

 <b>World Health Organization</b>	<b>REGULATION AND PREQUALIFICATION DEPARTMENT</b>
	<b>IN VITRO DIAGNOSTIC ASSESSMENT TEAM</b>
<b>EXTERNAL GUIDANCE – Instructions for submitting a Post-PQ change request</b>	
<b>Document Version Number: 0.2</b>	

## **SUBMISSION OF A CHANGE REQUEST FOR A PREQUALIFIED PRODUCT (IVDs and MCDs)**

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## 1. Scope

This guide outlines the procedures for the submission of a change request via 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.

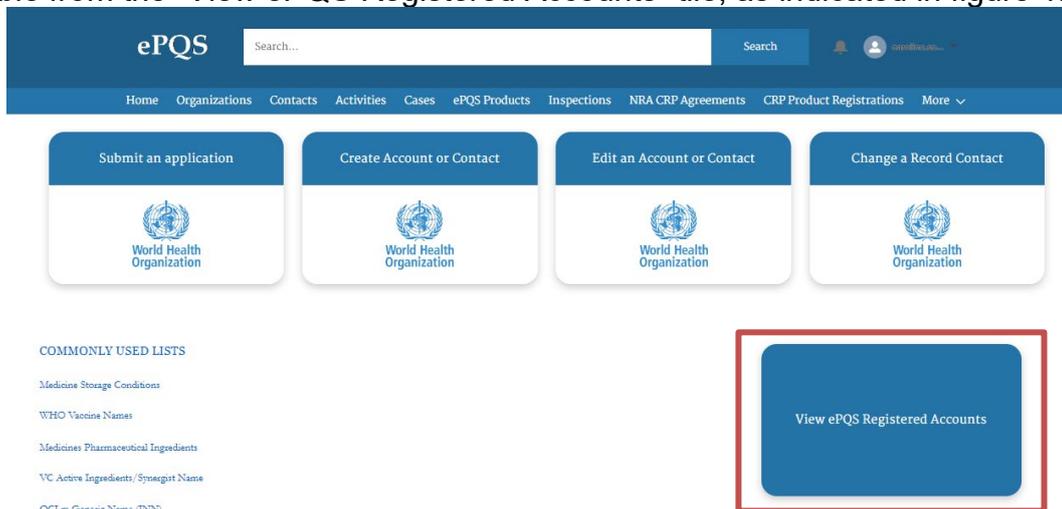


Figure 1 : The existence of an Account within the ePQS system can be determined by clicking on “View ePQS Registered Accounts”

## 3. Accessing the Portal

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

**Registered users** can access the Portal at this link: <https://who.my.site.com/ePQS/s/login/>

For ePQS Portal - Creating or editing a Contact or Account, please refer to **Creating or editing a Contact or Account.pdf**

