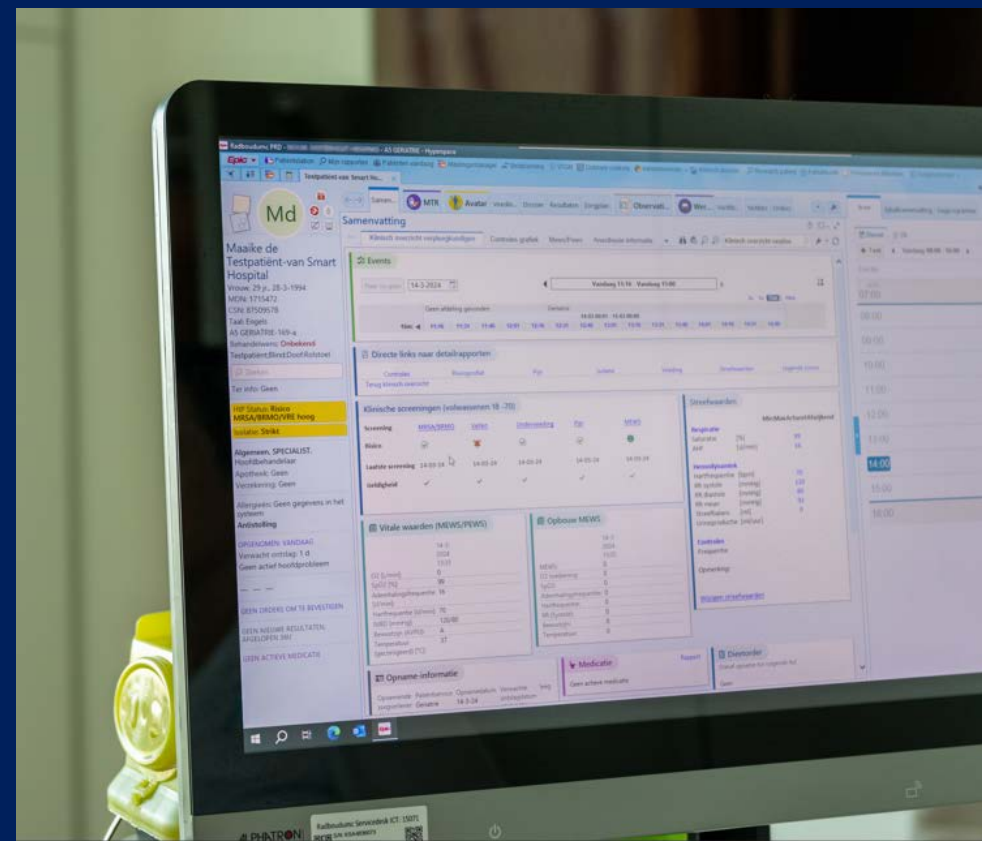


An introduction to the ePQS Portal

May 2025

v1



Introduction to this Slide Deck

The information in this slide deck is intended for external users of the Portal, and primarily those making applications to PQT teams via the ePQS Portal.

Guidance on application procedures, application-specific wizard guidance, and eCTD is covered elsewhere.

This training will focus on:

An overview of ePQS • What constitutes ePQS • Key features • Roll out	Users of the system • User registration process • Use of contact and account records • Implications for Record visibility
ePQS Features • Record types & features • List views and Searching • Document upload and down • Notifications and activities	Application Wizards

Where to obtain Information

Team specific training information, relating to the specifics of application procedures, and application wizard features, will be provided separately by Teams.

All ePQS-related information will be posted to the ePQS Webpage (<https://extranet.who.int/prequal/epqs-portal>).

In addition, teams will update aspects of their team-specific pages to refer to submissions via the ePQS portal.

Teams can be approached directly if the information sought is not on the ePQS webpage.

Team	Email address
In vitro Diagnostics	diagnostics@who.int
QCL Laboratories	prequallaboratories@who.int
Medicines	prequal@who.int
Vaccines	vaccprequalification@who.int
Vector Control	pqvectorcontrol@who.int
Facilitated Product Introduction	prequalreg@who.int
Inspections	prequalinspection@who.int

Terms

Term	Definition
ePQS	Electronic Pre-Qualification System
Account	This is the Salesforce term for the record that describes a person, entity or organization.
Applicant organization	This is the Account that applies for product prequalification and is responsible for maintaining its details.
Cases/Applications	Case is a Salesforce term for a set of records of a similar type. All application records in ePQS are cases. There are also other case records types in ePQS that are not applications.
Product site	The term given to a site that undertakes one of a number of activities related to a Product. Typically, these are locations for manufacturing or testing, but not always so.
Post-PQ change Applications	The harmonized term in ePQS for applications that request to change some aspect of the accepted or prequalified product's details. Often known as Amendments, or Variations.

