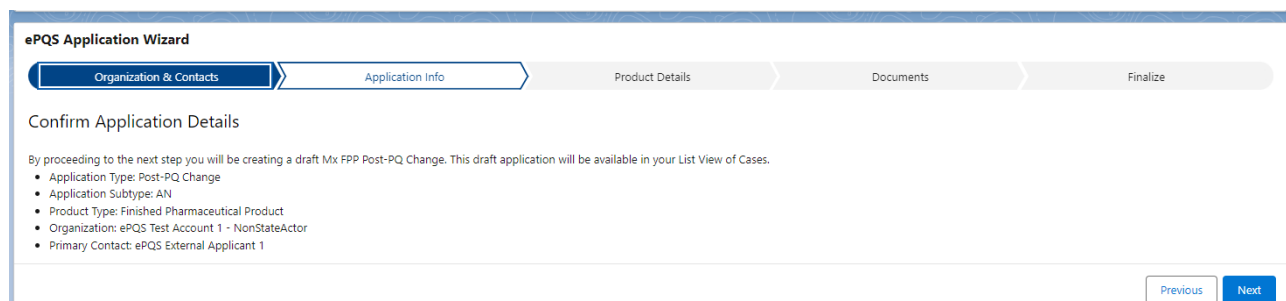
AN

- AN
- eCTD-Baseline
- IN
- Major
- Minor
- SRA-IN

Figure 6: Then you will be offered the application type and application sub-type to select.

Note: where grouped variations application is involved, the application sub-type should be consistent with the overall change severity (i.e highest severity/risk type).

The system will then display a preview of the application you are planning to create. By proceeding, a draft application record will be created in the system.



ePQS Application Wizard

Organization & Contacts | **Application Info** | Product Details | Documents | Finalize

Confirm Application Details

By proceeding to the next step you will be creating a draft Mx FPP Post-PQ Change. This draft application will be available in your List View of Cases.

- Application Type: Post-PQ Change
- Application Subtype: AN
- Product Type: Finished Pharmaceutical Product
- Organization: ePQS Test Account 1 - NonStateActor
- Primary Contact: ePQS External Applicant 1

Figure 7: The system both summarizes the application to be created and enables checks to confirm its correctness.

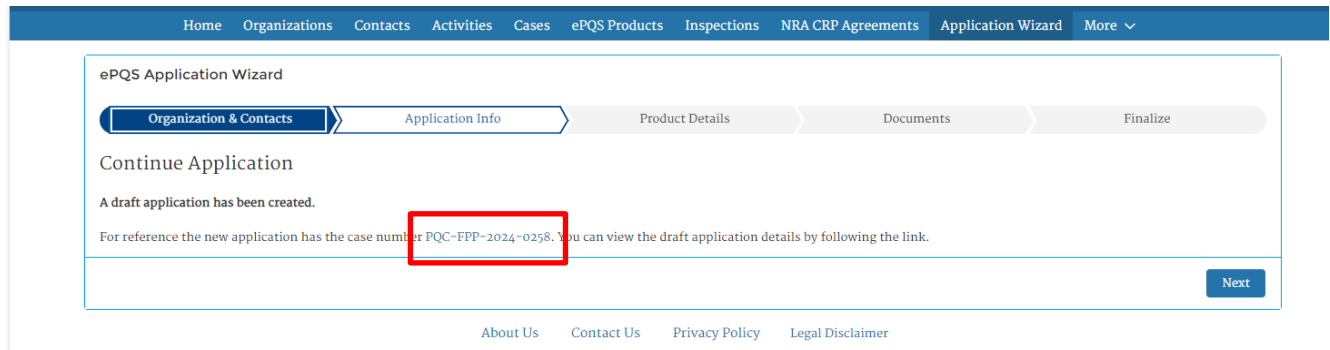


Figure 8: A draft application record has now been created in the system
[Note the assigned application number highlighted by the red rectangle].

You may save the application as a Draft application at this time and recommencing later as per section 9. This record can now be located via the global search bar or in the case list view using the assigned application number as shown in Figure 9.

