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Guidance	
Guidance: ePQS Portal Features, Uploading and Downloading documents	
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Table of Contents

Guidance on the ePQS Portal and Key Features	2
Home Page	2
List views	5
Record features - Application records	6
Record features - Product records.....	7
External Activities	8
Responding to requests	10
Uploading and downloading Documents.....	12
Application record - Upload.....	12
Initial submission	12
Responses	12
Document download	12
Inspection records	13
Organization record	13
Contact record	13

Guidance on the ePQS Portal and Key Features

The ePQS Portal is the external user facing Salesforce Community site of the ePQS system. It allows selective visibility of records relevant to the user, the creation of applications, uploading and downloading of documents, and to receive alerts for pending tasks.

Users must register to use the portal.

An introduction to features of the portal are described in this document. More detailed guidance documents are available to describe specific features and ePQS Portal processes.

Home Page



Figure 1. Features of the PQS Portal landing page

The Portal landing page offers the following features.

1) Global search facility

Key word searches will retrieve any record matching the entered criteria, provided the user has access to the record.

2) Notification “Bell” Icon

System generated notifications will be recorded here.

3) Personal Settings and Profile

Using this menu you can access your personal user details and log out of the system.

4) Object Menu Bar

List views of the major record types can be accessed from this menu. The menu items will vary depending on the type of external user.

5) Application wizard

This initiates the creation of a new application

6 to 8) Contacts and Accounts

These menu items download the relevant forms for completion.

9) Commonly Used Lists

These links provide access to a series of reference lists that are referred to at various points in some application wizards.

For instance, as part of the vaccine prequalification application wizard the applicant will be asked to nominate a WHO Vaccine Name. If the applicant is unfamiliar with the possible WHO Vaccine Names, they can review these from this list.

WHO Vaccine Names
WHO Vaccines Names (Portal) Printable View

50+ items · Sorted by WHO Vaccine Name (Full) · Filtered by All who vaccine names · Updated a few seconds ago

Search this list...

	WHO Vaccine Name (Full) ↑	WHO Vaccine Name	Vaccine Abbrevia...	WHO Reference	AT
1	BCG	BCG	BCG	WHO TRS 979, 2013. Annex 3	
2	Dengue tetravalent vaccine (live, attenuated)	Dengue tetravalent vaccine (live, attenuated)	TDV	WHO TRS 932	
3	Diphtheria and tetanus vaccine (adsorbed)	Diphtheria and tetanus vaccine (adsorbed)	DT	WHO TRS 980, 2014. Annex 6	
4	Diphtheria and tetanus vaccine (adsorbed, reduced diphtheria and tetanus antigen content)	Diphtheria and tetanus vaccine (adsorbed)	dt	WHO TRS 980, 2014. Annex 6	
5	Diphtheria and tetanus vaccine (adsorbed, reduced diphtheria antigen content)	Diphtheria and tetanus vaccine (adsorbed)	dT	WHO TRS 980, 2014. Annex 6	
6	Diphtheria vaccine (adsorbed)	Diphtheria vaccine (adsorbed)	D	WHO TRS 980, 2014. Annex 4	
7	Diphtheria, tetanus and (acellular) pertussis vaccine (adsorbed)	Diphtheria, tetanus and (acellular) pert	DTaP	WHO TRS 980, 2014. Annex 6 WHO TRS 927, 20...	
8	Diphtheria, tetanus and (acellular) pertussis vaccine (adsorbed, reduced diphtheria, tetanus and (acellular) pertussis antigen content)	Diphtheria, tetanus and (acellular) pert	dtap	WHO TRS 980, 2014. Annex 6 WHO TRS 927, 20...	
9	Diphtheria, tetanus and (whole cell) pertussis vaccine (adsorbed)	Diphtheria, tetanus and (whole cell) per	DTwP	WHO TRS 980, 2014. Annex 6 WHO TRS 927, 20...	
10	Diphtheria, tetanus, (acellular) pertussis and Haemophilus influenzae type b (X-) conjugate vaccine (adsorbed) (all-in-one or with separate freeze-dried Hib)	Diphtheria, tetanus, (acellular) pertuss	DTaP+Hib	WHO TRS 980, 2014. Annex 6	

Figure 2. One of the commonly referred to lists (WHO Vaccine Names)

10) View ePQS Registered Accounts

Account (Organisation) records are important records referred to on product, application, inspection and product site records.