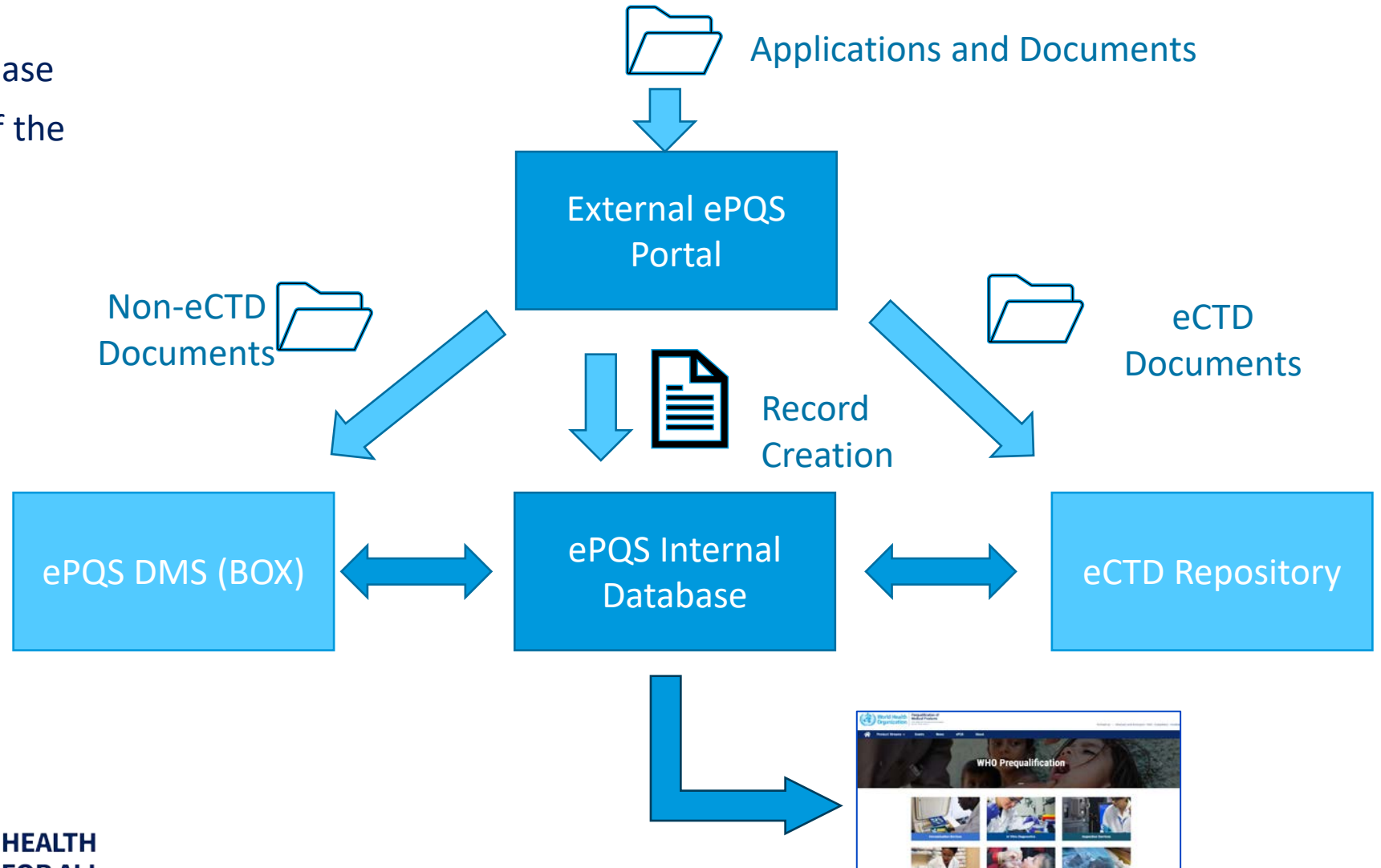
What is ePQS?



What is ePQS?

ePQS consists of:

- An internal Salesforce Database
- An external facing version of the ePQS (Portal)
- An integrated Document management system (BOX)
- A loosely integrated eCTD repository (EURSNext)
- Website integration



Advantages of ePQS

- A single database using common records across all PQT activities.
- Improved ability to track activities and milestones.
- Cloud based technology.
- Integrated document management systems.
- Permits an externally facing Portal of the database.
- Secure document upload and download.
- Automated publishing of pipeline and product lists to PQT website.

Portal Landing Page

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

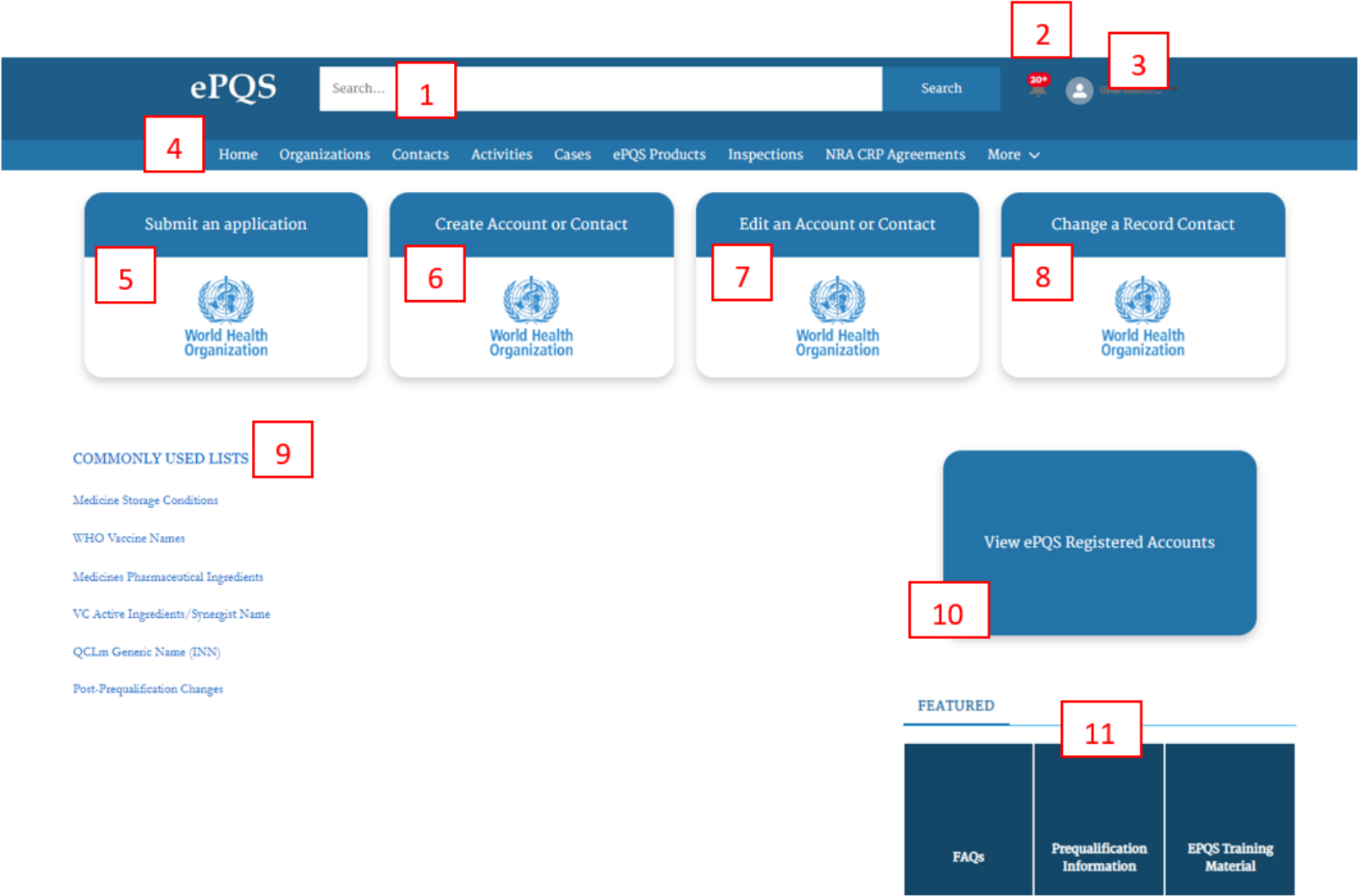
Using this menu you can access your personal user details and log out of the system.