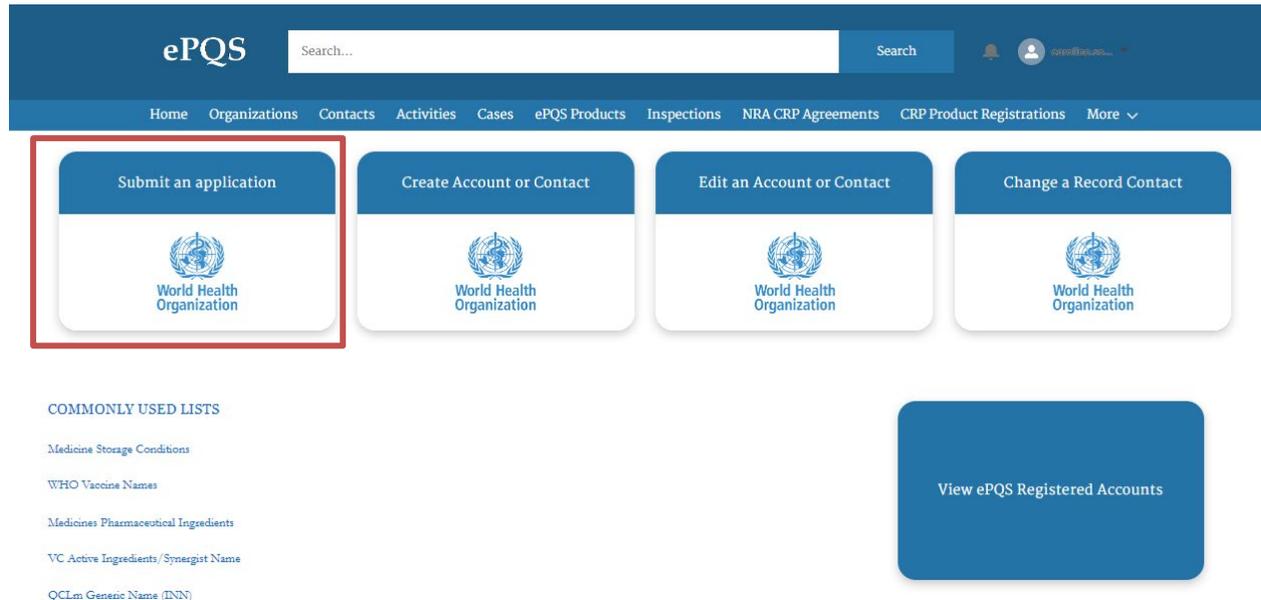
## 4. New submission

### ***Wizard commencement***

#### SUBMISSION OF A CHANGE REQUEST FOR A PREQUALIFIED PRODUCT (IVDs and MCDs)

1. Start a new application for a change request for a prequalified product (including product design, QMS and sites related to the product).

To submit a new application for a change request, on the ePQS Portal Home page, click on “Submit an application”



2. Create a New Application

Carefully read the information on this page.  
Click NEXT.

3. Choose Applicant Organization

Choose and verify that you choose the correct Organization.  
Click NEXT.

4. Choose Contact(s)

Choose and verify that you choose the correct Contact(s).  
Click NEXT.

5. Choose Product Type

Select one option: In Vitro Diagnostic or Male Circumcision Device, as applicable.  
Click NEXT.

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
- Immunization Device
- In Vitro Diagnostic
- Male Circumcision Device
- Quality Control Laboratory
- Vector Control Active Ingredient
- Vector Control Product
- WHO Prequalification Evaluating Laboratory

Previous Next

## 6. Choose Application Type

Select Post-PQ Change.  
Click NEXT.

## 7. Relevant Products Found

Select the product(s) related to the change request.  
Click NEXT.

## 8. Confirm Application Details

Click NEXT.

## 9. Continue Application

A draft application is created. The new application is created, and a case number assigned and indicated on this page for your reference.  
Click NEXT.

## 10. Add Change Information

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

## 11. Select Products

Choose a product that is the subject of a change from the list displayed on this section. You can choose one or more products.  
Click NEXT.

## 12. Add Products

Once the product has been added you will see the message “Success”.  
Click NEXT.

## 13. Add Change Information

### Add Change Info

Select the type of change from dropdown menu that appears on this page. Only one type of change can be selected.  
Click NEXT.

## 14. Add Change Info

Enter a clear and comprehensive Change Description.  
Click NEXT.

## 15. Add Change Info

Once the product has been added you will see the message “Success”.  
Click NEXT.

*Steps 12 to 15 can be repeated.*

## 16. Add Change Information

Once the Applicant is done adding products or information on the change, select the option “No more at this time”.  
Click NEXT.

## 17. Add Overall Change Info

Before finalizing the application enter a “Description of Changes Requested” of the different changes being submitted.  
Click NEXT.

## 18. ePQS Application Wizard

In this step the Applicant is asked to upload documents to *Case# PQC-XXX-2024-XXXX* in the following sections.  
Click NEXT.

## 19. Upload Documents

Please read carefully and follow the instructions provided on this page. The files will be stored in **box** (box, Inc. Cloud Storage Company) which is the integrated document management system in ePQS.

Please follow the instructions on guidance document “Guidance to submit change requests” available at XXXX.

Naming of the files and structure of the folders should follow the provided guidance.

Once the files and/or folders have been uploaded,  
Click NEXT.

## 20. Document Review

Please review the documents and folders you intend to upload. Please read carefully and follow the instructions provided on this page.

