

WHO e-Prequalification System (ePQS)

Learning materials 2025





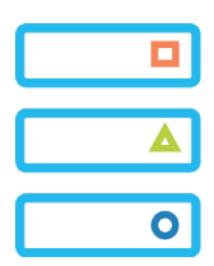
Key access links (for reference)

WHO ePQS Portal landing page:

https://extranet.who.int/prequal/epqs-portal

ePQS login link:

https://who.lightning.force.com/lightning



Intended audiences of these learning materials

AUDIENCES

- 1. Primarily: IMD-PQS Prequalification Holders (manufacturers and resellers of WHO prequalified immunization devices) and first-time applicants for WHO Immunization devices prequalification.
- 2. These learning materials may also be of interest to: IMD-PQS external experts engaged in the evaluation of application dossiers, as a complement to the dedicated materials provided for that group.



Purposes of these learning materials



Learning materials are to provide comprehensive resources to enable you to develop your capabilities (semi-) autonomously for the various feature and functions of ePQS, and the pilot requirements. This deck:



- 1. Presents the ePQS launch plan (for the pilot and universal launch phases)
- 2. Explains the role(s) of ePQS in the IMD-PQS prequalification process
- 3. Introduces ePQS navigation
- Guides PQ Holders and new applicants through the ePQS prequalification and post-prequalification applications
- 5. Introduces key concepts and terminology
- 5. Provides links to all detailed technical guidance where they exist



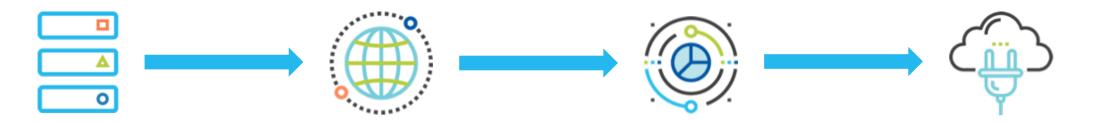


Q&A / coaching sessions with the IMD-PQS ePQS support team, via videoconference link, may be scheduled subsequent to this self-training..

Overview of these learning materials







SECTION A - SET-UP

- Introduction
- Pilot
- Registration
- Terminology

SECTION B – DISCOVERY

 Navigating ePQS features & functions

SECTION C – PROCEDURES

Step-by-step instructions of the application procdures

SECTION D – SUPPORT

Additional and forthcoming technical support

Contents



Links to further technical support



141

SECT	ION	Δ —	SFT-	UP
				$oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{oldsymbol{ol}}}}}}}}}}}}}}}}$

1.	ePQS portal introduction	10	c. <u>Correct record visibility</u>		70
2.	Registration & access	19		i. Record visibility - All	
3.	Concepts & terminology	22		ii. Record visibility - Products	
			d.	Personal use folder	77
	TION B - DISCOVERY		e.	Application submission procedure	81
5.	Navigating ePQS functions & features	31	f.	Post-PQ variation submission	99
SEC	TION C – APPLICATION PROCEDURES		g.	<u>Uploading of documents</u>	124
6.	Step-by-step guide	54	h.	Downloading of documents	130
	a. Verification of product data sheets	58	i.	Assigned activities	134
	b. Accessing registered accounts	65	j.	Bell & email notifications	137
		SEC	TION	D – TECHNICAL SUPPORT	



SECTION A - SET-UP



1
ePQS Portal
Introduction

1. ePQS Introduction – What is ePQS?



The ePQS "e-PreQualification System" platform provides prequalification applicants and PQ Holders (product manufacturers and resellers) a one-stop online portal to:

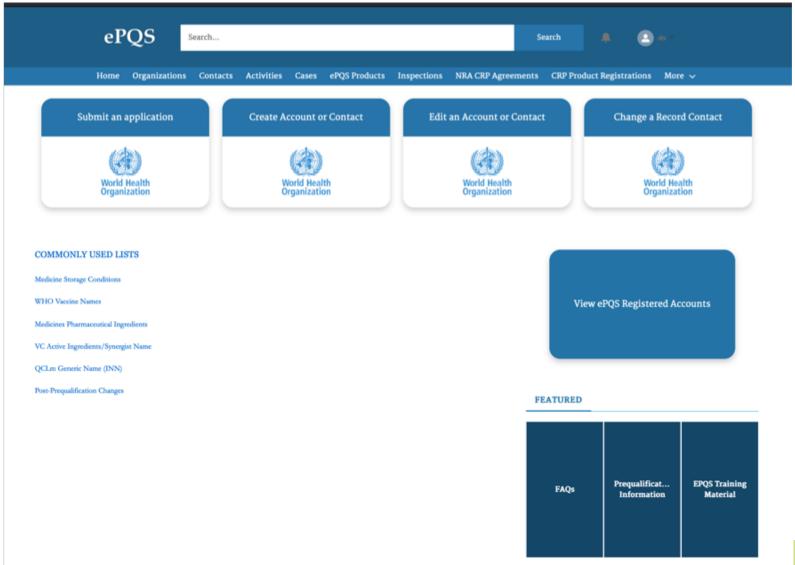
- submit & manage prequalification applications & post-PQ variations
- follow the site inspections process
- view records relevant to the user
- submit required changes to account, contact & product information
- upload and download <u>documents</u> securely
- view and monitor <u>notifications for pending activities</u>

<u>Product annual reassessment</u> (the IMD-PQS Annual Review) will be included in the ePQS system in future (2026/7).



In additional to these processes, the ePQS platform supports all communication between applicants, Prequalification Holders and the WHO prequalification divisions and external experts related to the workflows via a cloud file-sharing system integrated into ePQS system.

1. ePQS Introduction – Home page appearance



1. ePQS Introduction Communication with IMD-PQS





First contact with IMD-PQS - "offline"

- the first contact with the IMD-PQS Secretariat for a new application for prequalification remains by email (application pre-submission & fees).
- If the Secretariat deems that an application is warranted, the Secretariat will direct the applicant to register on the ePQS platform.
- hereafter all communication related to the prequalification application, up to and including the final decision, will pass through the ePQS platform.

Applications and post-PQ processes

- communication between applicants / Prequalification Holders and the IMD-PQS Secretariat will take place via:
 - o the application wizard,
 - o the downloadable request forms on the home page,
 - the up/download of documents to the relevant "External Communications" folder within each user's account.

1. ePQS Introduction Key components of the ePQS platform



The two key components of the WHO ePQS platform

The "application wizard"

Applications for prequalification, as well as submissions for postprequalification product variations, take place via the "Application Wizard" tool.

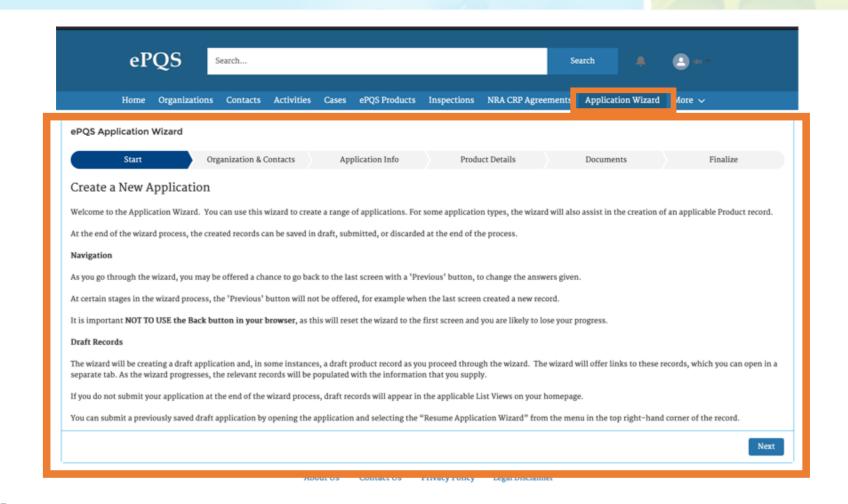


Cloud file-sharing facility ("Box")

