

## Table of Contents

1.	Scope .....	2
2.	Prerequisites.....	2
3.	Accessing the Portal .....	2
4.	Wizard steps.....	3
4.1.	Wizard commencement.....	3
4.2.	Wizard Selection.....	3
4.3.	eCTD or non-eCTD.....	6
4.4.	Entering application-specific wizard details.....	7
4.5.	Product site creation .....	8
5.	Document uploading.....	12
5.1.	eCTD document upload.....	12
5.2.	Common document upload steps .....	13
6.	Submitting the application .....	15
7.	Upon Submission .....	16
7.1.	Notifications .....	17
8.	Saving as a draft and recommending .....	18
9.	Acceptance for assessment.....	18
10.	Receiving and responding to questions .....	19
10.1.	Receiving requests .....	19
10.2.	Responding to requests.....	20
11.	Record monitoring.....	22

## 1. Scope

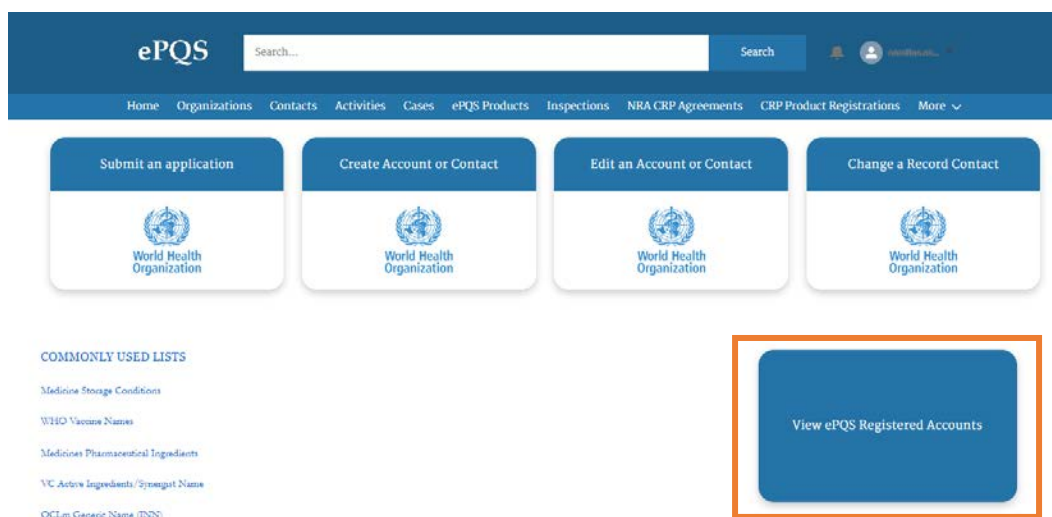
This guidance covers the submission of an application for the Active Pharmaceutical Ingredient Master File (APIMF) Procedure via the ePQS Portal Wizard.

## 2. Prerequisites

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

Some types of applications have prerequisite conditions. For instance, a 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 if 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.



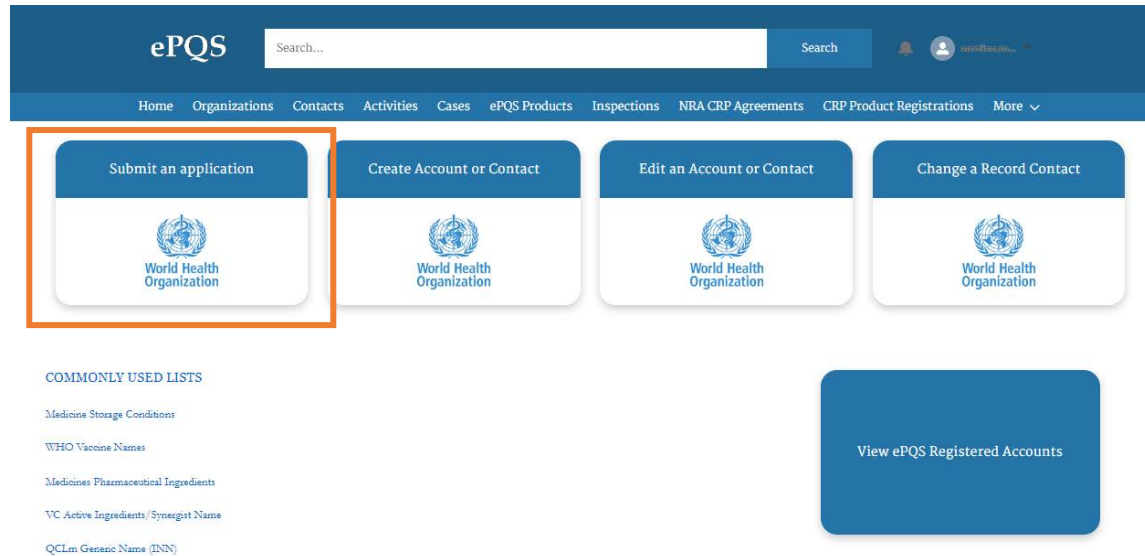
*Figure 1: The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts”*