Click NEXT.

## 21. Review Application

Please carefully review your application prior to submission. There are 3 options given:

“Yes”, submit application now

Click NEXT.

*NOT Ready to submit yet?*

You may decide to save the draft application for later submission

Please select “No, save existing draft application and product”

Click NEXT.

If you decide to discard the application,

Please select “No, discard this draft application and product”

all the information entered previously, and documentation uploaded will be lost and you will need to start again from the beginning.

**Note:** *if you have saved the draft application but not yet submitted it, the application will appear in the portal with status “Under screening”. However, PQ-IVD will not receive any notification and the application will not yet appear in the ePQS system until you have submitted the application. While the application is in draft and has not been submitted, the Case Owner will appear as the applicant. Once the case has been submitted.*

To later re-start the application, in the portal, open the application case. Then click on “Resume Application Wizard”.

## 22. Application Submitted

Once the application is submitted click on the **Finish** button.

### What happens next?

A notification will be sent to PQ-IVD informing that a new application has been submitted.

PQ-IVD will send an email acknowledging receipt of the application and informing you of the reference number assigned to the application.

In the Portal, you will be able to access the Product (with 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 showed. 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).

The application (Case) will have initially the Status as “Under Screening”.

**Note:** In addition to the ePQS Case ID number “PQC-XXX-2024-XXXX”, a 7-digit Case Number is given to the application. This number can be also used to find an Application in ePQS. However, ePQS Case ID number with format will continue to be used as the application identifier and main reference number “PQC-XXX-2024-XXXX” of the application.

### Screening of application

PQ-IVD will conduct screening of your application.

In case of missing information or need for clarification, a request for information will be sent.

PQ-IVD will send an email requesting the missing information and/or clarification.

You will also receive a notification that a new activity was created. A new activity called “Request for Information (Screening)” will appear on the Portal. You can access Activities either by clicking on the Activities tab or by clicking on the Activities tab in the application case. This activity will show the start date and due date for this request for information and will show the Status as “In Progress”.

To respond to this request for information, go to the Cases tab, select the appropriate application case and click on “Document Submission”.

Once a case is selected from the list of cases available in the Cases tab, the Applicant will see the following screen.

The screenshot displays the ePQS portal interface. At the top, there is a search bar and navigation tabs including Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows the details for Case PQC-IVD-2024-0005. A table lists case details: Case Record Type (Dx IVD Post-PQ Change), Case Number (00027818), Status (Under Screening), Applicant Organization (highlighted with an orange box), Date of Prequalification/Acceptance, and Case Owner (ePQS Dx IVD Queue). Below this, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'General Details' section is expanded, showing fields for ePQS Case ID (PQC-IVD-2024-0005), Product Type (In Vitro Diagnostic), Application Type (Post-PQ Change), Number of Rounds (1), Case Owner (ePQS Dx IVD Queue), Status (Under Screening), Applicant Organization (highlighted with an orange box), Applicant Organization (Legal) (highlighted with an orange box), Applicant Primary Contact (highlighted with an orange box), and Applicant Secondary Contact (highlighted with an orange box).

There are 6 different tabs available in the Case page.

## Details tab

ePQS

Search

Home Organizations Contacts Activities Cases ePQS Products Inspections NRA CRP Agreements CRP Product Registrations More

Case  
**PQC-IVD-2024-0005**

+ Follow
Edit
Resume Application Wizard
New Component(s)

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance
Dx IVD Post-PQ Change	00027818	Under Screening		

Details
Related
Activities
Preview Document
Document Download
Document Submission

General Details

ePQS Case ID	Case Owner
PQC-IVD-2024-0005	ePQS Dx IVD Queue
Product Type	Status
In Vitro Diagnostic	Under Screening
Application Type	Applicant Organization
Post-PQ Change	Applicant Organization (Legal)
Number of Rounds	Applicant Primary Contact
1	Applicant Secondary Contact
	Alternative Applicant Secondary Contact

Case Progress

Date Application Submitted	Date of Prequalification/Acceptance
20/06/2024	
Date Application Accepted For Assessment	Cancellation/Withdrawal/Rejection Reason