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



Portal Landing Page

6 to 8) Contacts and Accounts

9) Commonly Used Lists

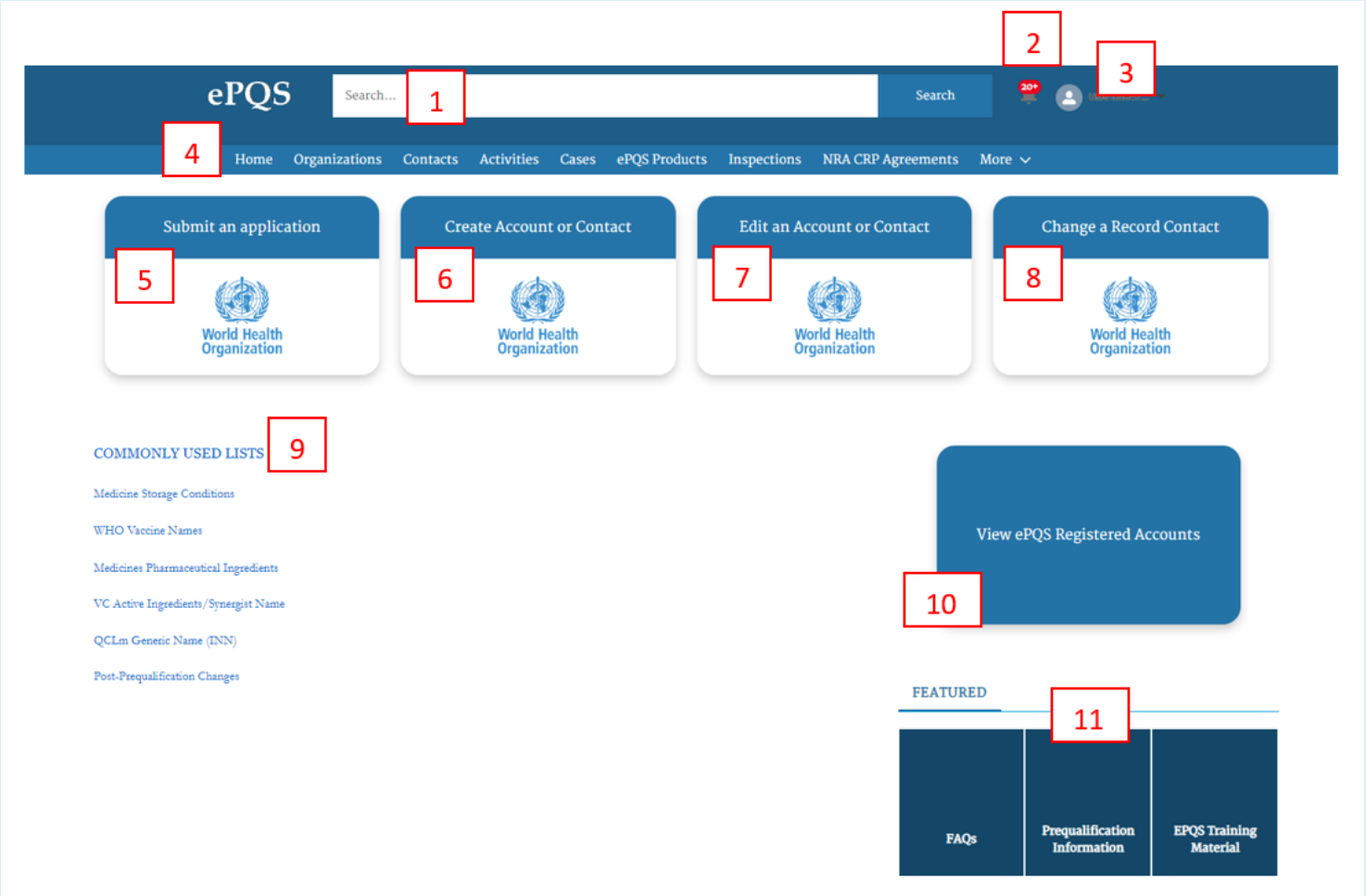
These links provide access to a series of reference lists that are referred to at various points in some application wizards.

10) View ePQS Registered Accounts

An excel file of all available Accounts can be downloaded so users can verify if the Account exists in the system before they commence the wizard.

11) FAQ and training materials

Relevant reference materials and information will be made available via these links. Currently this points to the ePQS webpage



ePQS Roll-out

- Greater than 90% of the functionality intended for the ePQS Portal is live.
- There are some known bugs, which will be addressed in due course – please bear with us!
- Teams will be making adjustments to guidance and processes as more experience is gained with the portal.
- The ePQS Portal is not mandatory currently, but this is the direction PQT is moving in.