## 3. Accessing the Portal

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

## 4. 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 directly on a screen requesting the nomination of the contacts for this application, figure 3. The system will offer for selection, any contact associated with this account.

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--

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

*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 that you wish to lodge an application for.

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

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

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

**PLEASE ENSURE YOU CHOOSE THE CORRECT OPTION. Choosing Active Pharmaceutical Ingredient Master File” means you will be offered to file an APIMF procedure application or an Amendment application. Choosing “Active Pharmaceutical Ingredient” means you will be offered to file an API Prequalification application.**

On the next screen you will be offered a list of the specific application type(s) and then application subtype(s) (if this is relevant) relevant to the product type (figure 5).

The screenshot shows the 'ePQS Application Wizard' interface. At the top is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. The wizard progress bar shows five steps: Organization & Contacts, Application Info (current), Product Details, Documents, and Finalize. The main heading is 'Choose Application Type'. Below it, a message states: 'Based on the product type, here is the list of application types available.' A red asterisk indicates a required field. Two radio buttons are present: 'APIMF Procedure' (selected) and 'Post-PQ Change'. At the bottom right are 'Previous' and 'Next' buttons. A footer contains links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

*Figure 5: Then you will asked to select application type and sometimes application sub-type.*

The system will then playback to you the application you are planning to create. By proceeding, the system will create a draft application record in the system.

The screenshot shows the 'ePQS Application Wizard' interface at the 'Confirm Application Details' step. The navigation bar and progress bar are identical to the previous step. The main heading is 'Confirm Application Details'. A message states: 'By proceeding to the next step you will be creating a draft Mx APIMF Application. This draft application will be available in your List View of Cases.' Below this is a bulleted list of application details: Application Type: APIMF Procedure, Application Subtype: Standard, Product Type: Active Pharmaceutical Ingredient Master File, Organization: ePQS Test Account 1 - NonStateActor, and Primary Contact: ePQS External Applicant 1. At the bottom right are 'Previous' and 'Next' buttons. A footer contains links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

*Figure 6: The system summarizes the application that is to be created.*

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Continue Application

A draft application has been created.

For reference the new application has the case number **New~APIMF~2024~0010**. You can view the draft application details by following the link.

Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 7: A draft application record has now been created in the system.*

This record can now also be located via the global search bar or in the case list view.

If the application sub-type you selected was Abridged, you will be asked to indicate the reference Authority. A picklist of options will be provided for selection.

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Choose Reference Authority

Indicate which Reference Authority will be linked to your application.

\* Reference Authority

AEMPS (Spain) - Parque Empresarial las Mercedes, Edificio 8, C/Capezo 1, Madrid, 28022, Spain

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 8: If an Abridged application was selected the applicant will be asked to select the Reference Authority.*

#### 4.3. eCTD or non-eCTD

ePQS Application Wizard

\* Select Document Format

☐ eCTD

☐ Non-eCTD

Previous Next

*Figure 9: 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.

#### 4.4. Entering application-specific wizard details

For the APIMF application wizard, the next steps involve completion of APIMF product-related information.

The screenshot shows the 'ePQS Resume Wizard' interface. At the top, a progress bar has five steps: 'Organization & Contacts' (checked), 'Product Details' (active), 'Documents', and 'Finalize'. Below the progress bar, the heading 'Create a Product' is followed by a 'New Product' section. It states: 'Since this is a APIMF Procedure type application, a new product will be created of type: Active Pharmaceutical Ingredient Master File (APIMF)'. It also notes: 'It will be linked to your application, New-APIMF-2024-0010.' A 'Next' button is located at the bottom right. At the very bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

*Figure 10: As a next step in the APIMF application wizard, an APIMF Product record is created.*

As indicated in figure 11, you will be asked to add the active pharmaceutical Ingredient. Note, that once the first two letters of the API are entered, the system will begin to offer options for selection.