## Related tab

ePQS

Search

Home Organizations Contacts Activities Cases ePQS Products Inspections NRA CRP Agreements CRP Product Registrations More

Case  
**PQC-IVD-2024-0005**

+ Follow
Edit
Resume Application Wizard
New Component(s)

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance
Dx IVD Post-PQ Change	00027818	Under Screening		

Details
Related
Activities
Preview Document
Document Download
Document Submission

Related Cases (0)

Commitments/Established Conditions (0)

Case History (5)

Date	Field	User	Original Value	New Value
20/06/2024, 15:06	Record Status		Draft	Active
20/06/2024, 15:06	Owner (Assignment)			ePQS Dx IVD Queue
20/06/2024, 14:09	Created			
20/06/2024, 14:09	ePQS Case ID			PQC-IVD-2024-0005
20/06/2024, 14:09	WHO Application Number			PQC-IVD-2024-0005

[View All](#)

## Activities tab

If the applicant needs to take action, it will be available here under “External Activities(0)”

The screenshot shows the ePQS interface for case PQC-IVD-2024-0005. The top navigation bar includes Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The case details section shows: Case Record Type: Dx IVD Post-PQ Change; Case Number: 00027818; Status: Under Screening; Applicant Organization (highlighted with an orange box); and Date of Prequalification/Acceptance. Below this, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'Activities' tab is active, showing a section for 'External Activities (0)'. At the bottom, there are links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

## Preview Document tab

Here the Applicant can see the content of the Correspondence (External) folder. WHO will provide documents, letters and or reports to the applicant via this folder.

The screenshot shows the ePQS interface for case PQC-IVD-2024-0005, specifically the 'Preview Document' tab. The top navigation bar is the same as in the previous screenshot. The case details section shows: Case Record Type: Dx IVD Post-PQ Change; Case Number: 00027818; Status: Under Screening; Applicant Organization (highlighted with an orange box); Date of Prequalification/Acceptance; and Case Owner: ePQS Dx IVD Queue. Below this, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'Preview Document' tab is active, showing a 'box' interface for file management. The search bar contains 'Search files and folders'. Below the search bar, there is a table with columns for Name, Modified, and Size. The table contains one entry: 'Correspondence (External)' with 'Today' in the Modified column and '0 Byte' in the Size column. At the bottom, there are links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

## Document Download

The screenshot shows the ePQS user interface. At the top, there is a search bar and a navigation menu with options like Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area displays case details for 'Case PQC-IVD-2024-0005'. The case record type is 'Dx IVD Post-PQ Change', the case number is '00027818', and the status is 'Under Screening'. The applicant organization is highlighted with an orange box. Below the case details, there are tabs for 'Details', 'Related', 'Activities', 'Preview Document', 'Document Download', and 'Document Submission'. The 'Document Download' tab is active, showing a 'box' search bar and a list of files. One file is listed: 'Correspondence (External)' with a size of '0 Byte'. At the bottom, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

## 5. Document Submission

### 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.

The screenshot shows the ePQS user interface for document submission. The top navigation and case details are the same as in the previous screenshot. The 'Document Submission' tab is active, displaying the 'Case Submission Wizard'. The main area contains a large box with a document icon and the text: 'Drag and drop files and folders' and 'Browse your device or Select Folders'. At the bottom right of the wizard, there are 'Cancel' and 'Upload' buttons.

- Completed Change Request Form (PQDx\_119)
- Attachments accompanying the change request form