Users of the system

Registration process

Contact and account records

Record visibility



Users and Registration

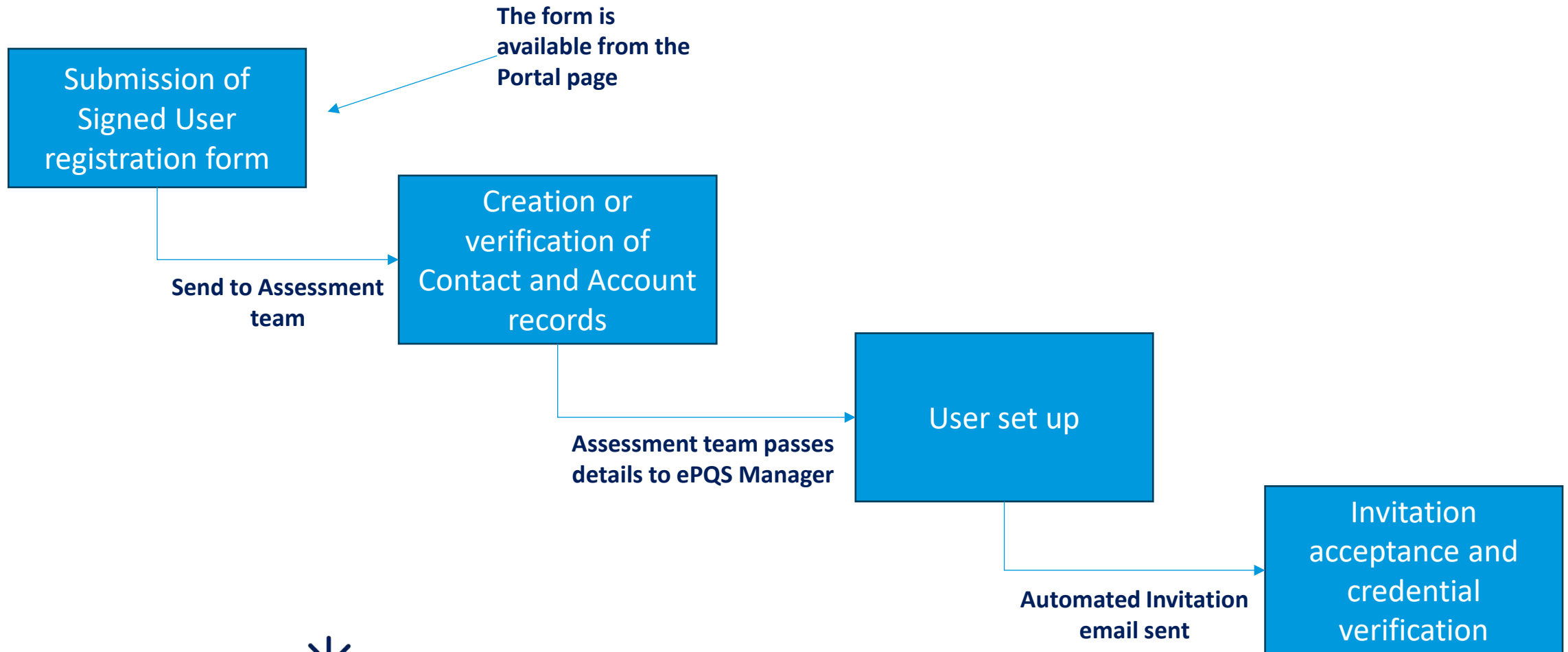
- There are three types of external users of the system: Applicants; National Regulatory Agencies and External Experts.
- Each user-type has different “abilities” and different record visibility.
- All users must be registered before access is granted.

Welcome to the ePQS Portal
Portal is provided to facilitate the submission of data and exchange of

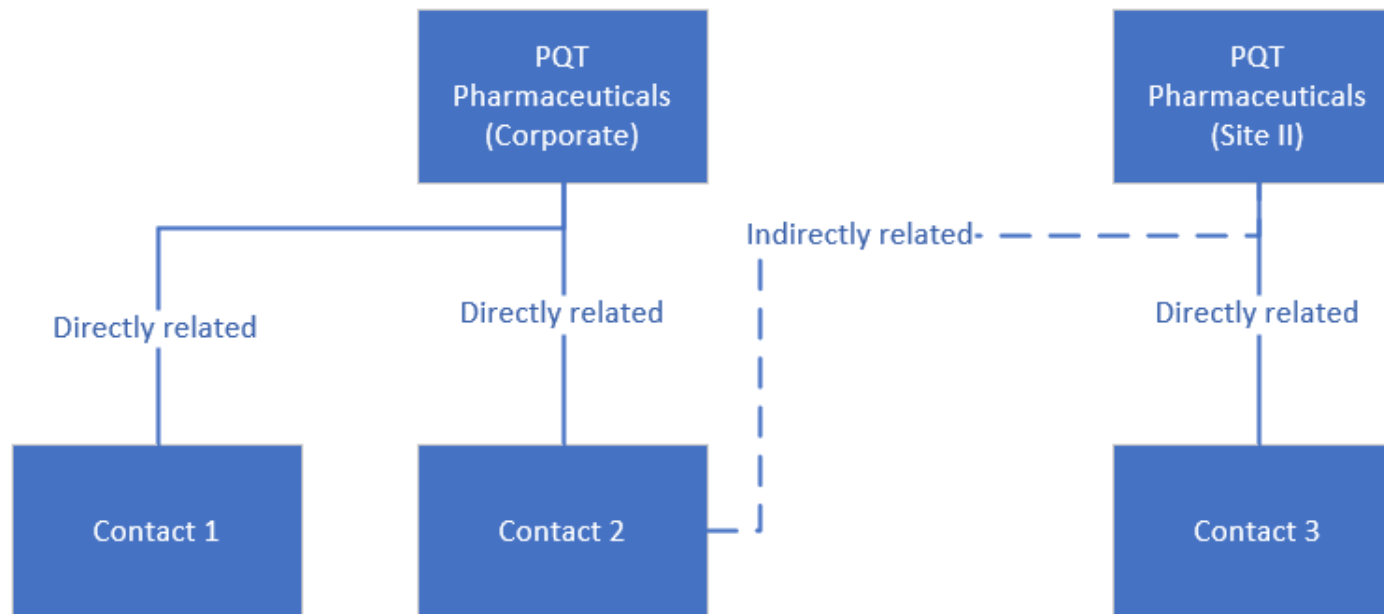


New User? Please complete and send by email this [registration form](#)

Registration Process



Contact and Account Relationships



Contact records and Account records are core system records.

They are referred to on multiple records and they are shared across all ePQS-teams.

Every contact record must be related to an Account.