This screenshot shows the 'ePQS Resume Wizard' at the 'Product Details' step. The progress bar shows 'Organization & Contacts' as the previous step and 'Product Details' as the current step. The 'Create a Product' section is titled 'New Mx APIMF Product' with a note '(Please fill out all required fields)'. There are two required fields: '\* Active Ingredient Name (Mx)' with a search bar labeled 'Search Mx Pharmaceutical Ingredients...' and a magnifying glass icon; and '\* Current APIMF Version Number' with a text input field. Below these is a section for 'Therapeutic Area(s):' with a note 'To select multiple items, hold down the Ctrl (PC) or Command (Mac) key'. A list of therapeutic areas is shown: Analgesics, Anesthetics, Antihemorrhagics (Haemophilia), Bacterial vaccines (Pneumococcal infections), and Covid-19. A 'Next' button is at the bottom right. Footer links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer' are at the bottom.

*Figure 11: Information relating to the API, version number, and relevant therapeutic area should next be entered.*

You will also be asked to enter the APIMF version number for the submission, and to select one or more therapeutic areas the API pertains to.

On the next screen, figure 12, you have the opportunity to go back to correct the entered information, by selecting “previous”.

ePQS Resume Wizard

Organization & Contacts ✓ Product Details Documents Finalize

### Create a Product

Please confirm the Mx Pharmaceutical Ingredient Active Name for Publishing selected:

- Ritonavir

If this is incorrect, select Previous and select the correct Active Ingredient.

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 12: By selecting the previous button you can correct the information entered in the previous screen.*

By selecting Next, an associated APIMF product record is then created as per figure 13.

ePQS Resume Wizard

Organization & Contacts ✓ Product Details Documents Finalize

### Create a Product

**Product Successfully Updated**

The details you have just entered have been updated on the new Active Pharmaceutical Ingredient Master File Product for your New-APIMF-2024-0010 application. By clicking on the link provided you can see the product record. The product record is also available in your Products' List View.

- APIMF Product: P-12646

Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 13: A new APIMF product record is created.*

## 4.5. Product site creation

Once the Product record is created, you are then offered the opportunity to create product site records for the sites undertaking various activities. It is expected that every product must have at least one manufacturing site. To do so, select the Product site radio button and press Next (see figure 14). You will return to this screen eventually in case you need to create another product site.

For APIMF product records, it is required to create product site records for:

- all sites of API manufacture;
- all intermediate manufacturing sites that are not also API manufacturing sites; and
- any micronisation sites if they are not also API sites of manufacture.



*Figure 14: Every APIMF product record must have at least one Product site record*

The first step in the product site creation is to identify the Account/Organization representing the site. Enter at least the first three letters of the Account into the Site search field and press next. On the next screen (figure 15), the system will offer to you available accounts within the system matching the entry criteria, to choose from.

*Figure 15: Based on the information entered into the site search field the system returns all accounts matching this name.*

As mention in *Section 2 – Prerequisites*, a list of sites is available for review before commencing. If the site is new to the system, the applicant will need to request creation of the Account before commencing the application. It is also possible to leave the current application and recommence this later. See section 8.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

### Add Product Sites

**Select Site Activity**  
Indicate the site activity and activity types relevant.

\* Site Activity  
API Manufacture

Activities Conducted at Manufacturing Site - press Ctrl (Cmd on Mac) + Left Arrow or Ctrl (Cmd on Mac) + Right Arrow to move items between lists

Available	Selected
API fermentation: Non sterile	API Synthesis: Non sterile
API fermentation: Sterile	
API intermediate Manufacture	
API micronisation	
API Synthesis: Sterile	

Previous Next

*Figure 16: Next, indicate what activity the site is undertaking.*

Having located and assigned the correct Account, you will then be asked to complete the type of activity that occurs at this site.

