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1. Scope

This guide outlines the procedures for the submission by a candidate laboratory of an application to become a Performance Evaluation Laboratory on the ePQS portal, as well as follow-up steps during the assessment process.

2. 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.

This application process includes a step that requires the applicant to select an account (the candidate laboratory) from within the ePQS database. 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.

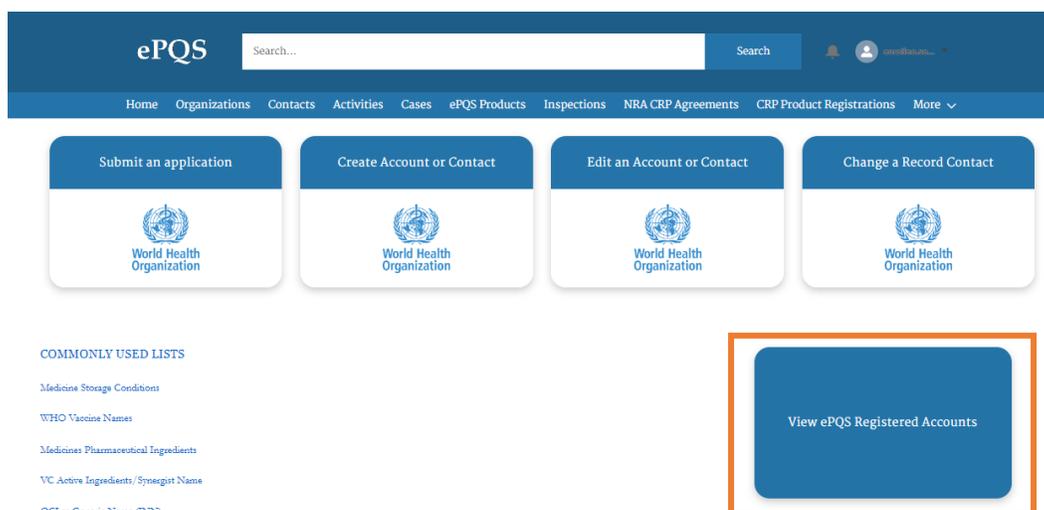


Figure 1 : The existence of an Account within the ePQS system can be determined by clicking on “View ePQS Registered Accounts”

3. Accessing the Portal

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

4. New submission

Wizard commencement

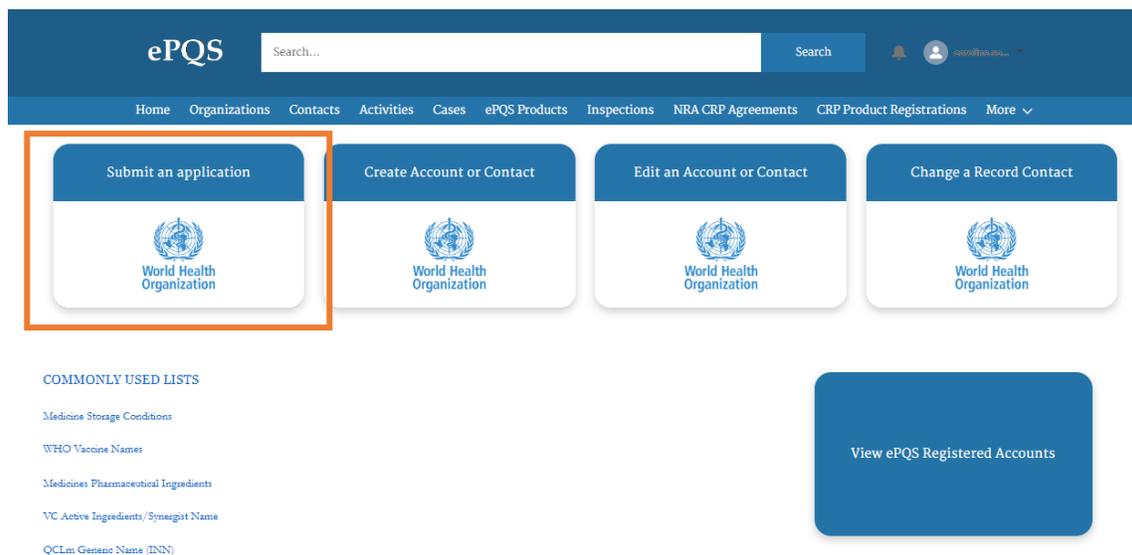


Figure 2: Commence the application process by selecting the Submit an Application tile

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

Choose Application Organization and Contact

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, figure 3. The system will offer for selection, any contact associated with this account.