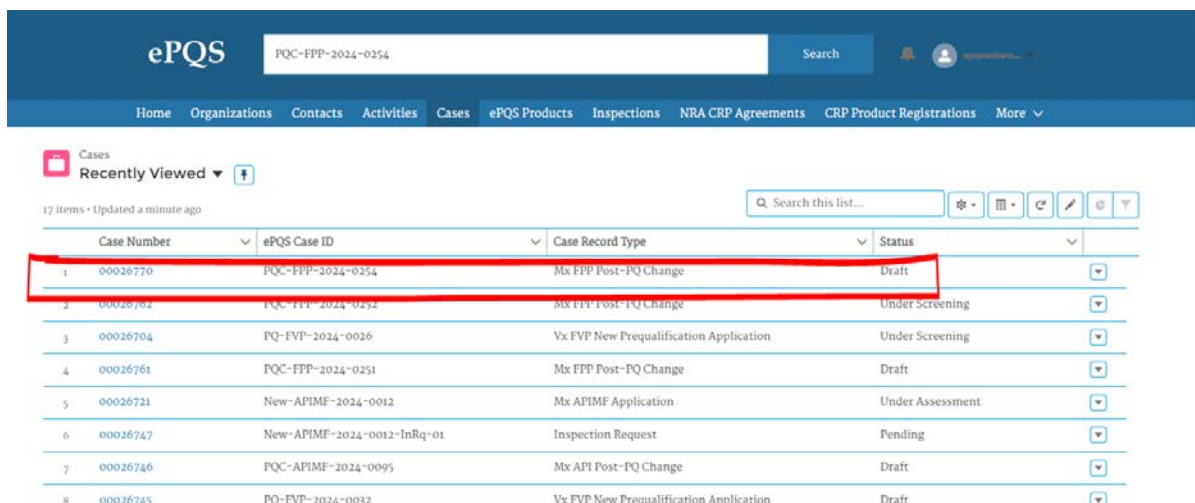


Figure 9: A draft application record can be located via the global search bar and in the "Case list view."

4.2.1 Subtype: eCTD-Baseline

One of the application sub-types available for selection, as shown in Figure 5, is eCTD-Baseline. This sub-type allows applicants to convert the dossier format of a prequalified product from non-eCTD to eCTD. Select eCTD-Baseline at the step depicted in Figure 5 to convert an associated product from eCTD non-compliant to eCTD compliant.

4.3 eCTD or non-eCTD

A screenshot of the 'ePQS Application Wizard' interface. It features a section titled 'Select Document Format' with two radio button options: 'eCTD' and 'Non-eCTD'. The 'eCTD' option is selected. At the bottom right, there are 'Previous' and 'Next' buttons.

Figure 10: A decision is required if the dossier being filed is in eCTD or non-eCTD format

The decision to file in eCTD or non-eCTD affects the document uploading steps at the end of the wizard. The decision to file in eCTD or non-eCTD also affects the prequalified products (dossier format) that may be associated with the Post-PQ Change application. A Post-PQ Change application in eCTD format requires all associated products (dossier format) to be eCTD compliant and vice versa.

4.4 Entering application-specific wizard details

The field for “Current Document Version Number” Figure 11 below may not apply to your application. In which case just enter “X” and click Next.

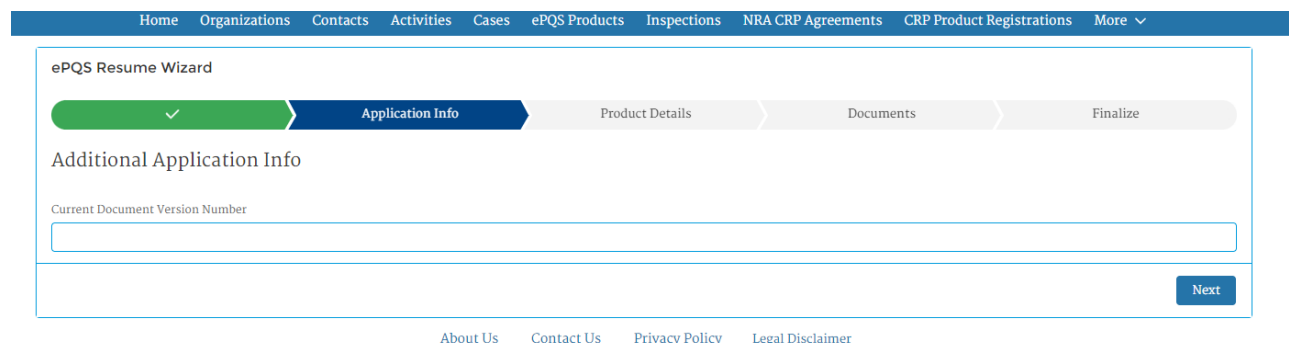
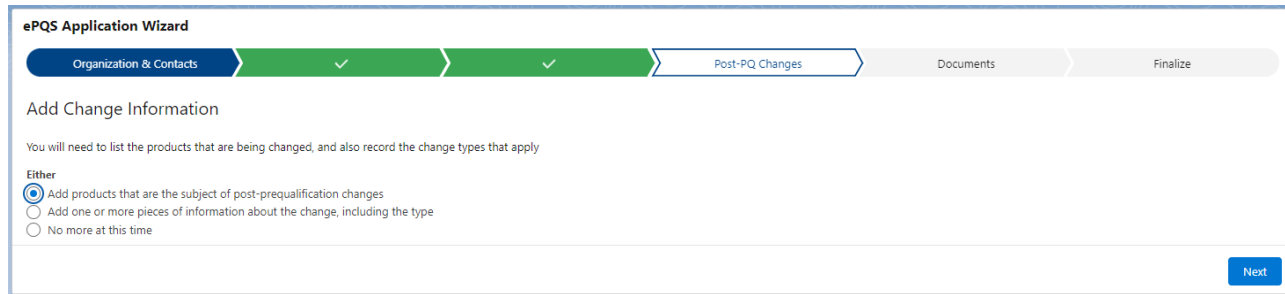
A screenshot of the 'ePQS Resume Wizard' interface. It shows a progress bar with five steps: 'Application Info' (active, highlighted in blue), 'Product Details', 'Documents', and 'Finalize'. Below the progress bar, the section is titled 'Additional Application Info'. There is a text input field labeled 'Current Document Version Number'. At the bottom right, there is a 'Next' button. A navigation bar at the top includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. A footer at the bottom contains links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