If intermediate manufacture is selected as an activity then you will be asked to enter the name of the intermediate.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

### Add Product Sites

**Enter Additional Details**  
(Please fill out all required fields)

\* Intermediate Chemical Name

Previous Next

*Figure 17: If the intermediate manufacture is selected as an activity then you will be asked to enter the name of the intermediate.*

As indicated in Figure 19 the system will confirm the details for the product site record. Press next to create the record, or Previous to return for corrections.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

### Add Product Sites

**Check**  
Is this the site you were expecting to be linked to this product?

- Site Name: ePQS External Expert 1 Account
- Site Street:
- Site City:
- Site Zip/Postcode:
- Site Country:

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

Figure 18: Press Next to confirm the details for the product site record and create the record.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

### Add Product Sites

**Success**  
A new Product Site PS-29980 has been created for the APIMF Product P-12656:

- Site Name: ePQS External Expert 1 Account
- Site Activity: API Manufacture
- Activity Types: API intermediate Manufacture
- Site Address:

Next

About Us Contact Us Privacy Policy Legal Disclaimer

Figure 19: Confirmation of the sites creation should follow.

You will be informed that the Product site has now been created. This is also viewable on the product record, in the record's related list (figure 20)

ePQS Product P-12656

+ Follow Edit Printable View Delete

Product Type: Active Pharmaceutical Ingredient Master File  
Applicant Organization: ePQS Test Account 1 - NonStateActor  
Product Assessment Procedure: APIMF Procedure - Abridged  
Date of Prequalification/Acceptance:

Details **Related** Preview Document Document Download

API Grades (0)

ePQS Product History (5)

Date	Field	User	Original Value	New Value
29/08/2024, 17:12	Active Ingredient	ePQS External Applicant 1		Ritonavir
29/08/2024, 17:12	Current APIMF Version Number	ePQS External Applicant 1		
29/08/2024, 17:12	Product Subtype	ePQS External Applicant 1		None
29/08/2024, 17:12	Therapeutic Area(s)	ePQS External Applicant 1		
29/08/2024, 17:12	Created	ePQS External Applicant 1		

View All

Product Sites (1)

Product Site ID	Product Site Status	Site	Site Activity
PS-29980	Pending	ePQS External Expert 1 Account	API Manufacture

View All

Figure 20: Once the site is created it can be seen on the draft Product record from the "related Tab.

You will then loop back to a screen asking if you wish to create another product site record. If all sites have been created select "I don't want to add any more..." to move to the document upload phase as indicated is figure 21.

The screenshot shows the 'ePQS Application Wizard' interface. At the top, a progress bar indicates the current step is 'Product-Related Info', with 'Organization & Contacts' completed and 'Documents' and 'Finalize' pending. Below the progress bar, the heading 'Add Product Related Information' is followed by a red asterisk and the instruction 'Choose Product Related Information to Add to Application'. Two radio button options are present: 'Product Site' and 'I don't want to add any more product related information at this time'. The second option is selected. At the bottom right, there are 'Previous' and 'Next' buttons. A footer contains links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Figure 21: You can move to the document upload phase by selecting “I do not want to...”

## 5. Document uploading

The screenshot displays the 'ePQS Resume Wizard' interface. A top navigation bar includes links for 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'CRP Product Registrations', and a 'More' dropdown. The main content area shows the wizard title and the message 'You are uploading documents to Product#P-12656'. A 'Next' button is located at the bottom right. The footer contains links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Figure 22: Initial document upload screen

### 5.1. eCTD document upload

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

The screenshot shows the 'ePQS Application Wizard' interface for 'eCTD Submission Module 1 Information'. It provides a list of values for the Module 1 envelope, including Salesforce Case Id, Application Type, Application SubType, Contact-email, Organization Name, Product Id, Product Type, Product SubType, Product Assessment Procedure, and Product Name. A note at the top states: '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.' At the bottom right, there are 'Previous' and 'Next' buttons.

Figure 23: Information is provided for the applicant to complete their Module 1 Envelope information

**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):

New-APIMF-2025-0007\_P-13429

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 24: The systems provides the exact name to be used for the uploaded zip file*

Next, the system displays the exact name the submitted file should be named. The dossier for a product should be formatted in a single “.zip” file.

## 5.2. Common document upload steps

The next steps are common to both eCTD and non-eCTD uploads.

**ePQS Resume Wizard**

Organization & Contacts Documents Finalize

**Upload Documents**

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

Previous Next

*Figure 25: Document upload screen*

On the document upload screen you can upload single files, multiple files or folders. Press next once these are selected.

**Please note that non-eCTD dossiers should not be uploaded as a Zip file, but as folders or documents.**

You will be asked to confirm upload, you can also cancel and go back to the previous screen (figure 26).

ePQS Resume Wizard

Organization & Contacts ✓ ✓ ✓ Documents Finalize

### Upload Documents

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**.