Home Organizations Contacts Activities Cases ePQS Products Inspections New/old Agreements Application Wizard more

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.

You will then be prompted to select the product type that you wish to lodge an application for. Select WHO Prequalification Evaluating Laboratory.

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

Figure 4: Select WHO Prequalification Evaluating Laboratory.

On the next screen you will be offered a list of the specific application type. Select WHO Performance Evaluation Laboratory.

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

- WHO Performance Evaluation Laboratory
- WPPEL Reassessment

Previous Next

Figure 5: Select WHO Performance Evaluation Laboratory.

The system will then playback to you the application you are planning to create. By proceeding, an application record will be created in the system. Please take note the application number.

The screenshot shows the 'ePQS Application Wizard' interface. At the top, there is a progress bar with five steps: 'Organization & Contacts' (highlighted in blue), 'Application Info', 'Product Details', 'Documents', and 'Finalize'. Below the progress bar, the heading is 'Confirm Application Details'. The main text reads: 'By proceeding to the next step you will be creating a draft Dx WPEL New Application. This draft application will be available in your List View of Cases.' Below this, there is a bulleted list of application details: 'Application Type: WHO Performance Evaluation Laboratory', 'Product Type: WHO Prequalification Evaluating Laboratory', 'Organization: [redacted]', and 'Primary Contact: [redacted]'. At the bottom right, there are two buttons: 'Previous' and 'Next'.

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

The screenshot shows the 'ePQS Application Wizard' interface. At the top, there is a progress bar with five steps: 'Organization & Contacts' (highlighted in blue), 'Application Info', 'Product Details', 'Documents', and 'Finalize'. Below the progress bar, the heading is 'Continue Application'. The main text reads: 'A draft application has been created.' Below this, there is a line of text: 'For reference the new application has the case number New-WPEL-2024-0004. You can view the draft application details by following the link.' At the bottom right, there is a 'Next' button.

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.

Create a Product

Click Next to proceed with providing information about the laboratory applying to become a PEL.

Type in the 2-3 first characters of the name of the laboratory – or more characters to limit the search. A search will be made, and a list of propositions will appear in the drop-down menu on the next screen.

Please note that the Laboratory listed here may be different from the Applicant Organization. For example, if different laboratories from the same institution apply for listing for different types of tests, then it is recommended to use the Institution as the Applicant Organization and the specific laboratory for the WPEL Laboratory Details. In this case, separate accounts must be created, one for the Institution and one for each of the specific laboratories. Separate applications must also be created for the different Laboratories.

ePQS Application Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

Further WPEL Laboratory Details 1
(Please fill out all required fields)

* Laboratory Site - enter at least 2 characters of the site you wish to add

Next

Figure 8: Type in at least 2-3 characters of the name of the laboratory.

A dropdown menu will, where you may select the laboratory. If it does not appear, click on previous and try using other letters of the names. If you cannot find the name of the laboratory, this may be due to the fact that the account is not registered, please contact us.

Select whether you are applying to conduct evaluation under Option 1, Option 2, or both. In the latter case, hold down the Ctrl key on a PC or Command key on an Apple computer.

ePQS Application Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

Further WPEL Laboratory Details 1a
Click 'Previous' if the organization you require is not on the list.

* Laboratory Organization

* WPEL Option List: To select multiple items, hold down the Ctrl (PC) or Command (Mac) key

Option 1
Option 2

Previous Next

Figure 9: Select the laboratory and whether applying for evaluations under option 1 and/or option 2.

The system confirms the creation of a Product. reference number P-xxxxx was given to your laboratory. However, we will assign a different reference number “ALE-xxx”, which will overwrite this number. This will be communicated to you by email when we confirm receipt of your application.

ePQS Application Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

Laboratory Successfully Updated
The details you have just entered have been updated on the new WHO Prequalification Evaluating Laboratory linked to your New-WPEL-2024-0004 application. By clicking on the link provided you can see the product record. The product record is also available in your Products' List View.