Figure 11: Additional Application Information; “Current Document Version Number”

The next steps involve completion of FPP Post-prequalification change product-related information.

As indicated in Figure 12, you will be offered three options under the Add Change Information. Selecting the “Add product that is the subject of the application option” will enable you to add the change-related product(s) as shown in Figure 13. At least one product needs to be added. To do so, select the radio button and click Next



ePQS Application Wizard

Organization & Contacts ✓ ✓ Post-PQ Changes Documents Finalize

Add Change Information

You will need to list the products that are being changed, and also record the change types that apply

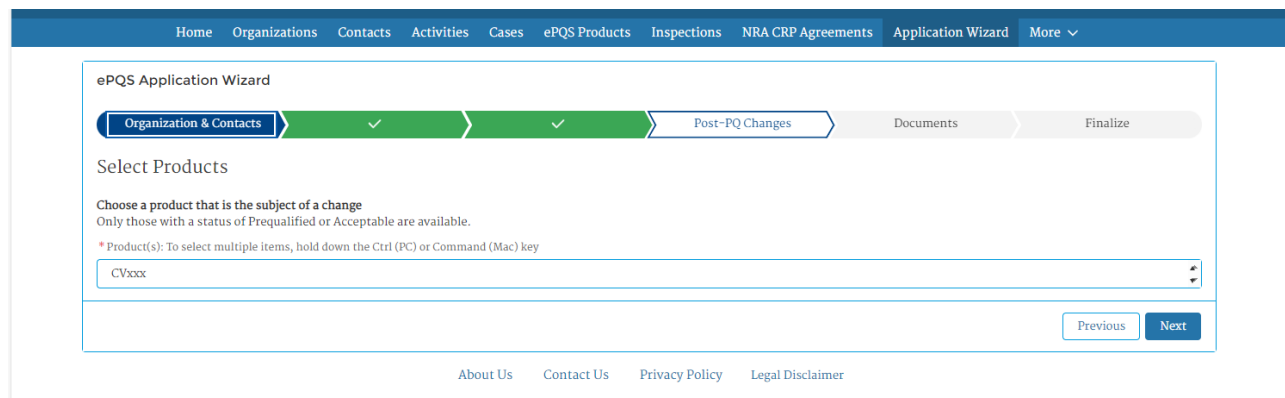
Either

- ☒ Add products that are the subject of post-prequalification changes
- ☐ Add one or more pieces of information about the change, including the type
- ☐ No more at this time

Next

Figure 12: Select “Add products that are subject to post-prequalification changes” to add the change-related product(s)

The system will provide a list of prequalified products of the applicant organization for selection. The list will display either eCTD or non-eCTD compliant products, depending on whether an eCTD or non-eCTD document submission format is selected (as shown in Figure 9).



ePQS Application Wizard

Home Organizations Contacts Activities Cases ePQS Products Inspections NRA CRP Agreements Application Wizard More ▾

Organization & Contacts ✓ ✓ Post-PQ Changes Documents Finalize

Select Products

Choose a product that is the subject of a change
Only those with a status of Prequalified or Acceptable are available.