100MB test folder

Cancel Upload

Previous Next

*Figure 26: Confirmation of the upload is required*

ePQS Resume Wizard

Organization & Contacts ✓ ✓ ✓ Documents Finalize

### Upload Documents

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**.

Success! Your files have been uploaded.  
Select More Files or Select More Folders

Cancel Upload

Previous Next

*Figure 27: If the documents have uploaded successful a confirmation screen will appear*

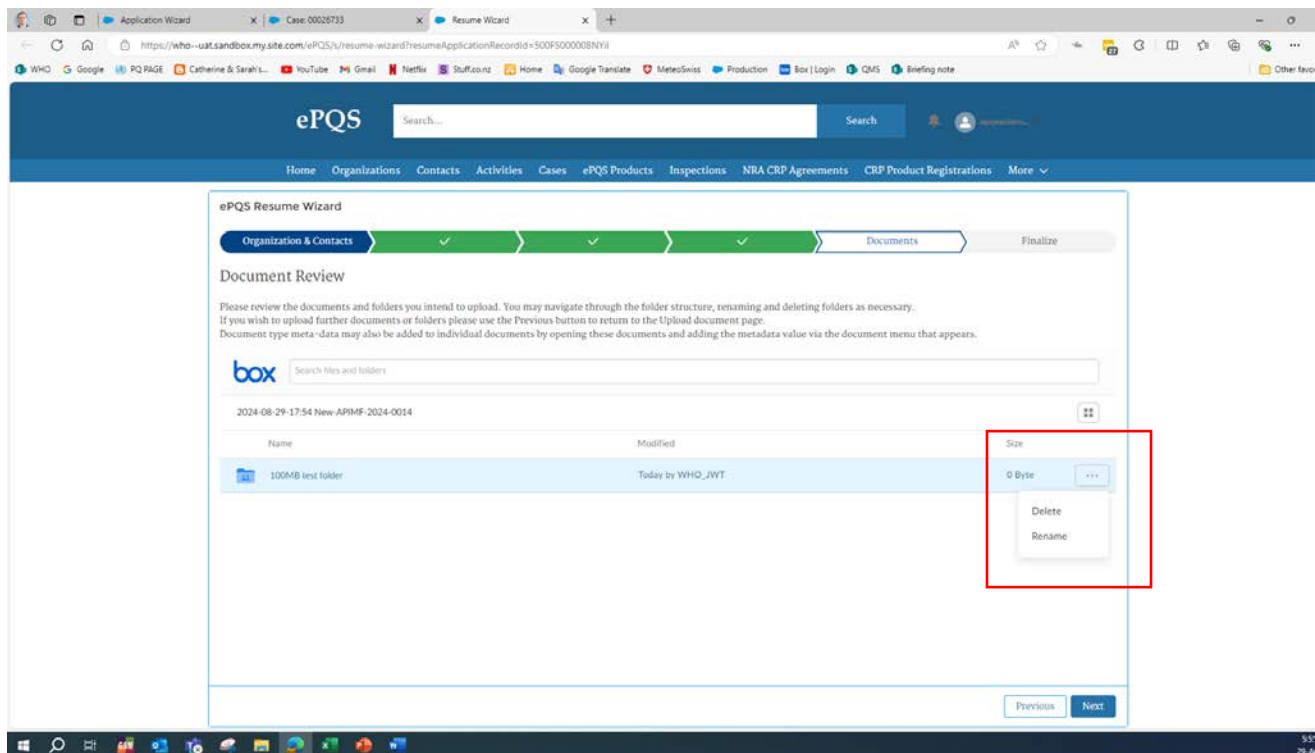


Figure 28: Document review screen where the uploaded files can be adjusted if necessary

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.

## 6. Submitting the application

ePQS Application Wizard

Organization & Contacts ✓ ✓ ✓ ✓ Finalize

### Review Application

It is important that you review your application prior to submission. Use the link provided to open it in a new tab and look at the information entered, and also review the related records (click on the Related sub-tab) of which you should be able to open those records too.

Case ID: New-APJMF-2025-0007  
Product or Laboratory ID: P-13429

**Submit, Save or Discard**  
Please choose whether you are ready to submit this application, if you need more time then save the existing draft, or discard if made in error.

\*Ready to submit?

