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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

Applications 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 via 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.

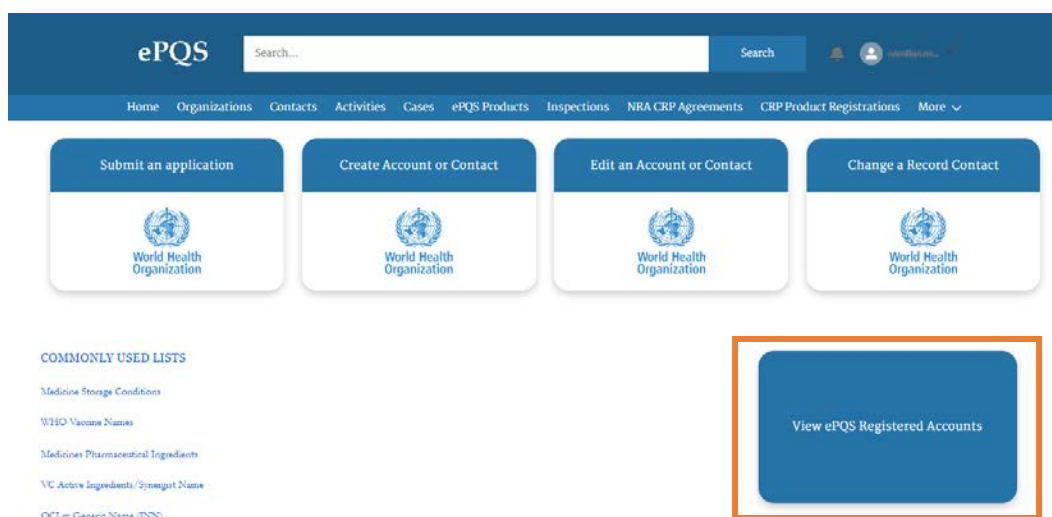


Figure 1: The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts”

3. Accessing the Portal

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

3.1. Understanding the relationship between an APIMF record and an API Prequalification record.

Many of the API Prequalification Product record's details depend upon the associated APIMF Product record's details. (See figure 2)

An APIMF dossier can be used in the APIMF Procedure; the API Prequalification procedure, or in both procedures.

An application to prequalify an API can be made using:

- an APIMF not previously submitted (application sub-type standard);
- an APIMF undergoing assessment via the APIMF procedure (application sub-type Parallel); or
- an APIMF already accepted in the APIMF Procedure (application sub-type Conversion).

The screenshot displays the 'ePQS Product API-PQ Test Product' record. The interface includes tabs for 'Details', 'Related', 'Document', 'Activity', 'Chatter', and 'Audit Trail'. The 'Details' tab is active, showing a 'Comments' section and an 'Information' section. The 'Information' section is divided into two columns. The left column contains fields for 'WHO Product ID', 'Product Type', 'Product Subtype', 'Responsible team', 'Product Assessment Procedure', 'Applicant Organization', 'Applicant Organization (Legal)', 'Primary Contact', 'Secondary Contact', 'Alternative Secondary Contact', 'Therapeutic Area(s)', 'Reference Authority', 'Referenced APIMF', and 'API Grade'. The right column contains fields for 'Product Status', 'Original Application', 'Expression of Interest', 'Date Application Accepted for Assessment', 'Date of Prequalification/Acceptance', 'Reason for Product Suspension', 'Date of Product Suspension', 'Date of Product Cancellation...', 'Reason for Product Cancellation...', and 'API Grade'. The 'Referenced APIMF' field is highlighted with a red box, showing the value 'APIMF test Product'.

Field	Value
WHO Product ID	API-PQ Test Product
Product Type	Active Pharmaceutical Ingredient
Product Subtype	None
Responsible team	Medicines Team
Product Assessment Procedure	
Applicant Organization	ePQS Test Account 1 - NonStateActor
Applicant Organization (Legal)	ePQS Test Account 1 - NonStateActor
Primary Contact	ePQS External Applicant 1
Secondary Contact	
Alternative Secondary Contact	
Therapeutic Area(s)	HIV/AIDS
Reference Authority	
Referenced APIMF	APIMF test Product
API Grade	
Product Status	Under Screening
Original Application	
Expression of Interest	
Date Application Accepted for Assessment	
Date of Prequalification/Acceptance	
Reason for Product Suspension	
Date of Product Suspension	
Date of Product Cancellation...	
Reason for Product Cancellation...	