* Product(s): To select multiple items, hold down the Ctrl (PC) or Command (Mac) key

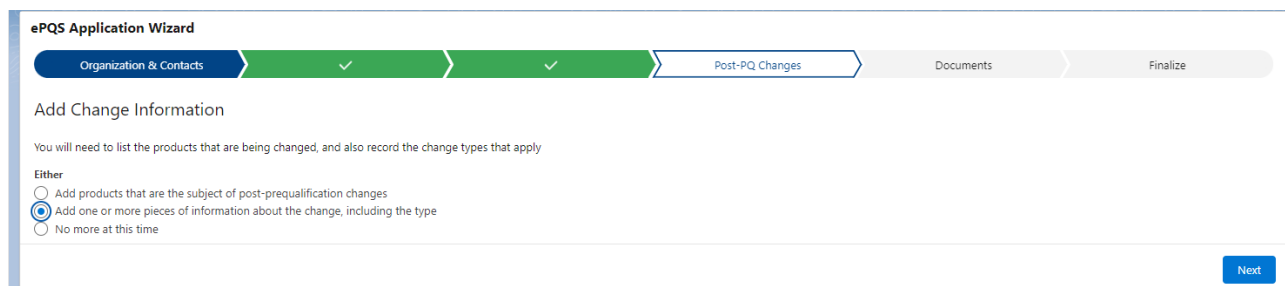
CVxxxx

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Figure 13: Select the change product(s) from the drop-down product list which records are linked to the applicant’s account.

Note: once a product is added as shown in Figure 13, the Wizard returns to the selections in figure 12, therefore when multiple products are involved, the selection shown in Figure 12 and 13 can be repeated until all the products are added, then proceed to add information about the change.



ePQS Application Wizard

Organization & Contacts ✓ ✓ Post-PQ Changes Documents Finalize

Add Change Information

You will need to list the products that are being changed, and also record the change types that apply

Either

- ☐ Add products that are the subject of post-prequalification changes
- ☒ Add one or more pieces of information about the change, including the type
- ☐ No more at this time

Next

Figure 14: Select “Add one or more pieces of information about the change” to add the change type.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Post-PQ Changes Documents Finalize

Add Overall Change Info

Enter the following before finalising the application

*Description of Changes Requested

xxxxxxxxx

Next

Figure 18: Add the description of all the requested change(s).

Please enter a concise summary of the change application, noting that a full description should be present in application document

After adding the Overall Change Information (description of changes requested), click Next and proceed to application document upload step (Figure 19).

6. Document uploading.

5.1 eCTD document upload

ePQS Resume Wizard

You are uploading documents to Case#PQC-FPP-2024-0261

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Figure 19: Initial document upload screen

If submission in eCTD format is intended, the system will display information that the applicant should use to complete the module 1 envelope for their dossier. The wizard may be paused at this stage and resumed once the dossier sequence file has been published.

ePQS Application Wizard

eCTD Submission Module 1 Information

Below are the Module 1 values required for your eCTD submission envelope. You can select and copy these values before proceeding to the next step to upload your zip file.

Salesforce Case Id : 00028353
Application Type : Post-PQ Change
Application SubType : eCTD-Baseline
Contact-email : awul
Organization Name :

2 of 2 items				
Product ID	Product Type	Product SubType	Product Assessment Procedure	Product Name
	Finished Pharmaceutical Product	Finished Pharmaceutical Product	Prequalification - Full	Artesunate Powder for solution for injection 120 mg
	Finished Pharmaceutical Product	Finished Pharmaceutical Product	Prequalification - Full	Zinc (sulfate) Tablet, Dispersible 20mg

Previous
Next

Figure 20: Information is provided for the applicant to complete their module 1 envelope information

Next, the system displays the exact name (as shown in Figure 21) the submitted file should be named. The dossier for each application submission should be formatted in “Zip” file format.

ePQS Application Wizard

File(s) for this application must be uploaded in .zip format.

Please copy and use the following exact name(s) for your submission file(s). This will ensure that your submission(s) can be transmitted to the eCTD repository.

Filename(s):

2 of 2 items	
FileNames:	
PQC-FPP-2025-0024_	
PQC-FPP-2025-0024_DI011	

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Figure 21: The system provides the exact name to be used for the uploaded zip file

5.2 Common document upload steps

ePQS Resume Wizard

Organization & Contacts | Upload Documents | Documents | Finalize

Please attach all supporting documentation for your application below. Either drag-and-drop or select one or more files from your desktop, and then click Upload to attach them to this application. You can review the folders for submission in the next page. There you can also rename, tag or remove documents. You can return to this screen to upload additional documents as part of this submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review documents once again before final submission. When finished, click Next.