During the wizard process, if an account is not present in the ePQS database, it will not be possible, for instance, to create a manufacturing site (Product Site) for a product referring to that Account. The wizard application can always be saved in draft, but this list of ePQS Registered Accounts can be used by prospective applicants to verify the account already exists in the system, prior to commencing the application. If the account does not exist then a request can be made to create this.

11) FAQ and training materials

Relevant reference materials and information will be made available via these links.

List views

For each Object Menu item, lists of relevant records will be presented by the system.

As indicated in Figure 3, by clicking the downward triangle (1) the user can access different list views (2). These list views differ either by some filter criteria or the fields being displayed.

A favourite list view can be pinned by pressing the pin icon (3).

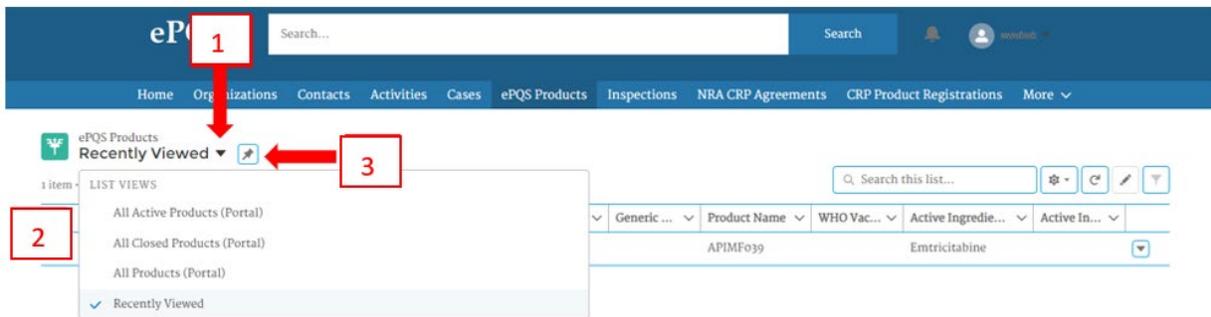


Figure 3. Using List views

Record features - Application records

Most application records have a common layout. Seven features have been highlighted in figure 4 below.