Figure 2: The information for an API Product record is based heavily on the information of the referenced APIMF record.

4. Wizard steps

4.1. Wizard commencement

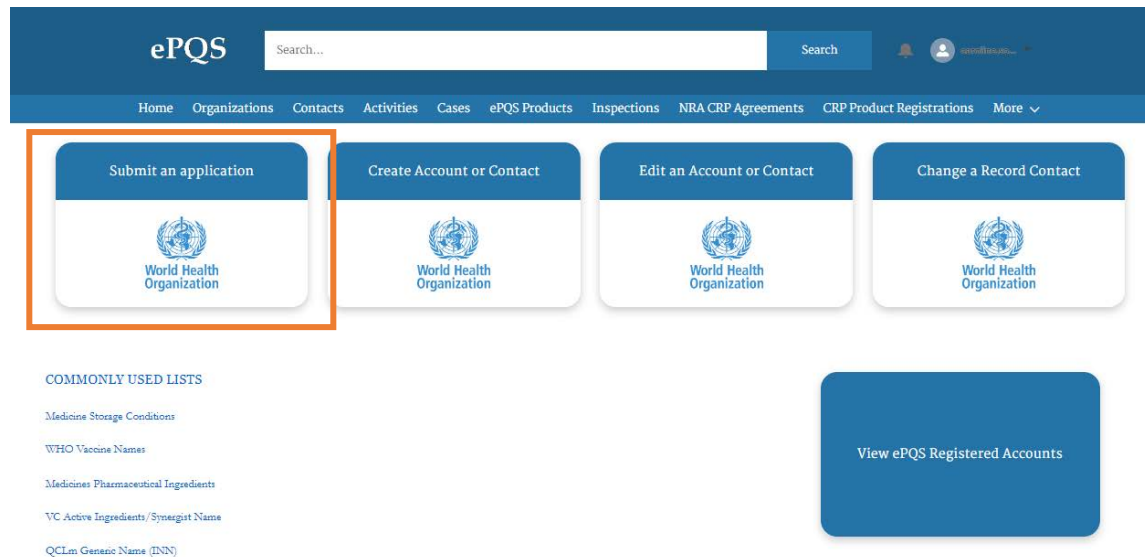


Figure 3: Commence the application process by selecting the Submit an Application tile

An application can be initiated by selecting the *Submit an Application* tile from the portal as indicated in Figure 3.

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 4. The system will offer for selection, any contact associated with this account. Note, the contacts do not need to be ePQS portal users, although pragmatically 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 4: 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

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Figure 5: 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(s) and then application subtype(s) (if this is relevant) relevant to the product type.