A single contact record can be related directly to only one account, but indirectly related to multiple accounts

Contact and Account relationship

Contact

Mr ePQS External Applicant 3

+ Follow

New Note

Make Contact Info Private

Job Title

Account Name

Phone (2) ▼

Email

Contact Owner

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

[epqscontact2@gmail.com](#)

[Kingsley Aboagye AWUKU](#)

Details

Related

Preview Documents

Download Documents

Preview Mx Documents

Download Mx Documents

Related Accounts (2)

Account Name	Direct	Active	Start Date
PQT Pharmaceuticals (Corp)	☐	☒	▼
PQT Pharmaceuticals Inc (Site II)	☒	☒	▼

View All

Record visibility

An applicant, manufacturer or Laboratory user will typically see the following record types in the ePQS Portal.

- Account records to which they are directly or indirectly related.
- Contact records of any accounts to which they are directly or indirectly related.
- Product records, if the Application Organization is an account they are related to.
- Application records, if the Application Organization is an account they are related to.
- Activity records assigned to themselves or any user of an account they are directly or indirectly related to.
- Inspection records, if the contact is directly or indirectly to the Account listed as the Site Organization. Note, Inspection records become visible once the inspection has commenced.
- All NRA CRP Agreement records.

Changing Account and Contact details



Forms to request new accounts/contacts, changes to accounts/contacts, or change to record contacts are available on the portal.



Guidance is available on the website regarding creation and editing contacts and Accounts.



A change to a contact record's details can be sent to the responsible team and normally this can be actioned with suitable evidence.



In contrast, changes to Accounts, since they might have implications for the details of a prequalified product, often need to be first accepted through a relevant application procedure.

Maintaining Contact details

 ePQS Product
APIMF Test Product 3

[+ Follow](#) [Printable View](#)

Product Type
Active Pharmaceutical Ingredient Master File

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

Date of Prequalification/Acceptance
10/10/2023

Details

Related

Preview Document

Document Download

Information

WHO Product ID
APIMF Test Product 3

Product Type
Active Pharmaceutical Ingredient Master File

Responsible team
Medicines Team

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

Applicant Organization (Legal)
PQT Pharmaceuticals Inc

Primary Contact
[ePQS External Applicant 2](#)

Secondary Contact

Alternative Secondary Contact

Product Status
Acceptable

Date Application Accepted for Assessment
03/10/2023

Date of Prequalification/Acceptance
10/10/2023

Date of Product Cancellation,... ⓘ

Ensuring a company’s contact details are accurate is a priority.

Applicants can view in the portal the current contacts nominated for an application, and product.

We encourage Applicants to keep these up-to-date

ePQS Features

Record types

Record features

List views

Searching

Document upload and download

Notifications and activities

Application wizards



Record types

There are many record types used in ePQS. Many record types share common features. Some of the most common records types include:

- Account records
- Contact records
- Product records
- Application records
- Inspections records
- Activity records
- CRP registration records
- NRA agreement records

Related Tabs

Most records have three important tabs:

Details

Related

Document tabs

 ePQS Product

Finished Vaccine Product

+ Follow

Delete

1

2

3

Applicant Organization

PQT Pharmaceuticals Inc (Site II)

WHO Vaccine Name

Diphtheria, tetanus, (acellular) pertuss

Vaccine Commercial Name

BCG Vaccine/VacWHO-Test

Details

Related

Preview Document

Document Download

Information

WHO Product ID

P-13571 - name change

WHO Vaccine Name

Diphtheria, tetanus, (acellular) pertuss

WHO Vaccine Name (Full)

Diphtheria, tetanus, (acellular) pertussis and Haemophilus influenzae type b conjugate vaccine (adsorbed)

Vaccine Abbreviated Name

DTaP-Hib

Vaccine Commercial Name

BCG Vaccine/VacWHO-Test

Product Type

Finished Vaccine Product

Responsible team

Product Status

Under Screening

Product Subtype

None

Product Name

Original Application

00029639

Date Application Accepted for Assessment

Reason for Product Suspension

Date of Product Suspension

Details Tab

This is the landing page of most records.

▼ Product Description

ATC Code

J07AG52

Bulk Supplier

1010 Textile Joint Stock Company – Hung Luc Factory

Pharmaceutical Form

Liquid: Active component to be mixed with second component before use

Presentation

Uniject

Presentation Other

No. of Doses per Primary Container

10

Total Volume Primary Container (mL)

10.0000

Route of Administration (Vx)

Intramuscular or deep subcutaneous

Shelf Life

10

Storage Temperature (°C)

25°C

Special Conditions Storage

Vaccine Vial Monitor

Type 7

Preservative

Thiomersal

Preservative Concentration

It contains descriptive information of the record, and fields for information where there is only ever one “answer”.

Related Tab

Product Packaging (1)			
Product Packaging Reference	Mx FPP Packaging Type	Pack Size	Configuration
PP-07206	Mx FPP-Testing 2	10	10
Product Sites (1)			
Product Site ID	Product Site Status	Site	Site Activity
PS-31292	Pending	WHO Sanity Test Manufacturer	FPP Manufacture
Applications (1)			
Case Number	ePQS Case ID	Status	Application Type
00029567	PQ-FPP-2025-0018	Under Screening	Prequalification

The related tab displays records that are associated with the record being viewed.

They might be related records, such as applications associated with a product record,
or

They may be “child” records that further describe the record being viewed, such as a product site record, or description of packaging.

Documents tab

 Case
PQC-FPP-2025-0151

+ Follow

Edit

Case Record Type

Case Number

Status

Applicant Organization

1

Mx FPP Post-PQ Change

00029655

Under Screening

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

Details

Related

Activities

Preview Document

Document Download

Document Submission

 Search files and folders

PQC-FPP-2025-0151

Name

Modified

 Correspondence (External)

Thu Apr 3 2025

Each record has different document folders associated with it.

Some of these folders are visible via the portal.

In most cases the folders are read-only but permitting downloading.

The use of the documents tabs is described later in the slide deck.