Drag and drop files and folders. Browse your device or Select Folders

Cancel Upload

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Figure 22: document upload screen

On the document upload screen, you can upload single files, multiple files, or folders. Click on **Next** once these are selected. You will be asked to confirm upload; you can also cancel and go back to the previous screen (Figure 23)

ePQS Resume Wizard

Organization & Contacts | Upload Documents | Documents | Finalize

Please attach all supporting documentation for your application below. Either drag-and-drop or select one or more files from your desktop, and then click Upload to attach them to this application. You can review the folders for submission in the next page. There you can also rename, tag or remove documents. You can return to this screen to upload additional documents as part of this submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review documents once again before final submission. When finished, click Next.

AGDD-2024-Day-2-Slides.zip

Cancel Upload

Previous Next

Figure 23: Confirmation of the upload is required

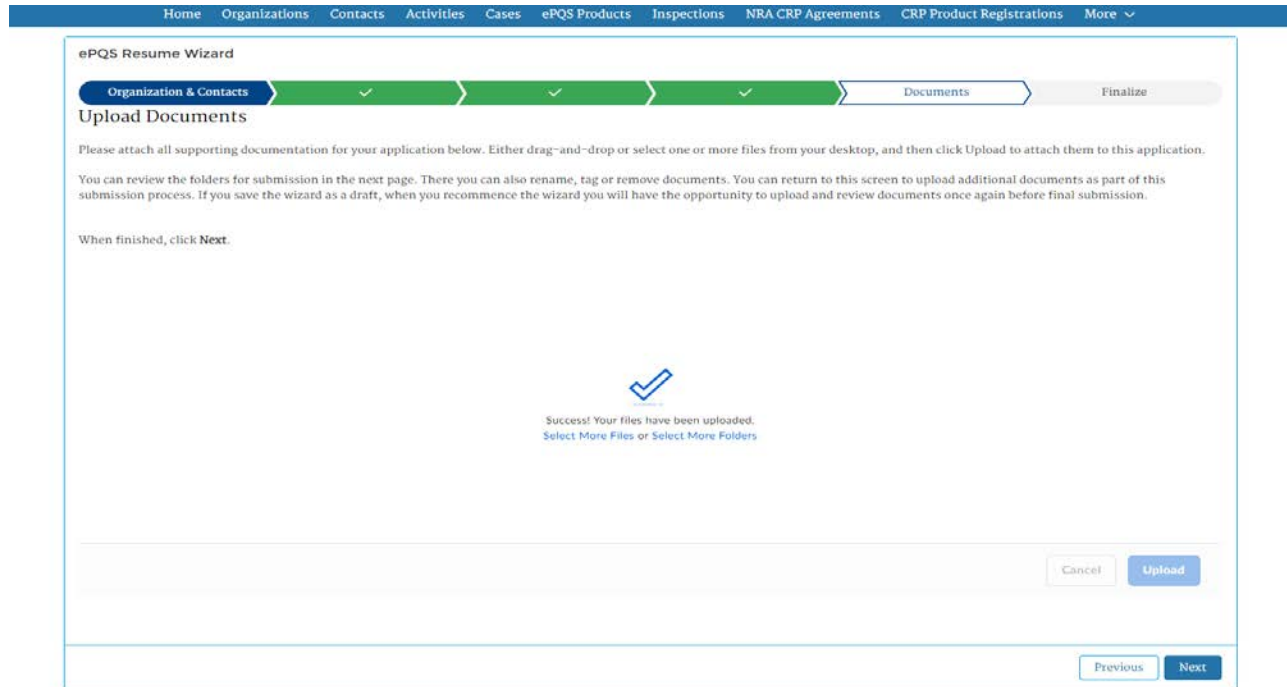


Figure 24: If the documents have uploaded successfully a confirmation screen will appear.