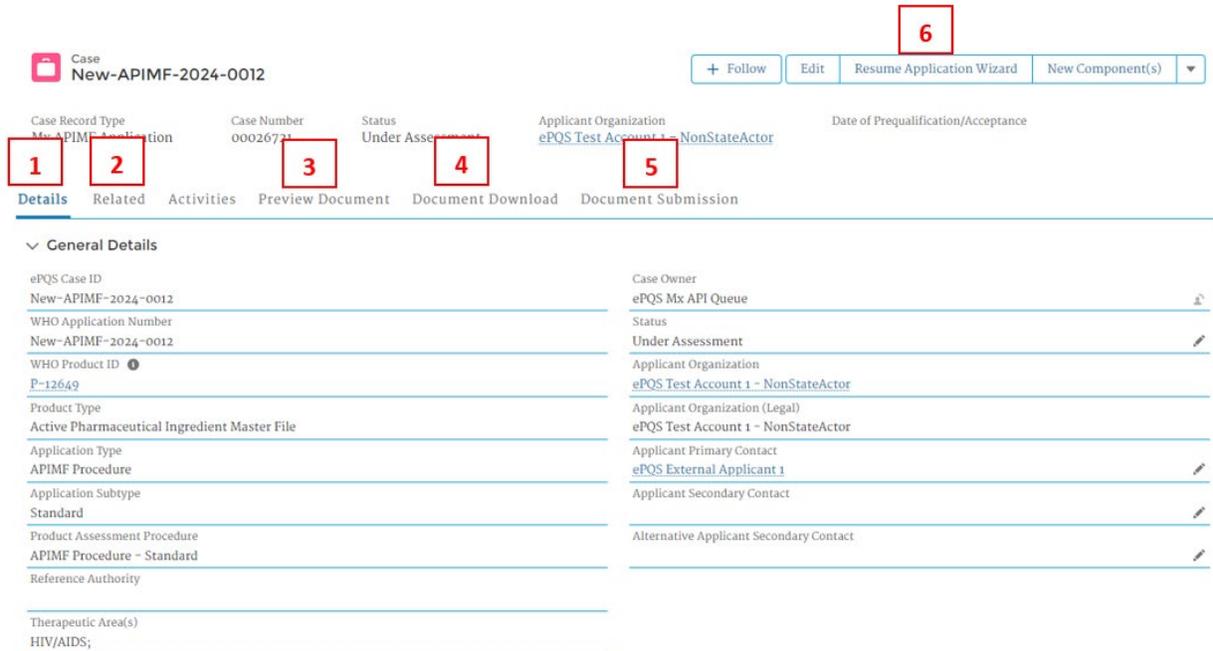


Figure 4. The features of a typical application record

Details tab (1)

Here general information regarding the record will be displayed. Some fields will be hidden from external users.

Generally speaking, unless the record is in Draft (that is, not yet submitted via the wizard) the external user cannot change the field values.

Related Tab (2)

On this tab will be a series of lists of records related to the selected record. For instance, if a product record is selected, the user would see on this tab any related applications for which the user has access that are related to the product.

Preview Documents (3)

From this tab the external user will see any documents to which they have read access.

Document Download (4)

From this tab the external user will be able to download any documents that they have permission to download.

Document Submission (5)

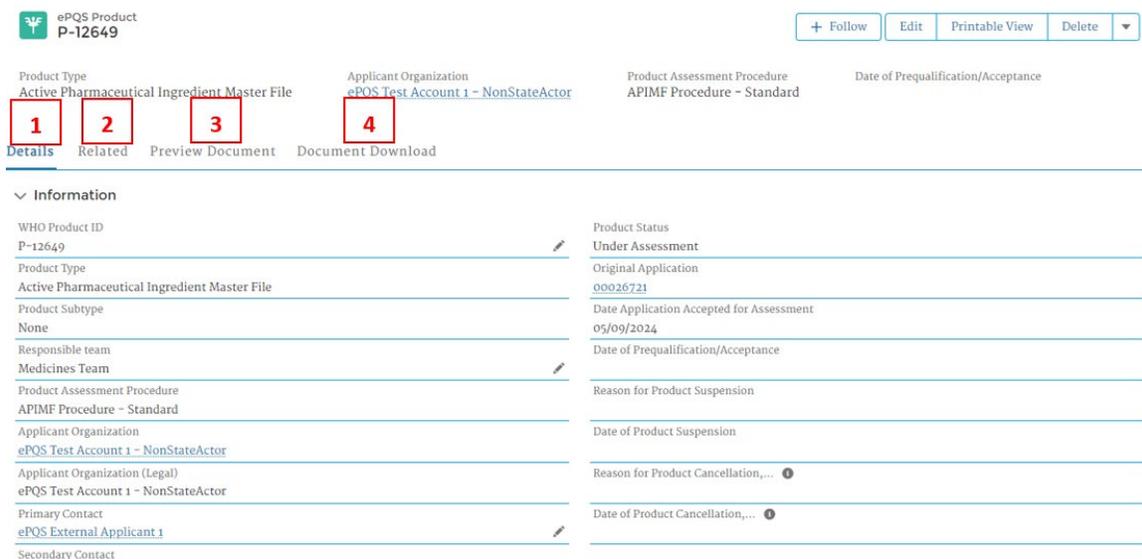
From this tab the external user will be able to upload any documents related to the record. For instance, in response to questions raised.

Resume wizard Button (6)

On application records only, applicants can resume the application wizard process on draft applications by selecting this button.