- Product: P-13161.

Previous Next

Figure 10: The product was created.

5. Document uploading

In the next screen, you will be able to upload documents to support your application.

Upload the following documents – these may be uploaded separately. Please limit the file names to 50 characters.

- Completed Expression of Interest form (IVD/TP/12a)
- Attachments requested as per the Expression of Interest

ePQS Application 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 11: Document upload screen

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

ePQS Application 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 12: If document upload was successful, this screen will appear.

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. You can also go back by clicking on Previous to add more files.

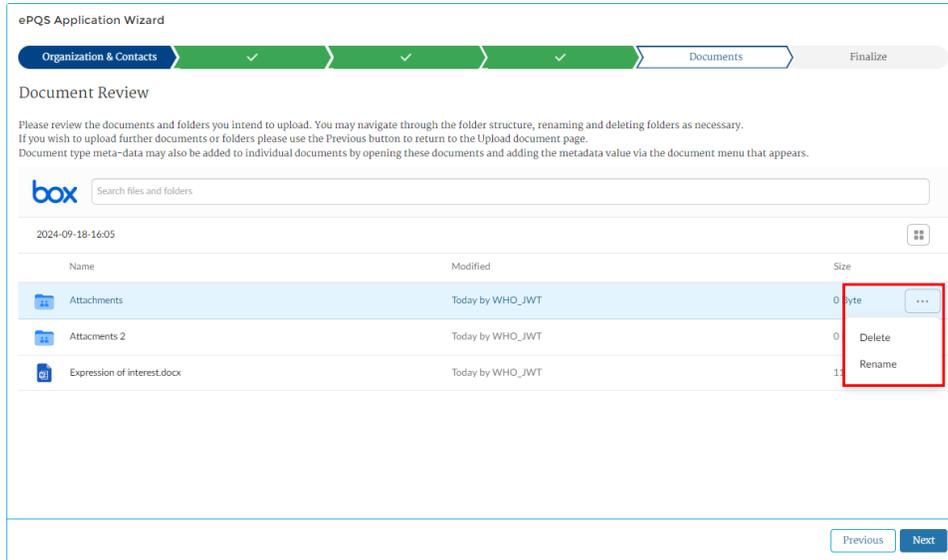


Figure 13: Document review screen where the uploaded files can be adjusted if necessary

6. Submission

The final screen before submitting has three options: submitting, saving as a draft (see section 7), 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.