4.3. Application sub-type selection

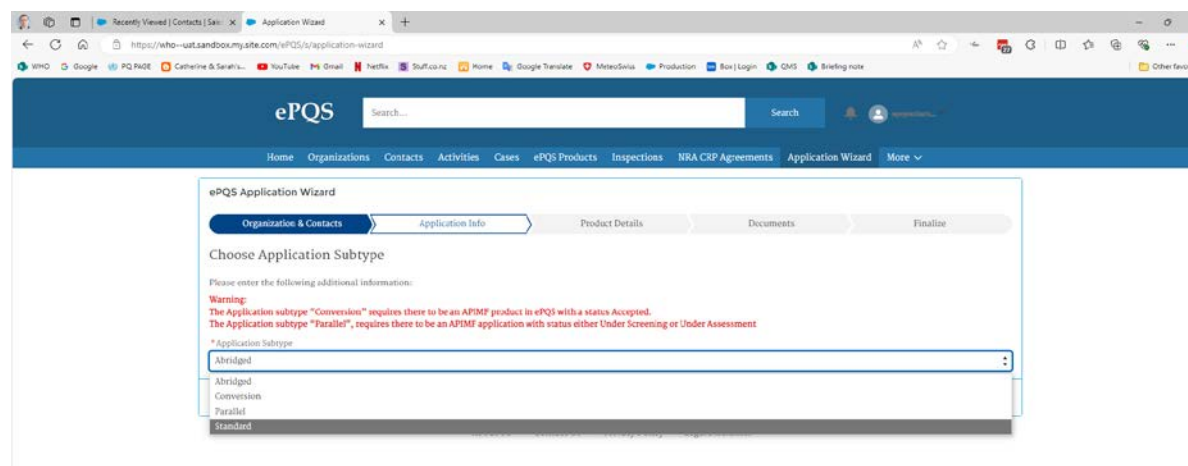


Figure 6: API Prequalification applications have 4 application sub-types.

There are four application subtypes for an API Prequalification application.

Application Sub-type	APIMF requirement	ePQS wizard action
Abridged	The APIMF has been accepted by a reference agency and their reports are available. The APIMF may already exist in the ePQS system as an abridged APIMF.	An API PQ Product and Application record is created. If the APIMF is new, an APIMF product record is created.
Conversion	The APIMF is currently accepted as part of the APIMF Procedure.	An API PQ Product and Application record is created based on the referenced APIMF record.
Parallel	The APIMF is currently undergoing assessment as part of the APIMF Procedure	An API PQ Product and Application record is created based on the referenced APIMF record
Standard	The APIMF has not been previously submitted for the APIMF Procedure	An API PQ Product and Application record is created. An APIMF product record is created.

Figure 7: Different API-PQ sub-application types

Please note the following bugs in the system:

When selecting Conversion the system offers APIMFs of any status, so please select carefully.

When selecting Parallel the systems recreates a new APIMF. Please do not use this sub-type, rather contact the API team who will do so for you.

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

The screenshot shows the 'ePQS Application Wizard' interface. At the top, a progress bar has five steps: 'Organization & Contacts' (active), 'Application Info', 'Product Details', 'Documents', and 'Finalize'. Below the progress bar, the heading 'Confirm Application Details' is followed by a message: 'By proceeding to the next step you will be creating a draft Mx API New Application. This draft application will be available in your List View of Cases.' Below this message is a bulleted list of application details: 'Application Type: Prequalification', 'Application Subtype: Abridged', 'Product Type: Active Pharmaceutical Ingredient', 'Organization: ePQS Test Account 1 - NonStateActor', and 'Primary Contact: ePQS External Applicant 1'. At the bottom right of the main content area are 'Previous' and 'Next' buttons. A footer contains links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Figure 8: The system summarizes the application is to be created.

The screenshot shows the 'ePQS Application Wizard' interface. The progress bar is identical to the previous step, with 'Organization & Contacts' active. The heading 'Continue Application' is followed by the message 'A draft application has been created.' Below this is a reference message: 'For reference the new application has the case number PQ-API-2024-0021. You can view the draft application details by following the link.' A 'Next' button is located at the bottom right. The footer with links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer' is also present.

Figure 9: A draft application record has now been created in the system.

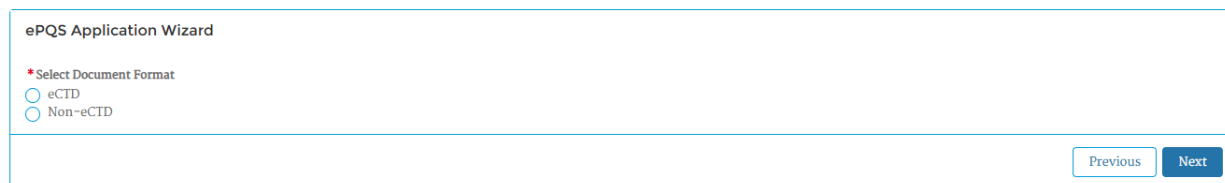
This record can now also be located via the global search bar or in the case list view.

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.

The screenshot shows the 'ePQS Application Wizard' interface. The progress bar is identical to the previous steps, with 'Organization & Contacts' active. The heading 'Additional Application Info' is followed by a label: '* Reference Authority to be used in Assessments'. Below this is a picklist menu showing the selected option: 'EDQM - CS 30026, 7 Allée Kastner, Strasbourg, 67081, France'. At the bottom right are 'Previous' and 'Next' buttons. The footer with links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer' is also present.