☐ Yes  
☐ No, save existing draft application and product (if applicable)  
☐ No, discard this draft application and product (if applicable)

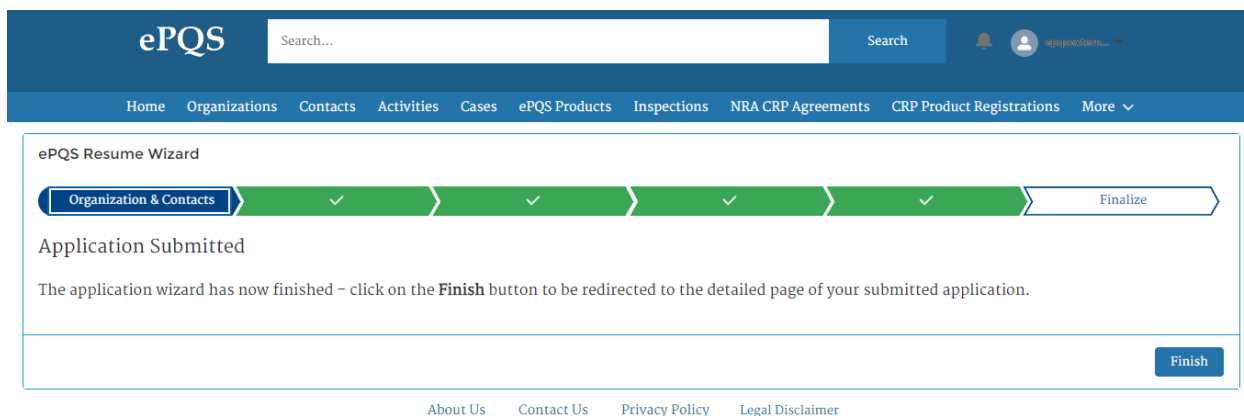
**Your application cannot be submitted. eCTD submissions require all files to be .zip format and named as specified in previous steps. Please click 'Previous' to correct your file(s) before submitting.**

Previous Next

Figure 29: Final screen before submitting

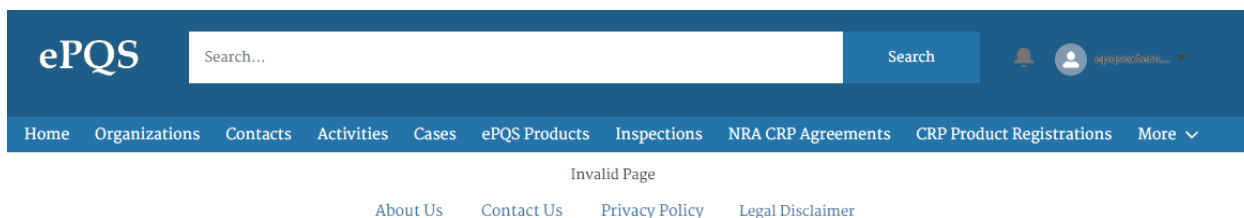
The final screen before submitting has three options. Save as a draft (see section 8), submitting, or discarding the application. If you discard the application, the application and product record will no longer be visible in the application and product lists. It can still be found via the global search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

The system will warn the applicant if the eCTD document requirements have not been met with respect to file name and the type and number of files. Press the “previous” button to move backwards in the wizard, back to the document upload step, to revise the files to be uploaded.



*Figure 30: Confirmation screen*

Currently there is a bug that displays “Invalid” once finished is selected. This can be disregarded. Simply select a new list or refresh the screen.



*Figure 31: Currently there is a bug once you press finish. Simply refresh the page to continue in the portal*

## 7. 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 32). Second, the status of the application changes from Draft to Under Screening. Finally, the Date Application Submitted is entered or updated by the system.



Case  
**New-APIMF-2024-0013**

+ Follow

Edit

Resume Application Wizard

New Component(s) ▼

Case Record Type

Case Number

Status

Applicant Organization

Date of Prequalification/Acceptance

Mx APIMF Application

00026722

Under Screening

[ePQS Test Account 1 - NonStateActor](#)

Details

Related

Activities

Preview Document

Document Download

Document Submission

▼ General Details

ePQS Case ID

New-APIMF-2024-0013

Case Owner

ePQS Mx API Queue

WHO Application Number

New-APIMF-2024-0013

Status

Under Screening

WHO Product ID

[P-12650](#)

Applicant Organization

[ePQS Test Account 1 - NonStateActor](#)

Product Type

Applicant Organization (Legal)

**Figure 32:** Record ownership and status changes once submitted

If an eCTD submission has been submitted, the eCTD compliance field on the application and product records 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 step is unsuccessful, the eCTD Compliance value will remain as Tentative.