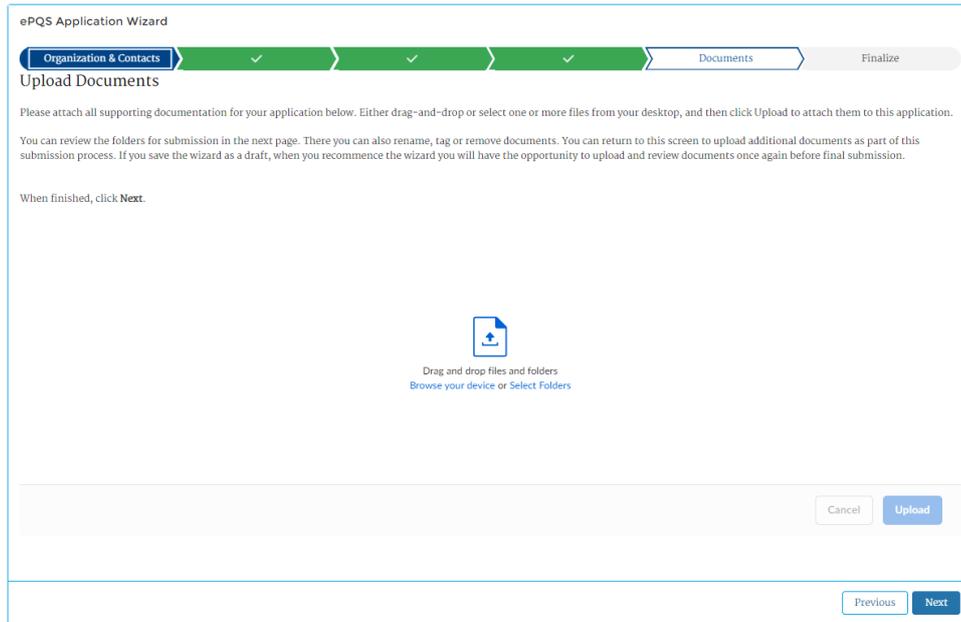


Figure 2: Document upload screen

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

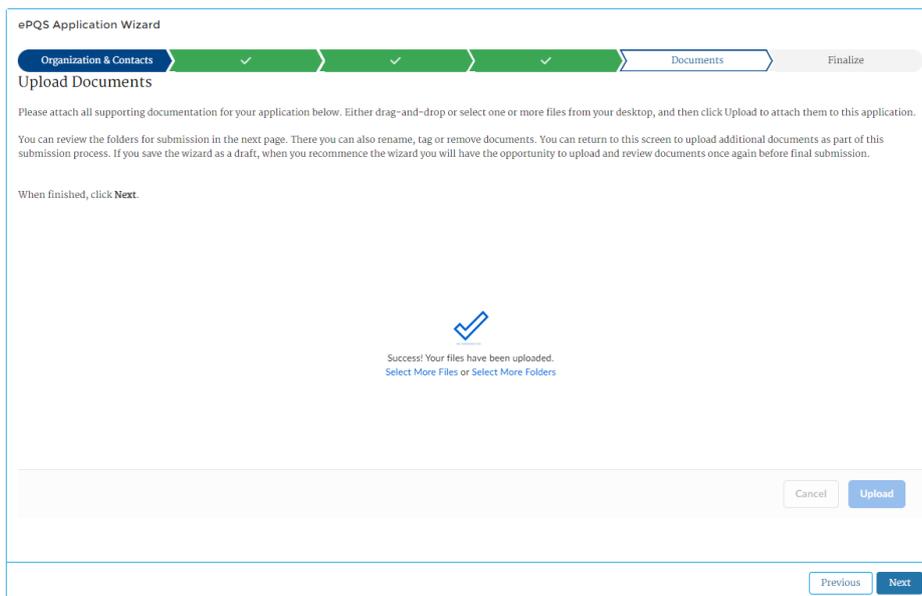


Figure 3: If document upload was successful, this screen will appear.

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.

- > **IMPORTANT: Once the application is submitted, the uploaded documents are no longer visible to the applicant.**