List Views

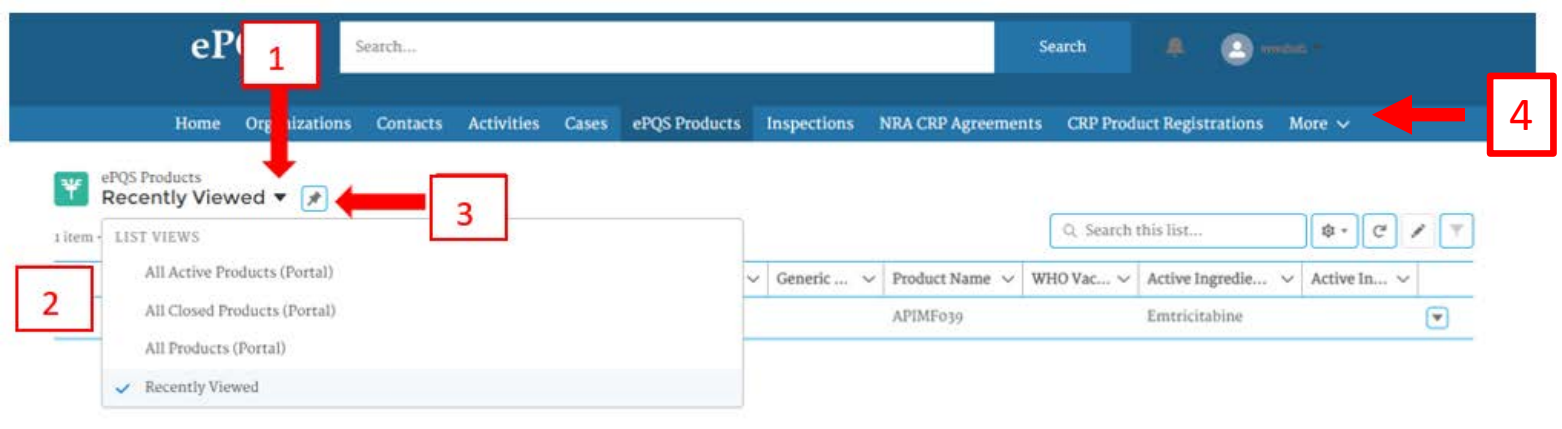
When a user clicks on any item from the Object Menu (4), the portal opens a list view of related records.

List views are a series of records that are filtered by specific criteria.

The portal presents the Recently Viewed list view by default.

A different list view can be chosen by selecting the downward triangle (1) next to the view's name

A preferred view can be pinned (3) to have this opened by default the next time the object is selected



Searching

Records can be located by using the search function.

There are two search function: List Search and Global Search

The list search interrogates only the records in the current list view

Global search attempts to match the search criteria to records across ePQS the user has access to.

It is recommended to use the Global Search field when trying to locate a record

Global Search

Search

Home

Organizations

Contacts

Activities

Cases

ePQS Products

Inspections

NRA CRP Agreements

CRP Product Registrations

More

ePQS Products

Recently Viewed

37 items • Updated a few seconds ago

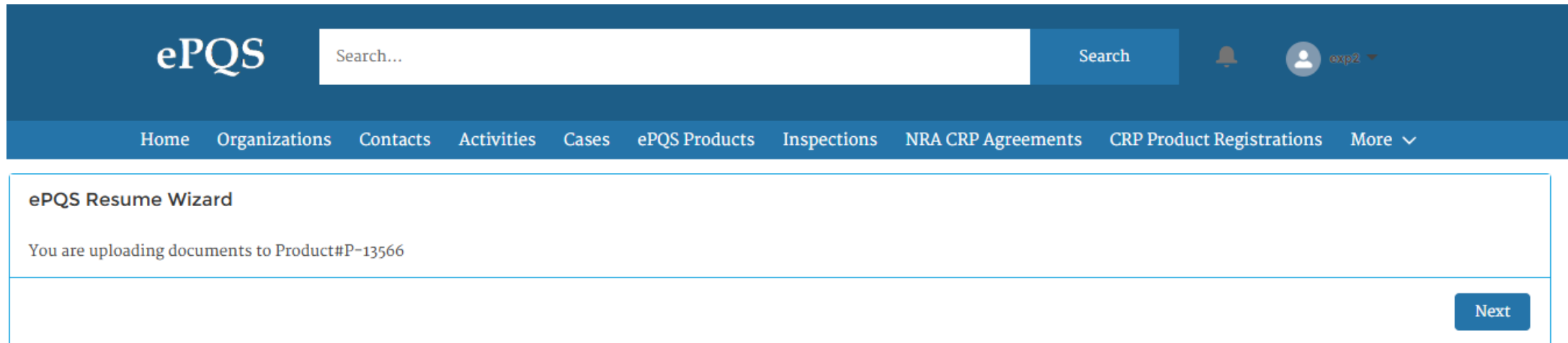
List Search

Search this list...

	WHO Product ID	Product Sta...	Applicant Organization	Generic Name	P...	WHO Vaccine Name	Active Ingredient Nam...	A...
1	P-13571 - name change	Under Screening	PQT Pharmaceuticals Inc ...			Diphtheria, tetanus, (acel...		
2	P-13576	Under Screening	PQT Pharmaceuticals Inc ...	Amodiaquine (hydrochlo...				
3	P-13536	Under Screening	PQT Pharmaceuticals Inc ...				Amodiaquine (hydrochlor...	
4	P-13588	Under Screening	PQT Pharmaceuticals Inc ...				Amodiaquine (hydrochlor...	
5	P-13589	Under Screening	PQT Pharmaceuticals Inc ...	Amodiaquine (hydrochlo...				
6	P-13587	Under Screening	PQT Pharmaceuticals Inc ...				Amodiaquine (hydrochlor...	

Application Documents – During Submission

- It is very common that documents will be uploaded as part of an application.
- The ePQS application wizard includes a dedicated step for this purpose.
- If the application is paused and then recommenced the user is still offered the opportunity to include documents before submission.



The screenshot shows the ePQS application wizard interface. At the top, there is a dark blue header with the ePQS logo on the left, a search bar with the placeholder text "Search..." and a "Search" button on the right, and a user profile icon labeled "exp2" on the far right. Below the header is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and a "More" dropdown menu. The main content area is titled "ePQS Resume Wizard" and displays the message "You are uploading documents to Product#P-13566". At the bottom right of this area is a blue "Next" button.