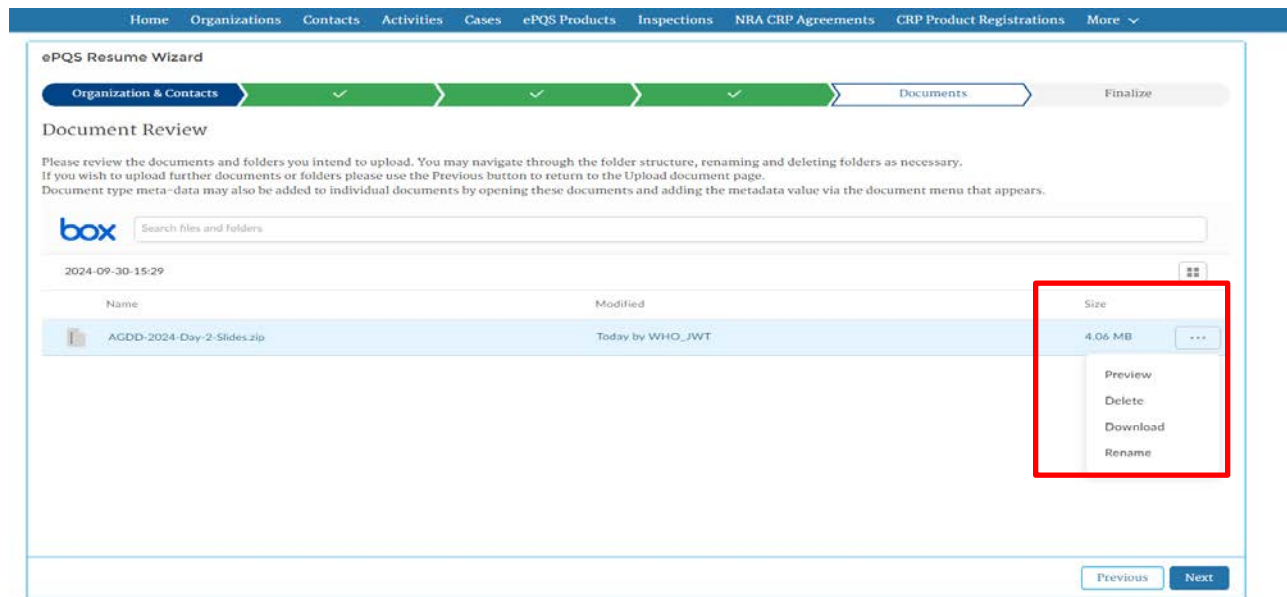


Figure 25: document review screen where the uploaded files can be adjusted if necessary.

Before moving to submission, you will be asked to review the files intended to be submitted. You can delete or rename the documents. You can also navigate through the uploaded folder structure to make more granular changes.

7. Submitting the application

The screenshot shows the 'ePQS Application Wizard' at the 'Review Application' step. A progress bar at the top indicates that 'Organization & Contacts' is the current step, followed by four completed steps (marked with checkmarks) and a 'Finalize' button. The main content area includes instructions to review the application, a case ID 'PQC-FPP-2025-0024', and a section titled 'Submit, Save or Discard' with three radio button options: 'Ready to submit?', 'No, save existing draft application and product (if applicable)', and 'No, discard this draft application and product (if applicable)'. A red error message states: 'Your application cannot be submitted. eCTD submissions require all files to be .zip format and named as specified in previous steps. Please click 'Previous' to correct your file(s) before submitting.' At the bottom right, there are 'Previous' and 'Next' buttons.

Figure 26: Final screen before submitting the application

The final screen before submitting the application has three options. Save as a draft (see section 8), submitting, or discarding the application. If you discard the application, the application and product record will no longer be visible in the application and product lists. It can still be found via the global search bar. Periodically, the ePQS Admin officer will delete these records.

If submitting, click on the “Yes” option in Figure 26 and then click on Next.

The screenshot shows the 'ePQS Resume Wizard' at the 'Application Submitted' step. The progress bar at the top shows 'Organization & Contacts' as the current step, followed by four completed steps (marked with checkmarks) and a 'Finalize' button. The main content area states 'Application Submitted' and provides instructions: 'The application wizard has now finished - click on the **Finish** button to be redirected to the detailed page of your submitted application.' A 'Finish' button is located at the bottom right. Below the wizard, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Figure 27: Submission confirmation screen

The screenshot shows the portal's navigation bar with links for 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'CRP Product Registrations', and 'More'. The 'ePQS Products' and 'Inspections' links are highlighted with a red box. Below the navigation bar, the text 'Invalid Page' is displayed, indicating a bug after clicking the 'Finish' button.

Figure 28: Currently there is a bug once you press finish. Simply refresh the page to continue in the portal

8. Upon Submission

Several changes are made to the application and product record once submitted. First, the ownership of the record changes to an internal assessment queue, meaning the record is no longer editable (see Figure 29). Second, the status of the application changes from Draft to Under Screening. Finally, the Date Application Submitted is entered by the system.