Figure 10: If an Abridged application was selected the applicant will be asked to select the Reference Authority.

4.4. eCTD or non-eCTD



ePQS Application Wizard

*Select Document Format

☐ eCTD

☐ Non-eCTD

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Figure 11: 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 Reference APIMFs offered by the system for the application sub-types: Abridged, Conversion and Parallel (see 4.6). If an eCTD application is made then the reference APIMF must already be eCTD compliant. Similarly if a non-CTD application is being made then the APIMF must not be eCTD compliant.

Therefore, it may be necessary to convert an existing APIMF to eCTD format, via the APIMF amendment procedure, prior to lodging an application for API Prequalification.

4.5. Product record creation



ePQS Application Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

New Product

Since this is a Prequalification type application, a new product will be created of type:

- Prequalified Active Pharmaceutical Ingredient (API PQ)

It will be linked to your application, PQ-API-2024-0021.

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Figure 12: As a next step in the application wizard, an API PQ Product record is created.

4.5.1. Referenced APIMF

If the Conversion, Parallel or Abridged application subtype was selected, then the system will offer the user a list of APIMFs that meet the specific requirement for these application subtypes. If the Abridged application is not based on an APIMF already held, then Not applicable can be selected (Figure 13).

ePQS Application Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

New Mx API Product Information
(Please fill out all required fields)

* Referenced APIMF

APIMF test Product - Ritonavir

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Figure 13: For Conversion, parallel, or abridged applications: the system will offer APIMFs that meet the criteria for each application subtype

If a standard application subtype was selected, or the abridged application has no existing reference APIMF, the system will prompt you to enter information to create a new reference APIMF as per figure 14.

ePQS Resume Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

New Mx APIMF Product
(Please fill out all required fields)

* Active Ingredient Name (Mx)

Search Mx Pharmaceutical Ingredients...

* Current APIMF Version Number

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

- Analgesics
- Anesthetics
- Antihemorrhagics (Haemophilia)
- Bacterial vaccines (Pneumococcal infections)
- Covid-19

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Figure 14: Information relating to the API, version number, and relevant therapeutic area should next be entered.

As indicated in figure 14, 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.

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 15, 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.

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Figure 15: 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 16.

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.

- API Product: P-12646

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Figure 16: A new APIMF product record is created.

ePQS Application Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

Product Created & Linked

New products have been created and linked to your application, PQ-API-2024-0034. By clicking on the links provided you can see the product records. The product records are also available in your Products' List View.

- API Product: P-12701
- APIMF Product: P-12702

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Figure 17: If an APIMF has been created as well as an API PQ product then the system will indicate this also

4.6. Product site creation

Once the Product record(s) 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. You will return to this screen eventually in case you need to create another product site.

For API PQ 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.

Depending on the application subtype, the same product site will also be added to the reference APIMF product record that is being created in parallel.

The screenshot shows the 'ePQS Resume 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 sub-instruction: '* Choose Product Related Information to Add to Application'. Two radio button options are presented: 'Product Site' (which is selected) and 'I don't want to add any more product related information at this time'. At the bottom right of the form area are 'Previous' and 'Next' buttons. A footer contains links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Figure 18: Every API PQ 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.

This screenshot displays the 'ePQS Application Wizard' in a web browser. The progress bar shows 'Product-Related Info' as the active step. The section 'Add Product Sites' includes a 'Choose Site' instruction: 'Click "Previous" if the site you require is not on the list. Please ensure you are choosing the manufacturing site address.' Below this is a search field labeled '* Site Name'. A dropdown menu is open, showing three search results: 'ePQS External Expert 1 Account -', 'ePQS External Expert 1 Account -', and 'ePQS Test Account 1 - NonStateActor - hello, Hyderabad, 1111 556, India'. The browser's address bar shows the URL 'https://who-uat.sandbox.my.site.com/ePQS/s/application-wizard'. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. The footer has links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Figure 19: Based on the information entered into the site search field the system returns all accounts matching this name.

On the next screen (figure 19), the system will offer to you available accounts within the system matching the entry criteria.