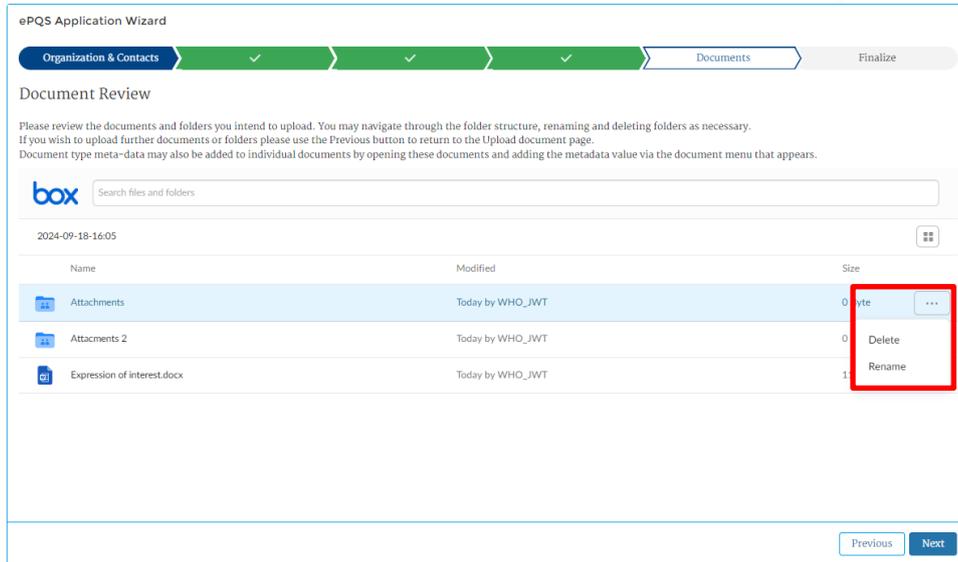


Figure 4: Document review screen where the uploaded files can be adjusted if necessary