[About Us](#) [Contact Us](#) [Privacy Policy](#) [Legal Disclaimer](#)

Application Documents – During Assessment (aka responses)

The screenshot displays the ePQS (ePharmaceutical Quality System) interface. At the top, there is a search bar and a navigation menu with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. Below the navigation menu, a case titled 'New-APIMF-2025-0013' is highlighted with a red box. To the right of the case title are buttons for '+ Follow', 'Edit', and 'Resume Application Wizard'. Below the case title, a table provides details about the application:

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance
Mx APIMF Application	00029513	Under Screening	PQT Pharmaceuticals Inc (Site II)	

Below the table, there are tabs for 'Details', 'Related', 'Activities', 'Preview Document', 'Document Download', and 'Document Submission'. The 'Document Submission' tab is highlighted with a red box. Below the tabs, the 'Case Submission Wizard' is displayed, with a welcome message: 'Welcome to Document Submission Wizard. Please click on **Next** to proceed for Case#00029513'.

At the bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Once the application has been submitted (status = Under Screening, or Under Assessment) document can be uploaded to the application.

Do not start a new application.

Instead go to the submitted Application record and select the “Document Submission” tab.

A short wizard takes the user through the upload steps.

The same process is undertaken for on-going Inspections also.

Application Documents - Downloads

Applicants can find related letters and eCTD validation reports in the Correspondence(External) folder via the relevant Application record by selecting the Preview or Document Download tabs.

 Case

New-APIMF-2025-0013

[+ Follow](#) [Edit](#) [Resu](#)

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequ
Mx APIMF Application	00029513	Under Screening	PQT Pharmaceuticals Inc (Site II)	

[Details](#) [Related](#) [Activities](#) [Preview Document](#) [Document Download](#) [Document Submission](#)

 Search files and folders

New-APIMF-2025-0013

Name	Modified
 Correspondence (External)	Fri Mar 21 2025

Application Documents - Downloads

 Case

New-APIMF-2025-0013

+ Follow

Edit

Resume Application Wizard

New Component(s) ▼

Case Record Type

Case Number

Status

Applicant Organization

Date of Prequalification/Acceptance

Mx APIMF Application

00029513

Under Screening

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

Details

Related

Activities

Preview Document

Document Download

Document Submission

box

Search files and folders

New-APIMF-2025-0013 > Correspondence (External)

↑↓

 REPLY_New-APIMF-2025-0013_P-13536_2025-03-21_05-11-49.pdf

Modified Fri Mar 21 2025 • 116.75 KB

☒

1 Selected

×

✓

To take a copy of the document open the Correspondence (External) Folder, select one or more documents and download as a Zip file.

Less common, is the need to upload or download documents related to your own account and not a specific application.

This might be needed to pass on more general information

**DO NOT UPLOAD APPLICATION
INFORMATION HERE**

Organisation/Account Documents

The screenshot displays the 'Account Documents' page for 'PQT Pharmaceuticals Inc (Site II)'. At the top, there's a header with the account name and three buttons: '+ Follow', 'New Note', and 'DocuSign Arms'. Below this, account details are listed: 'Account Record Type' (Non-State Actor), 'Address (2)', and 'Email'. A navigation bar contains tabs: 'Details', 'Related', 'Preview Documents', 'Document Download' (which is active), and 'Document Submission'. The main content area features a 'box' storage interface with a search bar 'Search files and folders'. Under the heading 'PQT Pharmaceuticals Inc (Site II)', two folders are listed: 'External correspondence' and 'Submitted Documents', both showing a modification date of 'Fri Jun 21 2024' and a size of '0 Byte'.

User Folder

Finally, every user has access to a personal folder which can be used to securely pass documents to PQT unrelated to an application.

Note, this folder is visible to all internal users and external users from the same Organisation

Contact

Mr ePQS External Applicant 3

+ Follow

New Note

Make Contact Info Private

Job Title

Account Name

Phone (2) ▼

Email

Contact Owner

PQT Pharmaceuticals Inc (Site II)

epqscontact2@gmail.com

Kingsley Aboagye AWUKU

Details

Related

Preview Documents

Download Documents

Preview Mx Documents

Download Mx Documents

box

Search files and folders

ePQS External Applicant 3-PersonalFolder

Name	Modified	Size
External Guidance - Q&A document v1.0.docx	Today	266.56 KB

Activities

- Activities are small records that track the assignment of a task to a person (user)
- They are located from the Activities Menu bar item.
- Together with correspondence from PQT teams they serve as a reminder of outstanding tasks

ePQS

Search...

Search

  exp2

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

 External Activities

All Activities (Applications - Portal) 

2 items • Sorted by Activity Name • Filtered by All external activities – Related To (Inspection) • Updated a few seconds ago

Q Search this list...

	Activity Na... 	Subject 	Owner Last N... 	Related To (... 	Status 	Start Date 	Due Date 	End Date 	
1	EA-025798	Request for Information (Screening)	Applicant 2	00029639	In-Progress	02/04/2025			
2	EA-026319	Request for Information (Screening)	Applicant 2	00028144	In-Progress	28/04/2025			

Notifications

Applicants receive various notifications from the ePQS system. Some of the key notifications are:

- When the application has been submitted.

The confirmation email is not an indication that the Application has been accepted for assessment.

- When an activity has been assigned to the applicant. Such as a request for information.
- When documents relating to an inspection are successfully uploaded.
- When document relating to an application are successfully uploaded (PENDING).