As mentioned in *Section 2 – Prerequisites*, a list of sites is available to 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 20: 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 site 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

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Figure 21: 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 22 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:

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Figure 22: 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

Figure 23: 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 24).

+ 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 24: 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 25.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Related Information

* Choose Product Related Information to Add to Application

☐ Product Site

☒ I don't want to add any more product related information at this time

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Figure 25: You can move to the document upload phase by selecting “I do not want to...”

5. Document uploading

ePQS Resume Wizard

You are uploading documents to Product#P-12656

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Figure 26: 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 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 : 00028928
Application Type : APIMF Procedure
Application SubType : Standard
Contact-email : epqscontact2@gmail.com
Organization Name : PQT Pharmaceuticals Inc (Site II)
Product Id : P-13429
Product Type : Active Pharmaceutical Ingredient Master File
Product SubType : None
Product Assessment Procedure : APIMF Procedure - Standard
Product Name : Ritonavir

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Figure 27: 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

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Figure 28: 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 29: Document upload screen

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

You will be asked to confirm upload, you can also cancel and go back to the previous screen (figure 30).

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 30: 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 31: If the documents have uploaded successful a confirmation screen will appear

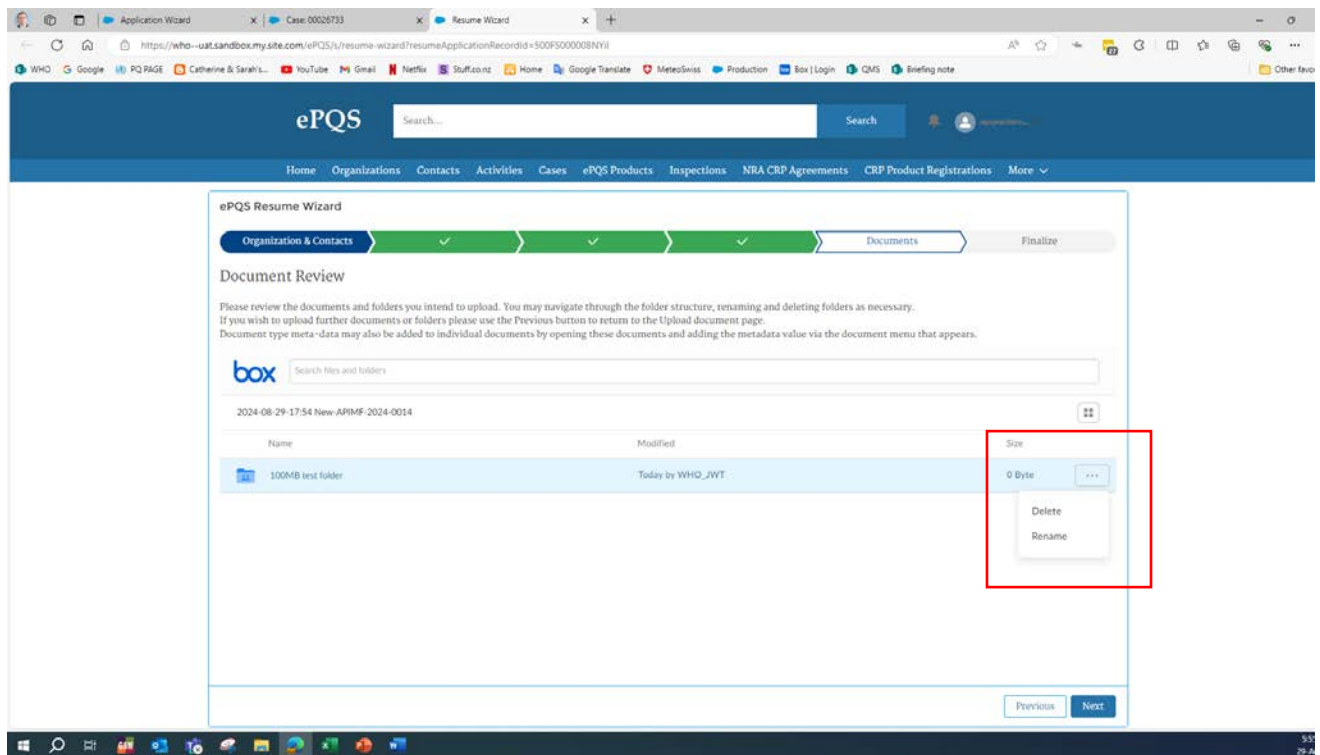


Figure 32: Document review screen where the uploaded files can be adjusted if necessary

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-APIME-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 33: 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.