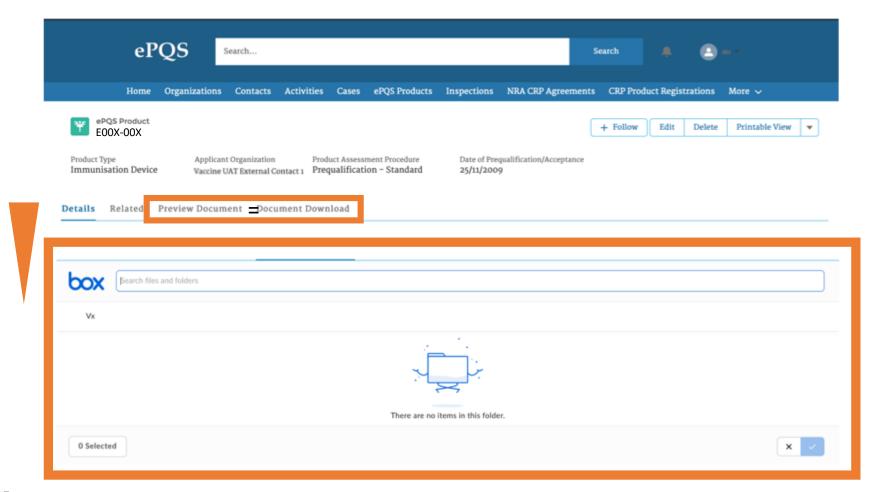
A cloud file-sharing facility manages the uploading, storage and sharing of documents between external applicants, WHO prequalification divisions and external experts. (The brand name of this cloud file-sharing facility is "Box".) The file-sharing takes place via an "External Correspondence" folder, accessible via document tabs within each ePQS *Account, Case Record* or *Product Record*.



1. ePQS Introduction Quick view - Application Wizard

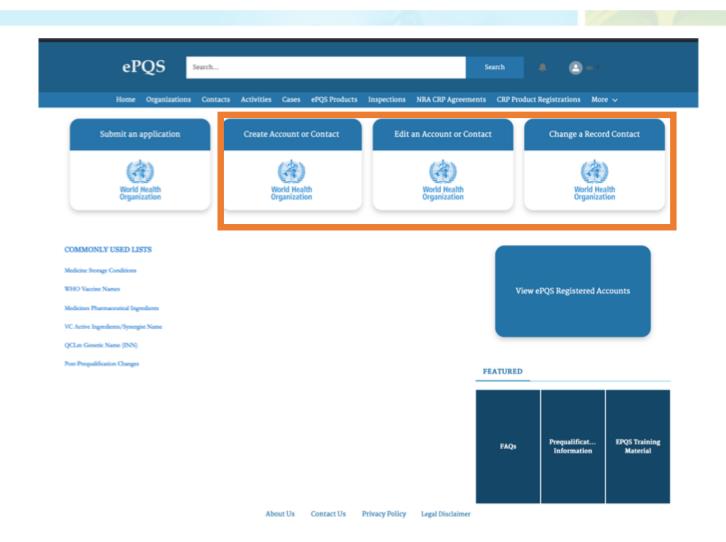


1. ePQS Introduction Quick view - Document up/download



1. ePQS Introduction

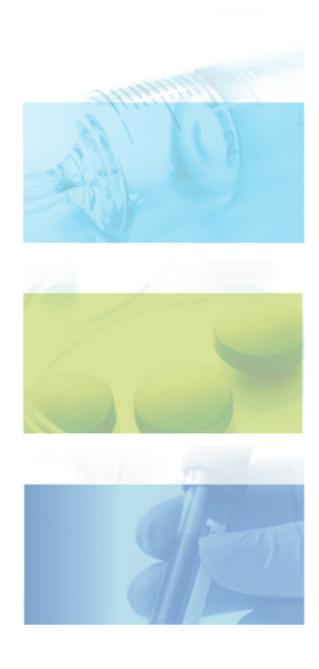
Quick view - Data change request forms



1. ePQS Introduction - ALL Features & functions overview

The ePQS platform offers the following features and functionalities to facilitate the prequalification-related processes:

❖ Global search facility	Outstanding/pending activities tab				
❖ Notification "Bell" icon	Document submission, preview & download				
Menu bar of major record types	❖ Contacts & accounts				
❖ Filterable list views	Personalized commonly-used lists				
❖ Application Wizard	FAQs and training materials				



2 Registration & Access

3. Registration

- 1. Account contacts have already been created for all IMD-PQS Prequalification Holders
- 2. Prequalification Holders must **verify their account and contact** details prior to registration. The IMD-PQS Secretariat will reach out individually to users with the required forms for this stage.
- Contacts need to "register" to gain access to the the system.
 Registration is via the:
 "External Form New ePQS User" linked here.



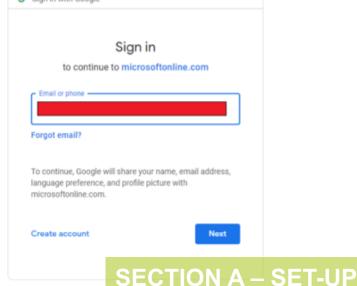
5. You must complete the "External Form - New ePQS User" and return it to epqs@who.int, with the IMD-PQS Secretariat in copy.