Record features - Product records

Most product records have a common layout. Four features have been highlighted in in figure 4 below.



ePQS Product P-12649 + Follow Edit Printable View Delete

Product Type: **Active Pharmaceutical Ingredient Master File** 1
 Applicant Organization: **ePQS Test Account 1 - NonStateActor** 2
 Product Assessment Procedure: **APIMF Procedure - Standard** 3
 Date of Prequalification/Acceptance: 4

Details | Related | Preview Document | Document Download

Information

WHO Product ID P-12649	Product Status Under Assessment
Product Type Active Pharmaceutical Ingredient Master File	Original Application 00026721
Product Subtype None	Date Application Accepted for Assessment 05/09/2024
Responsible team Medicines Team	Date of Prequalification/Acceptance
Product Assessment Procedure APIMF Procedure - Standard	Reason for Product Suspension
Applicant Organization ePQS Test Account 1 - NonStateActor	Date of Product Suspension
Applicant Organization (Legal) ePQS Test Account 1 - NonStateActor	Reason for Product Cancellation,...
Primary Contact ePQS External Applicant 1	Date of Product Cancellation,...
Secondary Contact	

Figure 5. The features of a typical application record

On the related tab different related records will be displayed depending on the Product type. Common related records include Product Site records, type of packaging, Product Codes, related applications.

ePQS Portal Features, Uploading and Downloading documents

Document Version Number: 1.3

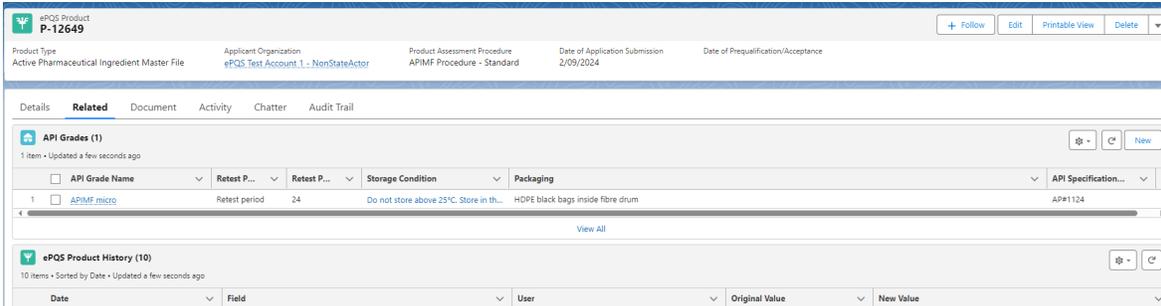


Figure 6. An example of a Product related list: API Grades

External Activities

Activities are small records that track the various steps in the assessment process of an application or inspection.

When an activity is assigned to an external user, this activity becomes visible in the portal and the user typically receives an email notification of this assignment. For manufacturers, this is normally associated with a request for information and the raising of the activity id often also associated with correspondence from the respective assessment team responsible relating to the request.

An activity is typically assigned to the primary contact of the application, but any user belonging to the applicant company can see the activity.