## 7.1. Notifications

An email notification is sent to the Primary contact of the application confirming the submission of the application.

If an eCTD application has been submitted, a further 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 seen in figure 33.

Case  
**New-APIMF-2025-0007**

+ Follow

Edit

Resume Application Wizard

New Component(s) ▼

Case Record Type

Case Number

Status

Applicant Organization

Date of Prequalification/Acceptance

Mx APIMF Application

00028928

Draft

[PQT Pharmaceuticals Inc \(Site II\)](#)

Details

Related

Activities

Preview Document

Document Download

Document Submission

box

Search files and folders

New-APIMF-2025-0007

Name	Modified	Size
Correspondence (External)	Today	0 Byte

**Figure 33:** eCTD validation reports are placed in the Correspondence (External) folder of the application

## 8. Saving as a draft and recommencing

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

The screenshot shows the ePQS application record page for Case New-APIMF-2024-0018. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, the case details are displayed, including Case Record Type (Mx APIMF Application), Case Number (00027852), Status (Draft), Applicant Organization, Date of Prequalification/Acceptance, and Case Owner. A red box highlights the 'Resume Application Wizard' button, which is located next to the 'Edit' button. Below the case details, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'Details' tab is selected, showing General Details for the case, including ePQS Case ID, WHO Application Number, WHO Product ID, Product Type, Application Type, Application Subtype, Product Assessment Procedure, and Reference Authority. The right side of the page shows the Case Owner, Status (Draft), Applicant Organization, Applicant Organization (Legal), Applicant Primary Contact, Applicant Secondary Contact, and Alternative Applicant Secondary Contact.

Figure 34: Figure 7: Select the Resume Application Wizard button to recommence the application wizard.

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](mailto: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.

## 9. Acceptance for assessment

If the screening is successful, the API Assessment group will accept the application for assessment. This results in the change in status of the Product and Application record to Under Assessment.

Subsequently, you will receive an email from the API assessment group confirming the acceptance of assessment of the application as per normal business processes.

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

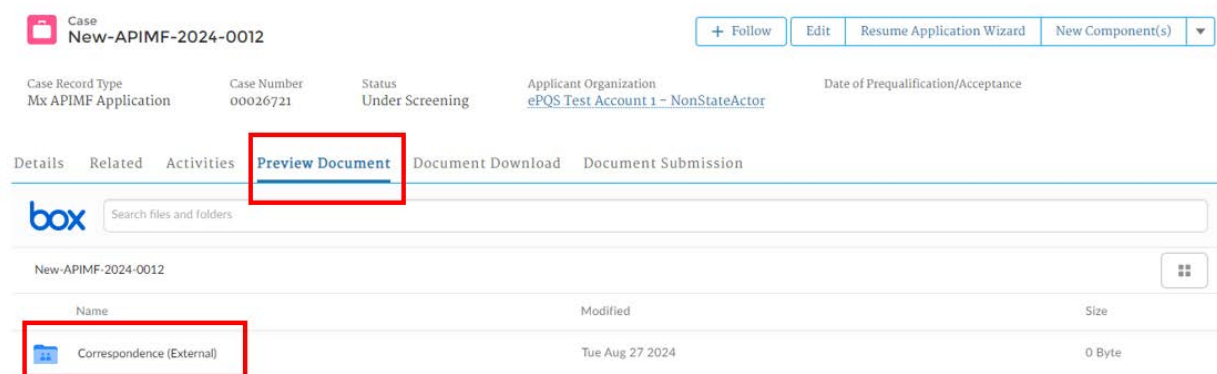
## 10. Receiving and responding to questions

Receiving and uploading documents in response to screening or assessment queries occurs in the same manner as described below.