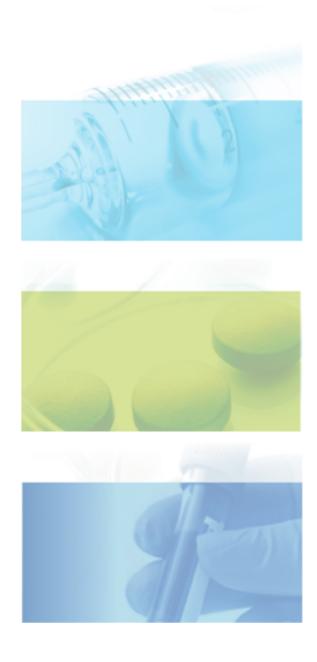
2. Access

Once the registration is successfully completed, access to the ePQS portal can be obtained by:

- Accessing the link: https://who.my.site.com/ePQS/s/login/
- Clicking the "WHO Login" button. The user will be directed to WHO Microsoft identity platform where they will be required to enter their username and click on the "Next" button.
- 3. OR, depending on which authentication mechanism is being used by their email address service, WHO's identity platform will direct the user to provide the password the user uses for the email service.







3 Concepts & terminology

3. Concepts & terminology



This section of the learning materials includes key terms that you will encounter whilst navigating ePQS.

It is intended as an ongoing reference guide throughout the training and your pilot activities.

3. Concepts & terminology – two critical terms

"Records" and "Cases"

Record

A single instance of object data. Records types include:

- Product Record,
- Product Variant Record,
- Contact Record,
- Account Record,
- Case Record.

Case

Every prequalification application or associated application (E.g. Inspection, post-prequalification product variant) begins with the creation of a *case*.



"Records" and "Cases"

Activity Any system activity taken in relation to an ePQS *case*.

Case record type For each WHO IMD-PQS case, the record type will be either "Vx

IMD Application", or "Vx IMD Post-PQ change" or "Vx IMD

Reassessment". These terms are defined below.

ePQS Case IDOnce opened, each case will be assigned an ID in the format

"PQ-IMD-YEAR-XXXX".



IMD-PQS processes on ePQS

Vx IMD Application IMD-PQS ePQS Application type meaning: "New application for

product prequalification".

Vx IMD Post-PQ change IMD-PQS ePQS Application type meaning: "Post-prequalification

variation, a change to product or manufacturing process".

Vx IMD Reassessment IMD-PQS ePQS Application type meaning: "IMD Annual Review of

prequalified products".



Terms related to applications

Application New application for product prequalification, post-PQ variation or

Reassessment. Submitted via the Application Wizard.

Applicant organization The legal entity submitting a prequalification application or post-

prequalification commitment.

Application number Unique code assigned to each new application in ePQS, in the

format "PQ-IMD-202X-XXXX". Identical to the "ePQS Case ID".

Application wizard ePQS process assistant: a user interface that leads users through

each ePQS process via a sequence of prompted, guided steps.



Terms related to products

IMD product Section of the application/case/product record that contains the basic

information about a product submitted for review. For example, the

product name, description and type and applicant organization.

IMD product variant Sub-section of the unique product application/case/product record that

contains the record of all of the detailed product technical specifications.

(WHO) Product ID number Once a prequalification application is completed and submitted in the

application wizard, the product will be assigned an ID number in the

format: "P-XXXXX".

External IDSubsequent to a successful application for prequalification, WHO IMD-

PQS will assign an External ID in the traditional format of the "PQS"

Product number": "IMD-E0XX-XXX".

Product site Location and facility at which a product is manufactured.





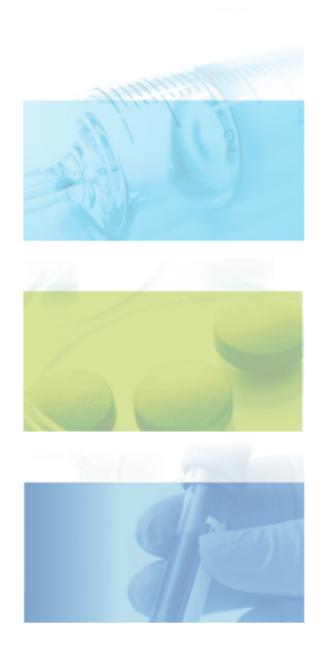
SECTION B - DISCOVERY

ePQS navigation & features - Discovery



This "discovery" section of the learning materials guides you through the different features and functions of ePQS and where you can find them.