## 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.

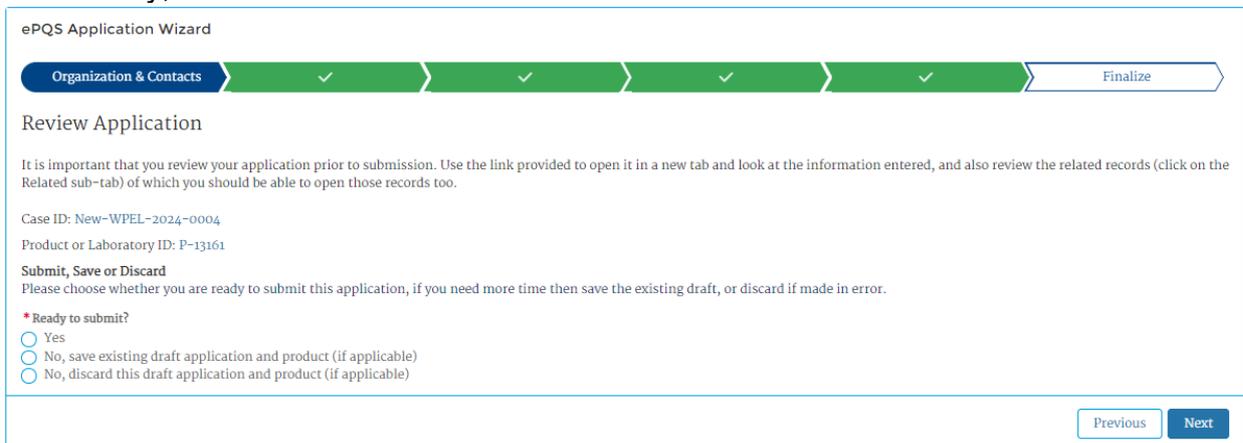


Figure 5: Final screen before submitting

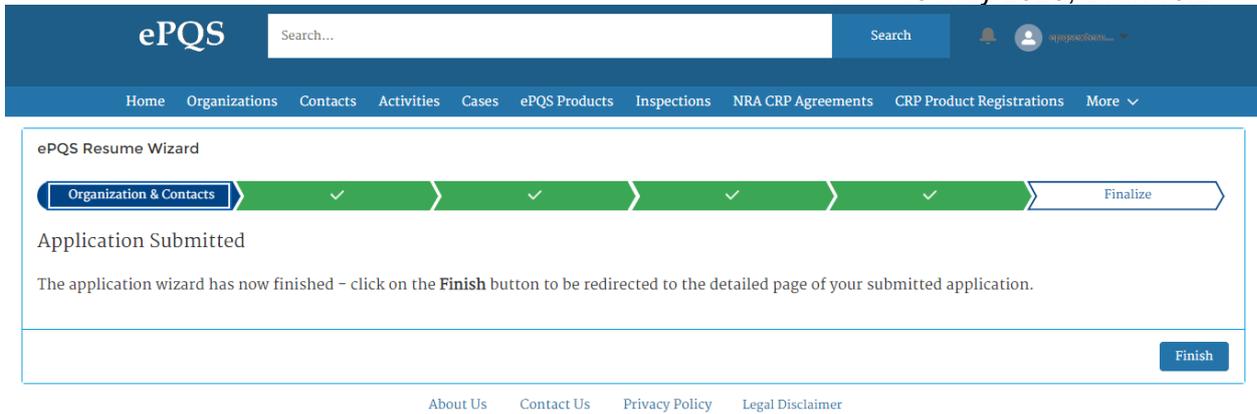


Figure 6: Confirmation screen

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 above).**

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

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



Figure 7: Record ownership and status changes once submitted.

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

- > **Remember: the uploaded documents cannot be seen once the application is submitted.**

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

In addition, the PQ team will send an email acknowledging receipt of the application and informing you of the reference number assigned to the change request case.

### Saving as a draft and recommencing

To re-start the application, click on Cases in the ePQS portal and locate the draft application.

Cases

Recently Viewed ▾

Q Search this list...

3 items · Updated a minute ago

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 8: 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  
New-WPEL-2024-0005

+ Follow Edit Resume Application Wizard New Component(s) ▾

Case Record Type	Case Number	Applicant Organization	Status	Date of Prequalification/Acceptance	Case Owner
Dx WPEL New Application	00026837	<a href="#">Abbott Molecular Inc.</a>	Draft		<a href="#">Caroline So...</a>

Details Related Activities Preview Document Document Download Document Submission

General Details

ePQS Case ID	New-WPEL-2024-0005	Case Owner	<a href="#">Caroline So...</a>
WHO Laboratory ID	<a href="#">P-13162</a>	Status	Draft

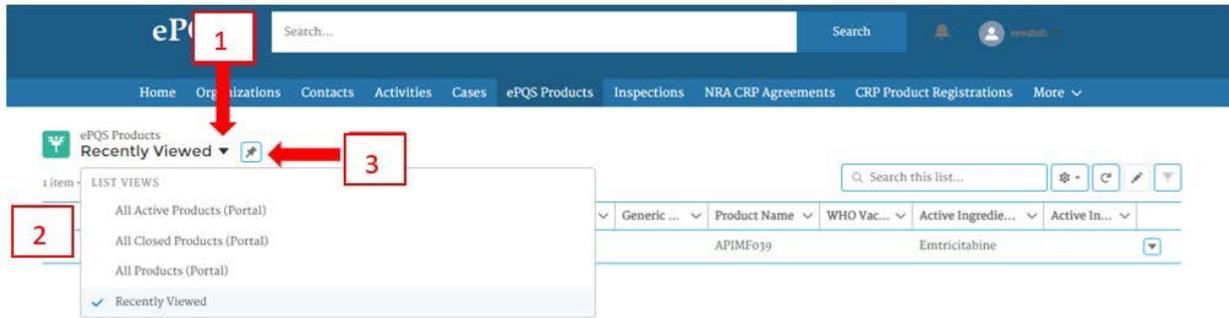
Figure 9: Select the Resume Application Wizard button to recommence the application wizard

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.

## 6. 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 showed. 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).

In such cases, in addition to the correspondent sent by WHO by email, you will notice that an Activity has been opened in the name of the primary contact (Figure 19). You will also receive an email alerting you to this (Figure 20).

Activities can be accessed either through the Activities (Figure 19) or through the Activity thumbnail in the corresponding application (Figure 21).