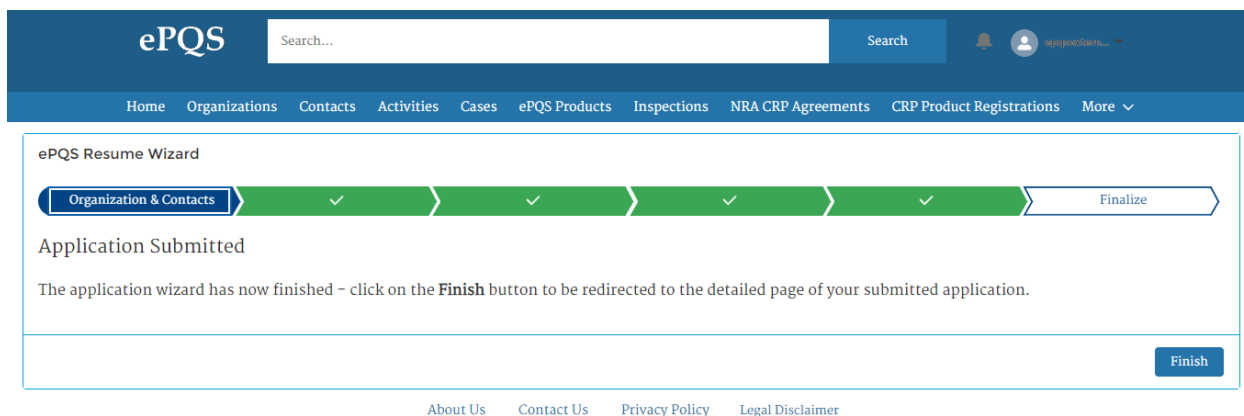


Figure 34: Confirmation screen

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.

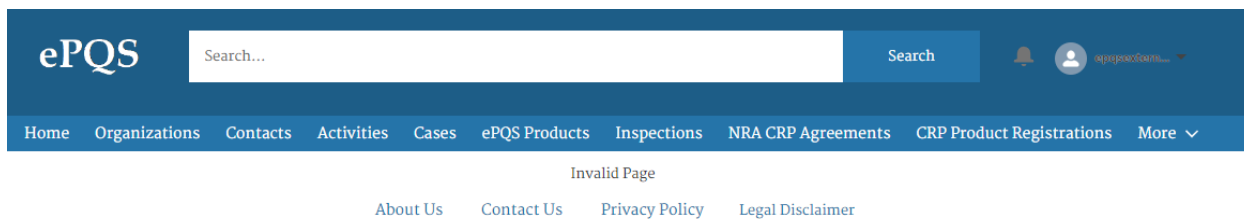


Figure 35: Currently there is a bug once you press finish. Simply refresh the page to continue in the portal

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. 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

WHO Application Number

New-APIMF-2024-0013

WHO Product ID

P-12650

Product Type

Case Owner

ePQS Mx API Queue

Status

Under Screening

Applicant Organization

ePQS Test Account 1 - NonStateActor

Applicant Organization (Legal)

Figure 36: 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

ePQS will send 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 37.

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 37: 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 in the top right corner. 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 ePQS Case ID (New-APIMF-2024-0018), WHO Application Number (New-APIMF-2024-0018), WHO Product ID (P-13080), Product Type (Active Pharmaceutical Ingredient Master File), Application Type (APIMF Procedure), Application Subtype (Standard), Product Assessment Procedure (APIMF Procedure - Standard), and Reference Authority. The right side of the details section shows the Case Owner, Status (Draft), Applicant Organization, Applicant Organization (Legal), Applicant Primary Contact, Applicant Secondary Contact, and Alternative Applicant Secondary Contact.