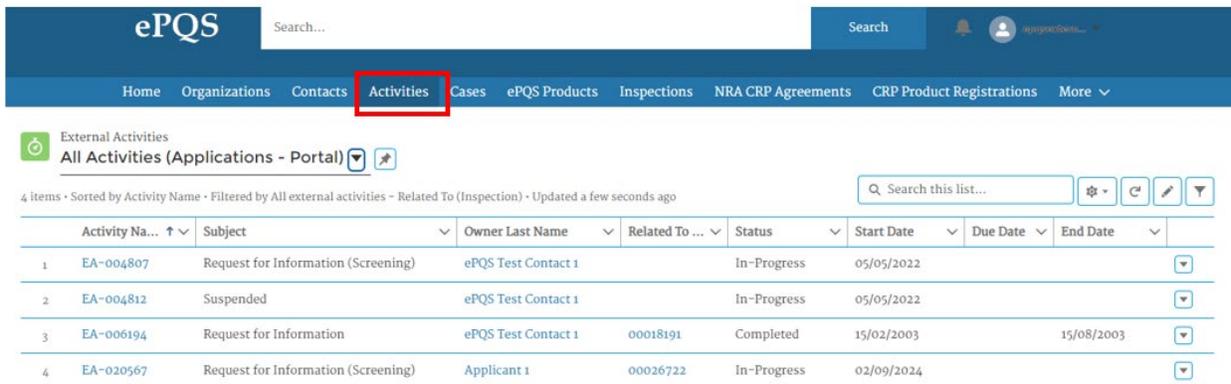


Figure 7. Outstanding tasks can be viewed via the activity list

ePQS Portal Features, Uploading and Downloading documents

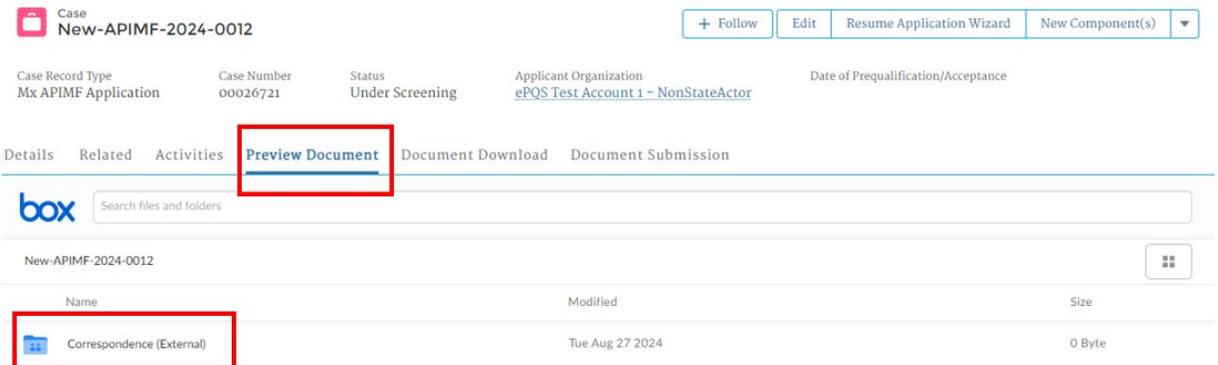
Document Version Number: 1.3

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 8. When an activity is assigned, an accompanying email is also sent



The screenshot displays the ePQS portal interface for a case titled "New-APIMF-2024-0012". At the top, there are navigation buttons: "+ Follow", "Edit", "Resume Application Wizard", and "New Component(s)". Below this, case details are listed: 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 menu bar includes "Details", "Related", "Activities", "Preview Document" (highlighted with a red box), "Document Download", and "Document Submission". Below the menu is a "box" search bar. The main content area shows a table with columns "Name", "Modified", and "Size". A row is visible with "Correspondence (External)" (highlighted with a red box), "Tue Aug 27 2024", and "0 Byte".

Figure 9. Formal correspondence is located in the applications external Correspondence folder. It can be previewed and downloaded.

Responding to requests

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



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 10. 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 can not be seen once submitted.

In addition to any correspondence you might undertake with the assessment team applicants should also signal the uploading of your response by changing the status of the activity to actioned as indicated in figure 38.

ePQS Portal Features, Uploading and Downloading documents

Document Version Number: 1.3

▼ **Information**

Related To (Case)
Related To (Inspection)

Activity Name
Request for Information (Screening)

Due Date

Start Date
05/05/2022

End Date

Owner
User16482068782195409890

Time Assignment

Manufacturer

* Status
Actioned

Activity Outcome

Activity Phase
Under Screening

Response Date

▼ **Case Information**

Case Record Type
This field is calculated upon save

WHO Product ID
This field is calculated upon save

▼ **System Information**

Created By
Kingsley Aboagye AWUKU, 05/05/2022, 14:26

Last Modified By
Kingsley Aboagye AWUKU, 26/05/2022, 13:51

Cancel Save Allow Task

Figure 11. 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 for completeness, the assessment team will change the status and outcome, 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 12. Once the response is reviewed the activity will be further updated

This completes the response to a request for screening information.

Uploading and downloading Documents

The ePQS portal is integrated with the PQT's document management system. Users of the portal can upload and download documents securely from several different record types as described below.