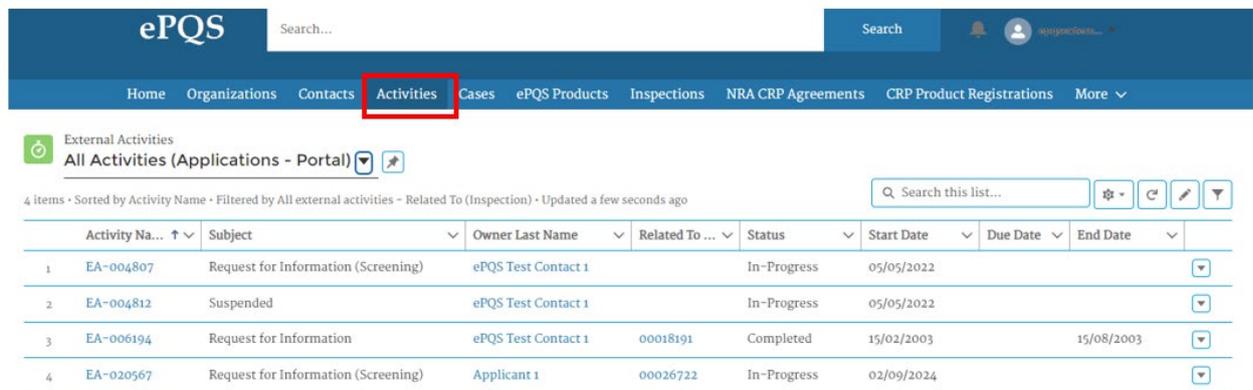


Figure 10: Outstanding tasks can be viewed via the Activities list

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 11: When an activity is assigned, an accompanying email is also sent.

Case **New-WPEL-2024-0004**

Case Record Type: Dx WPEL New Application | Case Number: 00026836 | Applicant Organization: [Abbott Molecular Inc.](#) | Status: Under Screening | Date of Prequalification/Acceptance: | Case Owner: ePQS Dx WPEL Queue

Details | Related | **Activities** | Preview Document | Document Download | Document Submission

**External Activities (1)**

Activity Name	Activity Name	Status	Activity Outcome
<a href="#">EA-020586</a>	Request for Information	In-Progress	

View All

Figure 12: Accessing activities for a specific application.

If a letter has been sent to you, a copy of this letter and, if applicable, attachments can be located in the Correspondence (External folder), which is accessible via the application record as indicated in Figure 22. It can be previewed and downloaded.

Case **New-WPEL-2024-0004**

Case Record Type: Dx WPEL New Application | Case Number: 00026836 | Applicant Organization: [Redacted] | Status: Under Screening | Date of Prequalification/Acceptance: | Case Owner: ePQS Dx WPEL Queue

Details | Related | Activities | **Preview Document** | Document Download | Document Submission

box Search files and folders

New-WPEL-2024-0004

Name	Modified	Size
<a href="#">Correspondence (External)</a>	Mon May 6 2024	0 Byte

Figure 13: Formal correspondence is located in the application's Correspondence (External) folder.

### Responding to requests

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

Case **New-WPEL-2024-0004**

Case Record Type: Dx WPEL New Application | Case Number: 00026836 | Applicant Organization: [Abbott Molecular Inc.](#) | Status: Under Screening | Date of Prequalification/Acceptance: | Case Owner: ePQS Dx WPEL Queue

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#00026836

Next

Figure 14: 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.

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. Go back to the Activities tab and open the relevant Activity. Click on the pen icon next to Status. Change the Status to “Actioned” to inform PQ-IVD that you provided a response to the request for information.

A notification will be sent to PQ-IVD, who will confirm receipt of the response and close the Activity, indicating that the information was received.

If no response has been provided, a reminder will be sent one week prior to the due date of the activity.

The screenshot shows the 'External Activity' interface for EA-020586. At the top right, there are 'Edit' and 'Change Owner' buttons. Below the activity title, there are tabs for 'Details' and 'Related'. A red asterisk indicates required information. The main content area is divided into 'Comments' and 'Information' sections. The 'Information' section contains fields for 'Related To (Case)', 'Related To (Inspection)', 'Activity Name', 'Request for Information', 'Due Date', 'Start Date', 'Owner', 'Time Assignment', 'Manufacturer', 'Status', and 'Activity Outcome'. The 'Status' dropdown menu is highlighted in yellow and set to 'Actioned'. The 'Start Date' is 18/09/2024.

Figure 15: Change the status of the Activity from In-Progress to Actioned to signal that a response was submitted.

Once your response has been reviewed for completeness, the assessment team will change the status and outcome, and enter the end date. The activity will not be visible from the application case anymore but will still be visible from the list of Activities and marked as completed.

End of document.