An introduction to the ePQS Portal

May 2025

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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 (<u>https://extranet.who.int/prequal/epqs-portal</u>).

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?



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





FAQs Prequalification EPQS Training Material

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



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





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

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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



Alternative Secondary Contact



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



PQS Product Finished Vaccine Product			+ Follow	Delete	
Applicant Organization WUO Vaccine Name POT Phat nagut cals Inc (Site II) Biph theria, tetanus, (acellular) pertuss Details Related Preview Document	V B	accine Commercial Name CG Vaccine/VacWHO-Test			
✓ Information					
WHO Product ID		Product Status			
P-13571 - name change		Under Screening			
WHO Vaccine Name		Product Subtype			
Diphtheria, tetanus, (acellular) pertuss		None			
WHO Vaccine Name (Full)		Product Name			_
Diphtheria, tetanus, (acellular) pertussis and Haemophilus influenzae type b conjugate vaccine (adsorbed)	!				
Vaccine Abbreviated Name		Original Application			
DTaP-Hib		00029639			
Vaccine Commercial Name		Date Application Accepted for Asses	sment		
BCG Vaccine/VacWHO-Test	and				
Product Type		Reason for Product Suspension			
Finished Vaccine Product					
Responsible team		Date of Product Suspension			

Details Tab

This is the landing page of most records.

✓ Product Description

ATC Code J07AG52		Route of Administration (Vx) Intramuscular or deep subcutaneous
Bulk Supplier		Shelf Life
1010 Textile Joint Stock Company – Hung Luc Factory	a start i	10
Pharmaceutical Form		Storage Temperature (°C)
Liquid: Active component to be mixed with second component before use	. and the	25°C
Presentation		Special Conditions Storage
Uniject	. and t	
Presentation Other		Vaccine Vial Monitor
	. and t	Туре 7
No. of Doses per Primary Container		Preservative
10	. and the	Thiomersal
Total Volume Primary Container (mL)		Preservative Concentration
10.0000	de la calegra	

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



Related Tab

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
	DO-EDD-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



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



eP 1 Search		Search		
Home Org tizations Contacts Activities Cases ePQS Product	s Inspections NRA	CRP Agreements CRI	P Product Registrations	More V
ePQS Products				
merently Viewed • 🖋 🛃 3	1	Q S	earch this list	\$• C / T
All Active Products (Portal)	✓ Generic ✓ Pro	oduct Name 🗸 WHO Vac	c ∼ Active Ingredie 丶	Active In V
All Closed Products (Portal)	API	IMF039	Emtricitabine	
All Products (Portal)				
✓ Recently Viewed				

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





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.







Application Documents – During Assessment (aka responses)

ePÇ	QS s	Search							Search	.
Home O	rganizations	Contacts	Activities	Cases	ePQS Products	Inspections	NRA CRP	Agreement	s CRP Pro	oduct Registrati
Case New-APIMF-2	025-0013	7				[+ Follow	Edit	Resume App	plication Wizard
Case Record Type Mx APIMF Application	Case Nu 000295	mber 13	Status Under Scr	reening	Applicant O PQT Pharm	rganization naceuticals Inc (Site II)	Date of	Prequalificati	on/Acceptance
etails Related Ac	tivities Pr	eview Docu	ment Do	cument I	Download Doc	cument Subm	ission			
Case Submission Wiz	ard mission Wizar	d. Please clicl	c on Next to pa	roceed for	Case# 00029513					

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 Mx APIMF Application	Case Number 00029513	Status Under Screening	Applicant Or PQT Pharm	ganization aceuticals Inc (Site II)	Date	of Prequ
Details Related Activiti	es Preview Doc	ument Document Do	wnload Doc	ument Subm	ission		
Search files and folde	ers						
New-APIMF-2025-0013							
Name			Modif	ied			
Correspondence (External)			Fri M	ar 21 2025			

Application Documents - Downloads

Case New-APIMF-2025	5-0013			+ Follow	Edit	Resume Application Wizard	New Component(s)	•
Case Record Type Mx APIMF Application	Case Number 00029513	Status Under Screening	Applicant Organization PQT Pharmaceuticals Inc	(Site II)	Date	of Prequalification/Acceptance		
Details Related Activit	ies Preview Docu	ment Document Do	wnload Document Subn	nission				
Search files and fold	lers							
New-APIMF-2025-0013 > Corres	spondence (External)							$\uparrow\downarrow$
REPLY_New-APIMF-202: Modified Fri Mar 21 2025 • 1	5-0013_P-13536_2025-0 16.75 КВ	3-21_05-11-49.pdf						
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



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

	ontact Ar ePQS External Applicant 3			+ Follow	New Note Make Contact Info Pr	rivate
Job Title	Account Name PQT Pharmaceuticals Inc (Sit	Phone (2) ▼ te II)	Email epqscontact2@gmail.com	Contact Owner Kingsley Aboagye AWUKU		
Details	Related Preview Documents	Download Documents	Preview Mx Documents Dow	nload Mx Documents		
60	Search files and folders					
ePQS E	xternal Applicant 3-PersonalFolder					
	Name		Modified		Size	
æ	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

	ePQ	S s	Search							Search		•			
	Home O	rganizations	Contacts	Activities	Cases	ePQS Produ	ucts Inspections	NRA CRP Agree	ments	s CRP Prod	uct Regis	trations	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															
2 items •	Sorted by Activity Nam	e • Filtered by Al	ll external activ	vities - Related	To (Insp	ection) • Updated	l a few seconds ago			Q Search	this list		\$ ×	C'	
2 items •	Sorted by Activity Nam	e • Filtered by Al	ll external activ	vities – Related	To (Insp V 0	ection) • Updated	 Related To (\) 	 Status 	~	Start Date	V Du	ue Date	v End Date	C"	
2 items • 1	Sorted by Activity Nam Activity Na… ↑ ~ EA-025798	e • Filtered by Al Subject Request for I	ll external activ	vities – Related Screening)	To (Insp V 0 A	ection) • Updated wner Last N pplicant 2	 Related To (\ 00029639 	 Status In-Progress 	\sim	Q Search Start Date 02/04/2025	V Du	ue Date	♥ ▼ End Date	C ² / / /) T



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





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

Home Organizations Contacts Activities Cases ePQS Products	Inspections NRA CRP Agreements CRP Product Registrations More 🗸
Case New-APIMF-2024-0018	+ Follow Edit Resume Application Wizard New Component(s) 💌
Case Record Type Case Number Status Applicant Organization Mx APIMF Application 00027852 Draft	Date of Prequalification/Acceptance Case Owner
Details Related Activities Preview Document Document Download Do	ocument Submission
✓ General Details	
ePQS Case ID New-APIMF-2024-0018	Case Owner
WHO Application Number New - APIMF-2024-0018	Status Draft /
WHO Product ID O P-13080	Applicant Organization
Product Type Active Pharmaceutical Ingredient Master File	Applicant Organization (Legal)
Application Type APIMF Procedure	Applicant Primary Contact
Application Subtype Standard	Applicant Secondary Contact
Product Assessment Procedure APIMF Procedure – Standard	Alternative Applicant Secondary Contact
Reference Authority	

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





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 (<u>https://extranet.who.int/prequal/epqs-portal</u>).

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