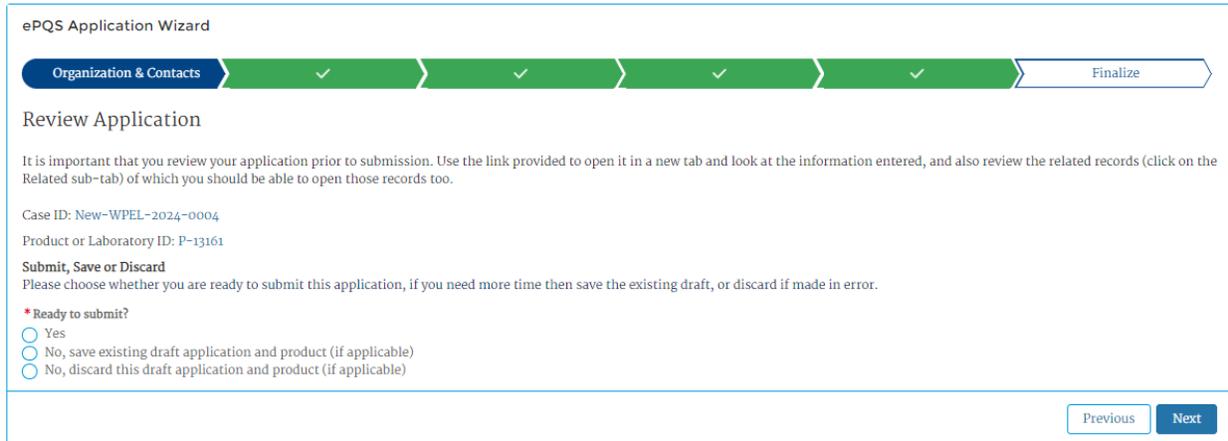


Figure 14: Final screen before submitting

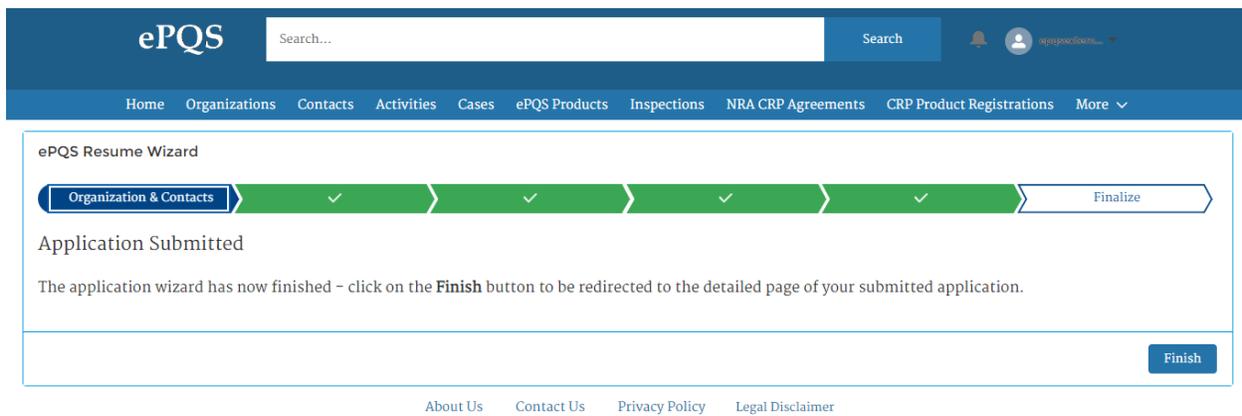


Figure 15: Confirmation screen

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).

Second, the status of the application changes from Draft to Under screening.

Finally, the Date Application Submitted is entered by the system.



Figure 16: Record ownership and status changes once submitted.

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

An email notification will be sent automatically by ePQS to the Primary contact of the application to confirm receipt of the application.

An email notification will also be sent by ePQS to the PQ team in charge. However, we recommend that you also send an email to diagnostics@who.int to confirm that an application has been submitted.

The PQ team will send an email acknowledging receipt of the application and informing you of the reference number assigned to the laboratory (ALE_ xxx). *

7. Saving as a draft and recommencing

To restart the application, click on Cases in the ePQS portal and locate the draft application.

1	00026837	New-WPEL-2024-0005	Dx WPEL New Application	Draft
2	00026836	New-WPEL-2024-0004	Dx WPEL New Application	Under Screening
3	00026808	PQ-IVD-2024-0029	Dx IVD New Prequalification Application	Under Screening

Figure 17: Locate the draft application in the list of Cases

Open the application record by clicking on the application number on the left of the list. In the draft application record, select the Resume Application Wizard button to restart the application.

Case Record Type: Dx WPEL New Application
Case Number: 00026837
Applicant Organization: Abbott Molecular Inc.
Status: Draft
Date of Prequalification/Acceptance:
Case Owner: Caroline So...

Buttons: + Follow, Edit, Resume Application Wizard, New Component(s)

Details: General Details, Related, Activities, Preview Document, Document Download, Document Submission

General Details:
ePQS Case ID: New-WPEL-2024-0005
WHO Laboratory ID: P-13162
Case Owner: [Redacted]
Status: Draft

Figure 18: Select the Resume Application Wizard button to recommence the application wizard