The screenshot shows the 'Case Details' page for Case PQC-FPP-2024-0261. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The case header shows the Case Record Type as 'Mx FPP Post-PQ Change', Case Number as '00026881', Status as 'Under Screening', Applicant Organization as 'PQT Pharmaceuticals Inc (Corp)', and Date of Prequalification/Acceptance. Below the header, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'General Details' section lists various fields: ePQS Case ID (PQC-FPP-2024-0261), WHO Application Number (PQC-FPP-2024-0261), Product Type (Finished Pharmaceutical Product), Application Type (Post-PQ Change), Application Subtype (AN), Case Owner (ePQS Mx FPP Queue), Status (Under Screening), Applicant Organization (PQT Pharmaceuticals Inc (Corp)), Applicant Organization (Legal) (PQT Pharmaceuticals Inc), Applicant Primary Contact (ePQS Pharma Applicant 1), Applicant Secondary Contact, and Alternative Applicant Secondary Contact. The 'Change Details' section shows the Overall Change Severity Rating (Vmin). The 'Case Progress' section shows the Date Application Submitted (30/09/2024) and the Date Application Accepted For Assessment.

Figure 29: Record ownership and status will change, and date the application is submitted is reflected in the system, once submitted.

If the submission is in eCTD format, the eCTD compliance field on the application record will be updated initially to Tentative. If eCTD validation step is successful, the eCTD Compliance will then be set to Yes. If the eCTD validation is unsuccessful, the eCTD Compliance value will remain as Tentative.

The application and product will now remain visible in the portal for on-going review.

7.1 Notifications

An email notification will be sent to the primary contact of the application to confirm the submission. Please note that this email only confirms the successful submission of the application, not its acceptance for assessment. Subsequently, an email acknowledging receipt of the application for assessment will be sent from [prequalvariation@who.int] following satisfactory screening of the application.

If the submission is in eCTD format, an additional email notification will be received within approximately 30 minutes informing the applicant of the validation outcome of the submitted sequence. The eCTD validation report is placed in the Correspondence (External) folder of the application record as shown in Figure 30.

Figure 30: eCTD validation reports are placed in the Correspondence (External) folder of the application

9. Saving as Draft and recommencing

Draft applications can be restarted from the application record by selecting the Resume Application Wizard button on the specific draft application.

Figure 31: Select the resume application Wizard button to re-commence the application wizard (see also figure 9)

The application wizard when restarted commences from the next applicable section.

NOTE: There is a bug in the wizard currently. This means that upon resumption the user is taken directly to the document upload section. Please avoid closing the wizard before reaching the document upload steps. If this occurs for any reasons, please reach out to ePQS@who.int for assistance.

Should the application stay in draft for more than 60 days, an email reminder will be sent to the application's primary contact.

10. Acceptance for assessment

If the screening is satisfactory, the medicines prequalification team will accept the application for assessment. This results in the change in the status of the Application record to Under Assessment.

Subsequently, you will receive an acknowledgement email from the medicines prequalification team (PQTm) via prequalvariation@who.int, acknowledging the receipt of the application of the application in case of IN, Vmin and Vmaj subtypes of variation. This is usually accomplished within seven (7) days of receipt of your submission by the team.

This ends the initial steps in the wizard and initial application process.

11. Receiving and responding to questions

Receiving queries and uploading documents in response to the screening or assessment queries occur in the same manner.

11.1 Receiving requests for additional information

The application submitted is next reviewed internally to determine if it meets technical and procedural requirements.

In case further information is required, you will be contacted by the Medicines Prequalification Team (PQTm) by email or a letter.

In addition, you will notice that an Activity has been opened in the name of the primary contact (Figure 32). And, you will have been sent an email alerting you to this (Figure 33).



The screenshot shows a web application interface for 'External Activities'. The main heading is 'My Open Activities (portal)'. Below it, a table lists activities. The table has columns: Activity Name, Related To, Related To, Subject, Status, Due Date, Start Date, and Owner Last Name. There is one row of data.

Activity Name	Related To	Related To	Subject	Status	Due Date	Start Date	Owner Last Name
EA-020025	00020881		Request for Information (Screening)	In-Progress		30/09/2024	Applicant 1

Figure 32: Outstanding task(s) could be accessed via the activity list

Please note that the activity described below has been assign to you.

- Activity Name: Request for Information (Screening)
- Component case Type:
- Component Case:
- Case number: 00026722
- WHO Product ID: P-12650

Should you require further information please log into ePQS, If you are unable to do so or should not be receiving these emails, please contact contactepqs@who.int

Figure 33: When an activity is assigned, an accompanying email is also sent

If a letter has been sent to you, a copy of this letter can be located in the Correspondence (External folder), which is accessible via the application record as indicated in Figure 34.