ePQS Application wizards



World Health
Organization



HEALTH
FOR ALL

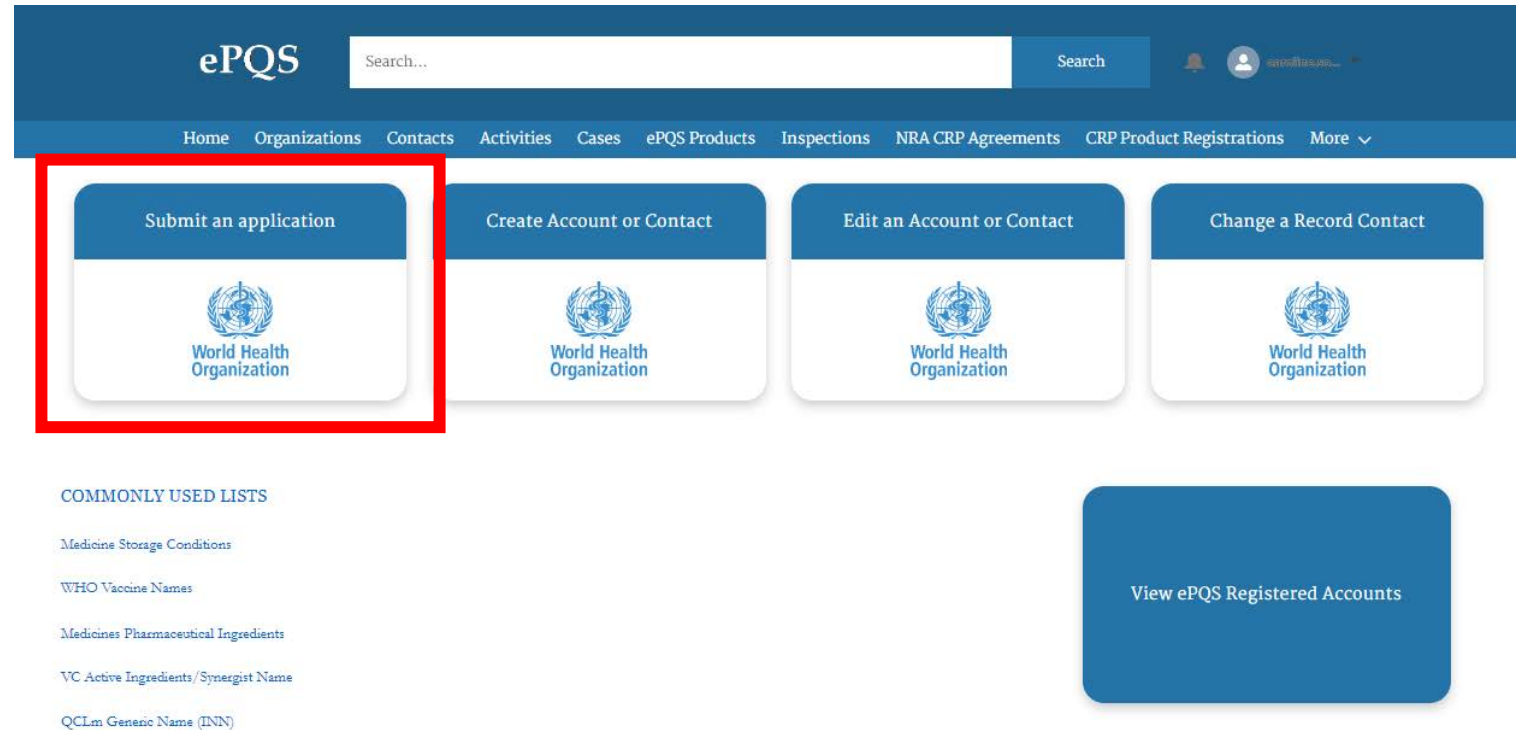


Wizard Overview

Wizards are step-by-step tools that assist and guide applicants to create and submit application records.

Training and guidance on specific application wizards will be undertaken by the respective assessment teams.

General guidance on application wizards can be located on the ePQS webpage.



How to start

In general wizards follow the following sequence.

- Selection of applicable product type
- Selection of applicable application for the selected product-type
- Selection of contacts for the application
- Creation and completion of application and related records
- Creation and completion of product and related records (depends on application type)
- Uploading of documents
- Submission of application

As records are created these will be visible in the portal under the applicable menu item.

How to recommence a Wizard

The screenshot displays the WHO ePQS interface. At the top, a navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and a More dropdown. Below this, a case header for 'New-APIMF-2024-0018' is shown, featuring a '+ Follow' button, an 'Edit' button, and a 'Resume Application Wizard' button highlighted with a red rectangle. To the right of the 'Resume Application Wizard' button is a 'New Component(s)' dropdown menu. Below the case header, a table lists case details: Case Record Type (Mx APIMF Application), Case Number (00027852), Status (Draft), Applicant Organization (redacted), Date of Prequalification/Acceptance, and Case Owner (redacted). Below the table, a tabbed interface shows 'Details', 'Related', 'Activities', 'Preview Document', 'Document Download', and 'Document Submission'. The 'Details' tab is active, showing 'General Details' for the case. The details include: 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 lists contact information: Case Owner (redacted), Status (Draft), Applicant Organization (redacted), Applicant Organization (Legal) (redacted), Applicant Primary Contact (redacted), Applicant Secondary Contact (redacted), and Alternative Applicant Secondary Contact (redacted).

If a wizard is closed before submission (even accidentally), then it is possible to recommence the wizard.

To recommence the wizard, locate the application record and select the button

Please do not start a new wizard since this will create a further application

Responding to requests for information

Requests for information from applicants are common during the application screening and assessment process.

Applicant should not create a new application to respond to a request.

Rather the Applicant should:

- Close the open activity
- Upload the requested document from the existing application
- Email the assessment team confirming they have responded

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a navigation menu including Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. Below the header, a red box highlights the case identifier 'Case New-APIMF-2025-0013'. To the right of this box are buttons for '+ Follow', 'Edit', and 'Resume Application Wizard'. Below these, a table provides details about the case:

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance
Mx APIMF Application	00029513	Under Screening	PQT Pharmaceuticals Inc (Site II)	

Below the table, a navigation bar includes tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'Document Submission' tab is highlighted with a red box. Under this tab, the 'Case Submission Wizard' is active, displaying the message: 'Welcome to Document Submission Wizard. Please click on **Next** to proceed for Case#00029513'. At the bottom of the page, there is a footer with links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

Where to Obtain Information

Team-specific training, relating to the specifics of application procedures, and application wizard features, will be available separately.

All ePQS-related information will be posted to the ePQS Webpage (<https://extranet.who.int/prequal/epqs-portal>).

Teams can be approached directly if the information sought is not on the ePQS webpage. Technical enquires can be sent to the ePQS Manager (epqs@who.int).

Team	Email address
In vitro Diagnostics	diagnostics@who.int
QCL Laboratories	prequallaboratories@who.int
Medicines	prequal@who.int
Vaccines	vaccprequalification@who.int
Vector Control	pqvectorcontrol@who.int
Facilitated Product Introduction	prequalreg@who.int
Inspections	prequalinspection@who.int

Thank you