### 10.1. Receiving requests

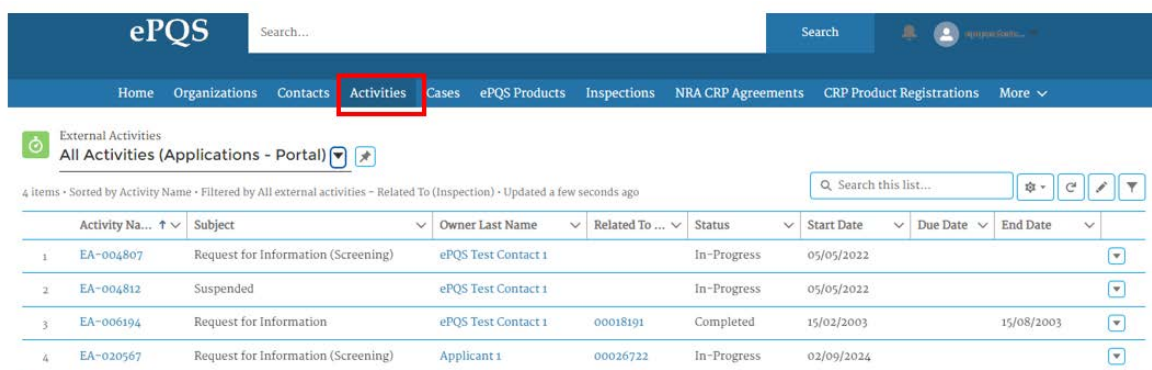
The primary means for alerting an applicant that there are questions or information required is via email. In case further information is required, you will be contacted by the API group by email.

If a letter has been sent with the email, a copy of this letter can be located in the Correspondence (External) folder, which is accessible via the application record as indicated in figure 35.



*Figure 35: Formal correspondence is located in the applications external Correspondence folder. It can be previewed and downloaded.*

In addition, you will notice that an Activity has been opened in the name of the primary contact (figure 36). And, the system will have been sent an email alerting the assignee to this (figure 37).



*Figure 36: Outstanding tasks can be viewed 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](mailto:contactepqs@who.int)

*Figure 37: When an activity is assigned an accompanying email is also sent*

## 10.2. Responding to requests

To upload documents in response to questions raised, or in response to eCTD validation requests, proceed to the application and select the document submission tab. **Do not start a new application wizard.**

Case New-APIMF-2024-0012

+ Follow Edit Resume Application Wizard New Component(s)

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance
Mx APIMF Application	00026721	Under Screening	ePQS Test Account 1 - NonStateActor	

Details Related Activities Preview Document Document Download Document Submission

Case Submission Wizard

Welcome to Document Submission Wizard. Please click on Next to proceed for Case#00026721

Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 38: Documents can be uploaded via the application record, using the Document submission tab.*

This commences a short wizard to upload documents. 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.

If the application was made in eCTD format, then subsequent responses must also be in eCTD. In such situations, the system will display the information for the Module 1 envelope and exact file name, as it did for the initial submission (see figure 23 and 24).

The system does not currently alert internal or external users when additional information is uploaded. This is being fixed. In the meantime, please ensure an email is sent to [APIassessment@who.int](mailto:APIassessment@who.int) alerting them that documents have been uploaded.

In addition to any correspondence you might send to the assessment team alerting them to the response, you can also signal your response by changing the status of the activity to “actioned” as indicated in figure 39.

The screenshot shows a form with three main sections: Information, Case Information, and System Information. In the Information section, the 'Status' dropdown menu is highlighted in yellow and set to 'Actioned'. Other fields include 'Related To (Case)', 'Related To (Inspection)', 'Activity Name', 'Due Date', 'Start Date', 'End Date', 'Owner', 'Time Assignment', 'Manufacturer', 'Activity Outcome', 'Activity Phase', and 'Response Date'. The Case Information section includes 'Case Record Type', 'WHO Product ID', and 'Component Type'. The System Information section includes 'Created By' and 'Last Modified By'. At the bottom, there are 'Cancel' and 'Save' buttons.

*Figure 39: By changing the status of the pending activity to Action this signals to the assessment team a response has been submitted.*

Once your response has been reviewed, and assuming this is a valid response, the assessment team will change the status and outcome of the activity, and enter the end date.

The screenshot shows the same form as Figure 39, but with updated values. The 'Status' dropdown menu is now set to 'Completed' and the 'Activity Outcome' is 'Received'. The 'End Date' is now '03/09/2024'. The 'Owner' is 'ePQS External Applicant 1'. The 'Response Date' is '02/09/2024'. The 'Case Record Type' is 'Mx APIMF Application' and the 'WHO Product ID' is 'P-12650'. The 'Component Type' is empty.

*Figure 40: Once the response is reviewed the activity will be further updated*

This completes the response to a request for screening information.

## 11. Record monitoring

Further guidance on other aspects of the portal will be provided in separate documents, but generally speaking 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