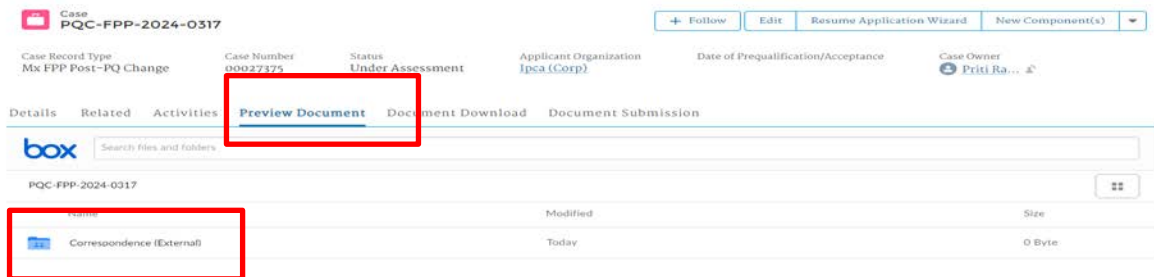


Figure 34 Formal correspondence is located in the applications external Correspondence folder. It can be previewed and downloaded.

11.2 Responding to requests for additional information

To upload documents in response to questions raised, proceed to the application and select the document submission tab.

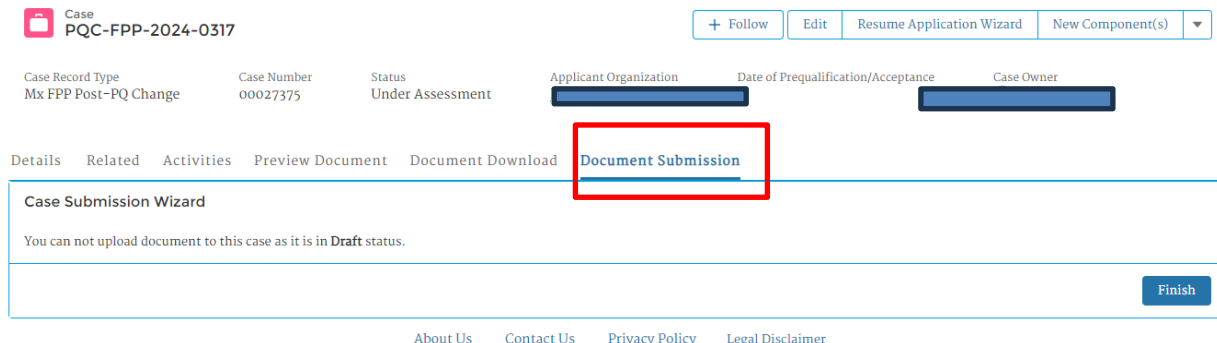


Figure 35: Documents can be uploaded via the application record, using the Document submission tab.

This initiates a short wizard to enable documents upload. The wizard functions in the same way as the document steps in the initial wizard. Note, like initial submission information, uploaded information cannot be seen once submitted.

In addition to any correspondence you might undertake with the assessment team, you can also signal the uploading of your response by changing the status of the activity to “actioned” as indicated in Figure 36.

Information

Related To (Case)
00027375
Related To (Inspection)

Activity Name
Request for Information (Screening)
Due Date

Start Date
08/10/2024
End Date

Case Information

Case Record Type
Mx FPP Post-PQ Change
This field is calculated upon save
WHO Product ID
This field is calculated upon save

System Information

Created By
User ID: 10000, 08/10/2024, 16:19

Owner
Time Assignment
Manufacturer

* Status
Actioned

Activity Outcome

Activity Phase
Under Screening
Response Date

Component Type
This field is calculated upon save

Last Modified By
User ID: 10000, 08/10/2024, 16:19

Record Type
ePQS Workflow Task

Figure 36: By changing the status of the pending activity to Action, this signals to the assessment team a response has been submitted.

Upon responding to the request for additional data on the portal, you should also send an email to FPPassessment@who.int notifying the team of your response to the request for additional information. Subsequently, an email confirming the successful upload of your documents to the ePQS portal will be sent to you from FPPassessment@who.int.

Once your response has been reviewed, and assuming this is a valid response, then assessment team will change the status and outcome, and enter the end date as indicated in Figure 37.

External Activity
EA-021904

Edit Change Owner

Details Related

Comments

Comments

Information

Related To (Case)
00027375
Related To (Inspection)

Activity Name
Screening of Application
Due Date

Start Date
08/10/2024
End Date
08/10/2024

Case Information

Case Record Type
Mx FPP Post-PQ Change
WHO Product ID

System Information

Owner
Time Assignment
WHO

Completed
Activity Outcome
Accepted

Under Screening
Response Date

Component Type

Figure 37 Once the response is reviewed the activity will be further updated

This completes the response to a request for additional information.

12. Record monitoring.

Further guidance on other aspects of the portal will be provided in separate documents, but you can monitor the status of your applications, product and activities using the various list views available from the menu bar at the top of the portal landing page.