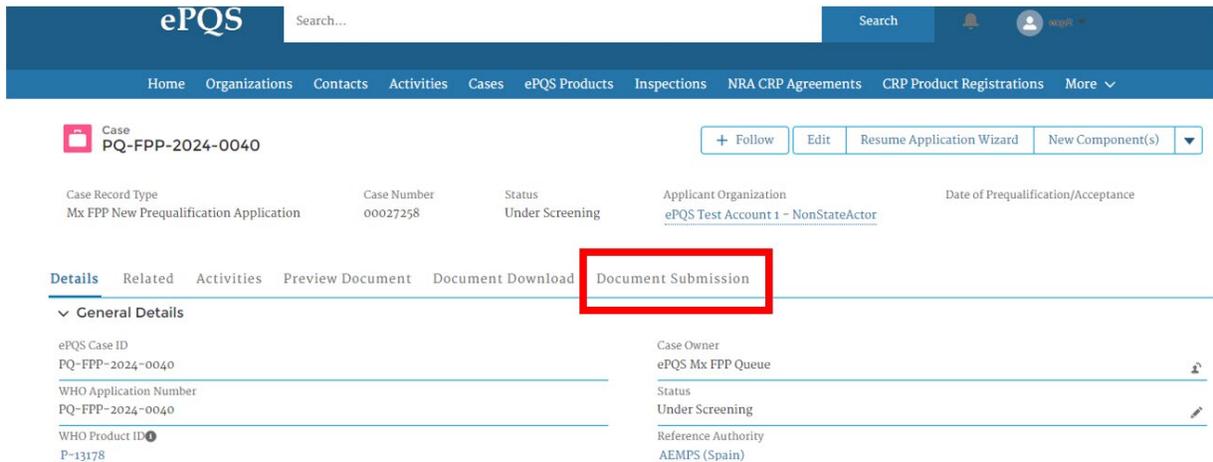
Application record - Upload

Initial submission

As part of the initial application creation and submission, the application wizard in the portal includes a document upload step. This is described in individual application wizard guidance documents.

Responses

Documents pertaining to an on-going application should be uploaded from the applicable application record. To do so go to the application record and select the Document submission tab.



The screenshot shows the ePQS portal interface. At the top, there is a search bar and navigation tabs: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation, there is a case record for 'Case PQ-FPP-2024-0040'. The case details include: Case Record Type (Mx FPP New Prequalification Application), Case Number (00027258), Status (Under Screening), Applicant Organization (ePQS Test Account 1 - NonStateActor), and Date of Prequalification/Acceptance. Below the case details, there are several tabs: Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'Document Submission' tab is highlighted with a red box. Below the tabs, there is a 'General Details' section with the following information: ePQS Case ID (PQ-FPP-2024-0040), WHO Application Number (PQ-FPP-2024-0040), WHO Product ID (P-13178), Case Owner (ePQS Mx FPP Queue), Status (Under Screening), and Reference Authority (AEMPS (Spain)).

Figure 13. From the application record, select the Document submission tab to begin the document upload process

You will then be guided through a document upload process.

Document download

On each application record under the preview and download tab is a folder called Correspondence (External). This is where assessment teams will place correspondence for download. These documents may have been already sent via email or mail, as per team processes.

Inspection records

If a document pertaining to an on-going inspection needs to be uploaded, go to the applicable inspection record and select the document submission tab as per an application.

Similarly, if there is inspection correspondence this will be present in the Correspondence (External) folder on the document tabs of the inspection record.

Note, inspection records only become visible in the portal once the initial inspection review has occurred.

Organization record

Documents pertaining to an application or inspection must be uploaded via the applicable application or inspection record. However, there will be occasions when documents may be required to be submitted that are not specific to a particular application or inspection. In such circumstances, these may be uploaded via the company's account record.