Figure 38: 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 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.

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, a copy of this letter can be located in the Correspondence (External folder), which is accessible via the application record as indicated in figure 39.



Figure 39: Formal correspondence is located in the applications external Correspondence folder. It can be previewed and downloaded.

In addition, an Activity will have been opened in the name of the primary contact (figure 40). And, an email sent to the primary contact alerting them to the activity (figure 41).

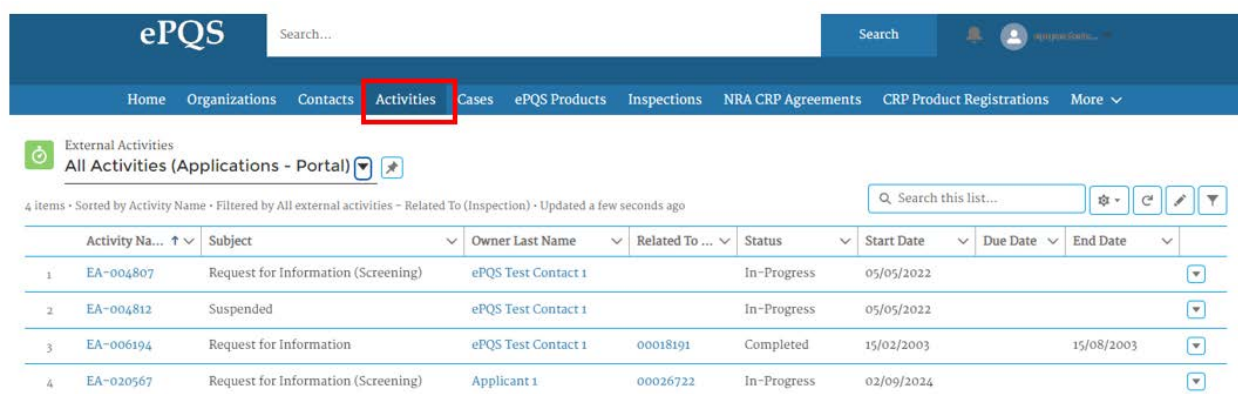


Figure 40: Outstanding tasks can be viewed via the activity list

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

Figure 41: 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.

The screenshot displays the ePQS application interface for Case New-APIMF-2024-0012. At the top, there are buttons for '+ Follow', 'Edit', 'Resume Application Wizard', and 'New Component(s)'. Below this, a table lists case details: Case Record Type (Mx APIMF Application), Case Number (00026721), Status (Under Screening), Applicant Organization (ePQS Test Account 1 - NonStateActor), and Date of Prequalification/Acceptance. A navigation bar includes tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission (which is highlighted with a red box). The 'Document Submission' tab leads to the 'Case Submission Wizard', which displays a welcome message and a 'Next' button.

Figure 42: 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 27 and 28).

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 alerting them that documents have been uploaded.

In addition to any correspondence you might undertake with the assessment team, you can also signal your response by changing the status of the activity to “actioned” as indicated in figure 43.

Information Related To (Case) Related To (Inspection) Activity Name Request for Information (Screening) Due Date Start Date 05/05/2022 End Date		Owner User16482088782195409890 Time Assignment Manufacturer * Status Actioned Activity Outcome Activity Phase Under Screening Response Date
Case Information Case Record Type <i>This field is calculated upon save</i> WHO Product ID <i>This field is calculated upon save</i>		Component Type <i>This field is calculated upon save</i>
System Information Created By Kingsley Aboagye AWURU, 05/05/2022, 14:26		Last Modified By Kingsley Aboagye AWURU, 26/05/2022, 13:51
<div> <div>Cancel</div> <div>Save</div> <div>Done Task</div> </div>		

Figure 43: 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.

Information Related To (Case) 00026722 Related To (Inspection) Activity Name Request for Information (Screening) Due Date Start Date 02/09/2024 End Date 03/09/2024		Owner ePOS External Applicant 1 Time Assignment Manufacturer Status Completed Activity Outcome Received Activity Phase Under Screening Response Date 02/09/2024
Case Information Case Record Type Mx APIMF Application WHO Product ID P-12650		Component Type

Figure 44: 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.