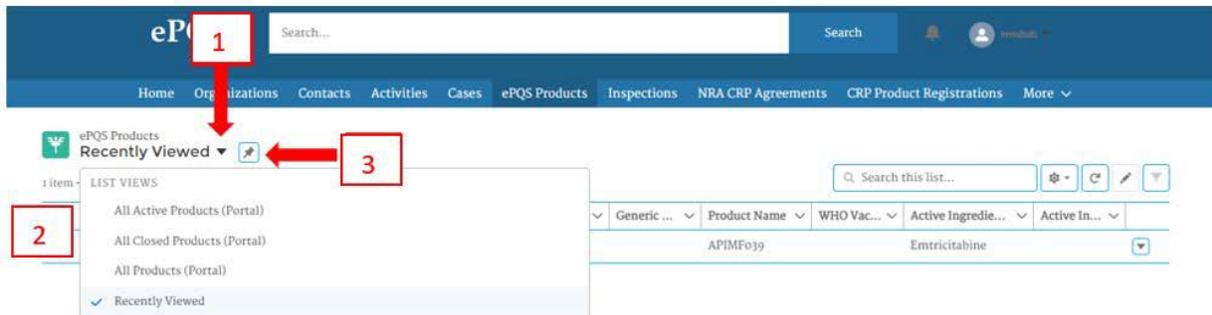
The application wizard when restarted commences from the next applicable section.

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

8. Exchanges between WHO and applicant during screening and assessment of the application

In the Portal, you will be able to access the Product (with the new reference number) in ePQS Products and the application in Cases.

Note: in the portal, by default, the lists of Products, Cases or Activities only show those that were recently viewed. You may change the lists by clicking on the arrow (1) and selecting the appropriate list that you wish to see (2). To keep this list as the default list, click on the pin icon (3).



WHO requests for information

During screening and assessment of the application, WHO may send emails or letters to request information or to share assessment reports including further requests, such as a request for a corrective action plan (CAP).

If a letter has been sent to you, a copy of email can be located in the Correspondence (External folder), which is accessible via the application record as indicated in Figure 19. It can be previewed and downloaded.

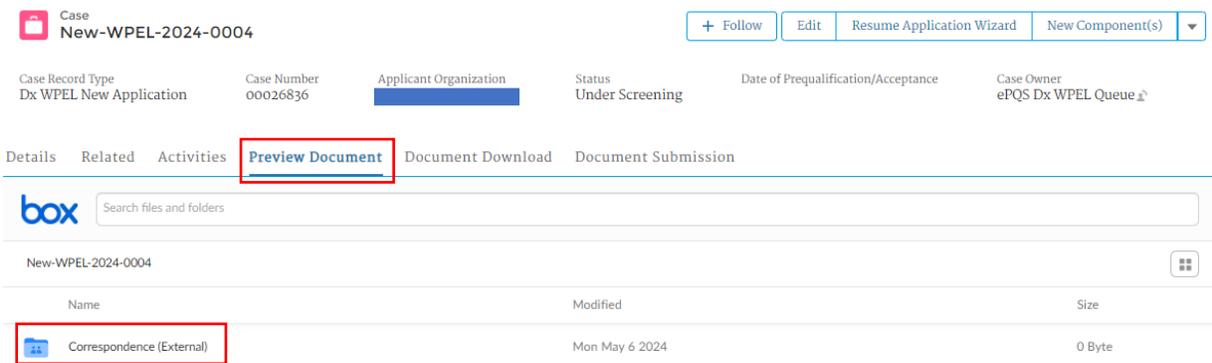


Figure 19: Formal correspondence is located in the application's Correspondence (External) folder.

Submitting documents in response to requests

To upload documents in response to the requests raised, open the corresponding application that can be found in the Cases and select the Document Submission tab.



The screenshot displays the user interface for a case titled "New-WPEL-2024-0004". At the top, there are action buttons: "+ Follow", "Edit", "Resume Application Wizard", and "New Component(s)". Below this, a table lists case details:

Case Record Type	Case Number	Applicant Organization	Status	Date of Prequalification/Acceptance	Case Owner
Dx WPEL New Application	00026836	Abbott Molecular Inc.	Under Screening		ePQS Dx WPEL Queue

Below the table is a navigation menu with tabs: "Details", "Related", "Activities", "Preview Document", "Document Download", and "Document Submission". The "Document Submission" tab is highlighted with a red border. The content of this tab is titled "Case Submission Wizard" and includes the text: "Welcome to Document Submission Wizard. Please click on **Next** to proceed for Case#00026836". A "Next" button is located at the bottom right of the wizard area.

Figure 20: Documents can be uploaded via the application wizard, 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.

Please also respond to the email received to confirm that the requested documents were submitted through the ePQS portal.