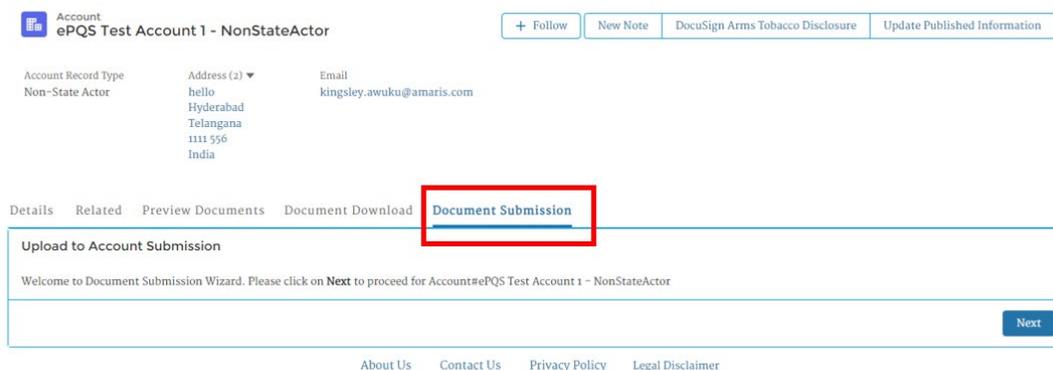


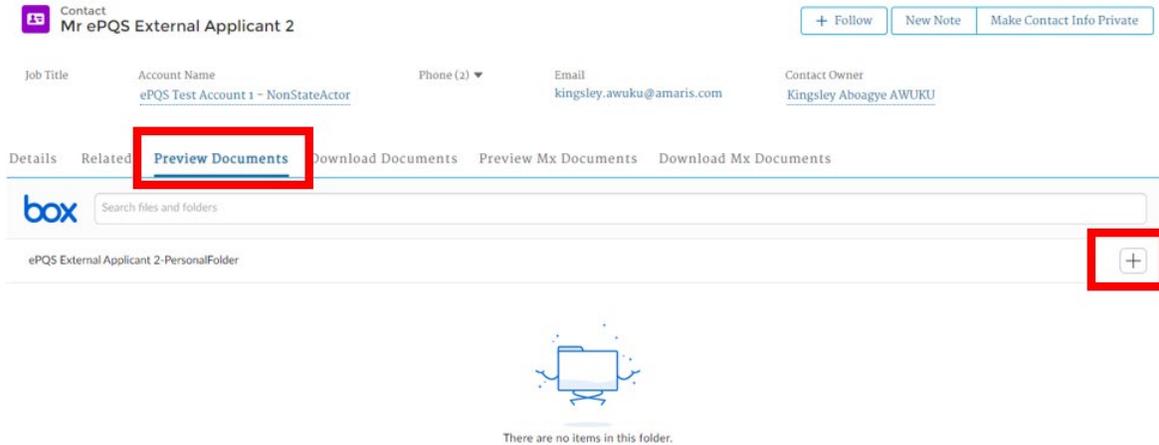
Figure 14. Non-application and inspection specific document can be upload securely via the account record's document tab.

Contact record

Via the contact record a user can also securely upload document. This folder is only visible to that specific user in the portal, not other contacts for the same organization. All internal users can see this folder. To upload document to this folder use the plus sign as indicated in figure 7, from the preview documents tab.

ePQS Portal Features, Uploading and Downloading documents

Document Version Number: 1.3



The screenshot displays the ePQS portal interface. At the top, there is a contact profile for "Mr ePQS External Applicant 2" with fields for Job Title, Account Name (ePQS Test Account 1 - NonStateActor), Phone (2), Email (kingsley.awuku@amaris.com), and Contact Owner (Kingsley Aboagye AWUKU). Below the profile, there are navigation tabs: "Details", "Related", "Preview Documents" (highlighted with a red box), "Download Documents", "Preview Mx Documents", and "Download Mx Documents". The "Preview Documents" tab leads to a "box" interface with a search bar and a folder named "ePQS External Applicant 2 - PersonalFolder". A red box highlights a "+" sign in the bottom right corner of the folder view. Below the folder view, there is a folder icon and the text "There are no items in this folder."

Figure 15. Document can be uploaded to a users personal folder via the previous documents tab using the "+" sign