It is intended as a learning aid and ongoing reference guide.

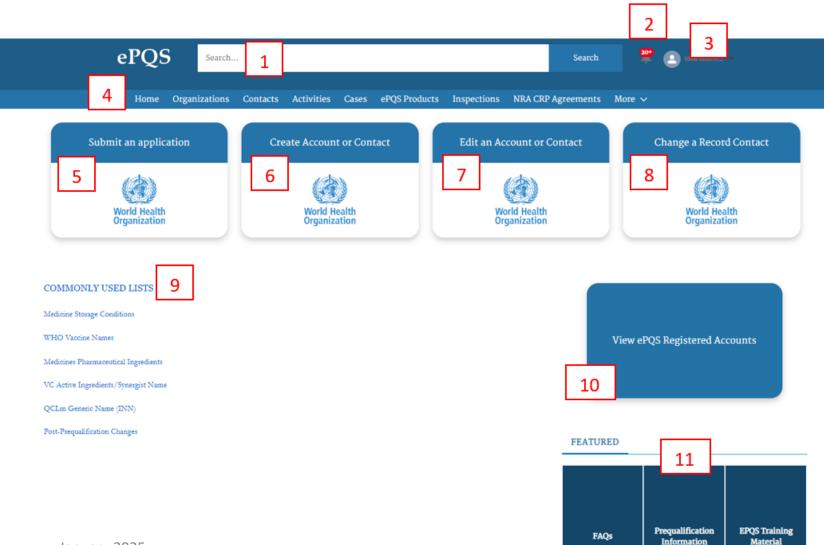


4

Navigating ePQS

- General guide

4. ePQS navigation – Homepage map



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.

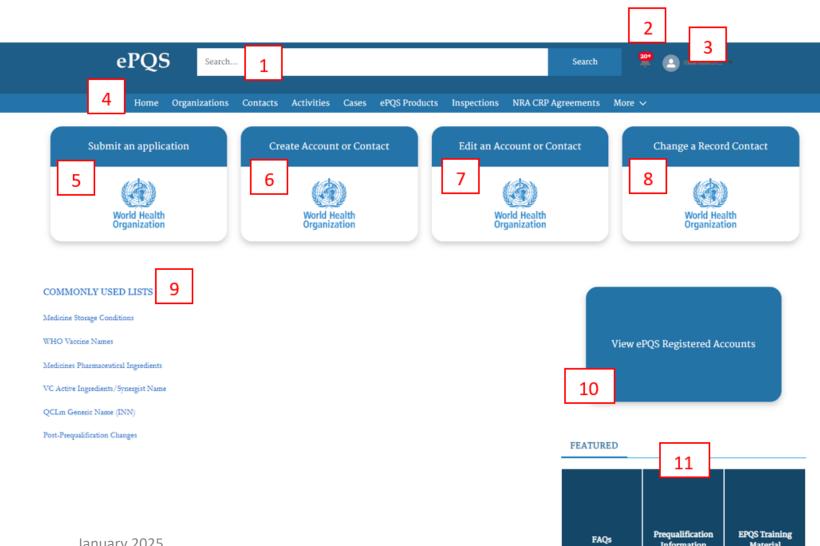
5) Application wizard

This initiates the creation of a new application

6 to 8) Contacts and Accounts

These menu items download the relevant forms for completion.

4. ePQS navigation – Homepage map



9) Commonly Used Lists

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

For instance, as part of the FVP 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.

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.

11) FAQ and training materials

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

4. ePQS navigation – My profile



The "My Profile icon is an important tool on the platform.

Select "My profile" to refer to the information that is stored in ePQS about your contact account.



4. ePQS navigation – My profile



"My profile" appearance.

	еP	QS	Search						Search		<u>Clc</u> ▼
	Home	Organizations	Contacts	Activities	Cases	ePQS Products	Inspections	NRA CRP Agreemen	s CRP Pr	oduct Registra	Home
Name							Manager				My Profile
											My Account
litle							Company N	ame			Logout
							Active				
							Contact				
Email							Phone				
Address							Mobile				

4. ePQS navigation – My account



The "My account" icon provide you with access to most actions.

Select "My account" to access all related products and documents as well as actions.



4. ePQS navigation – My account

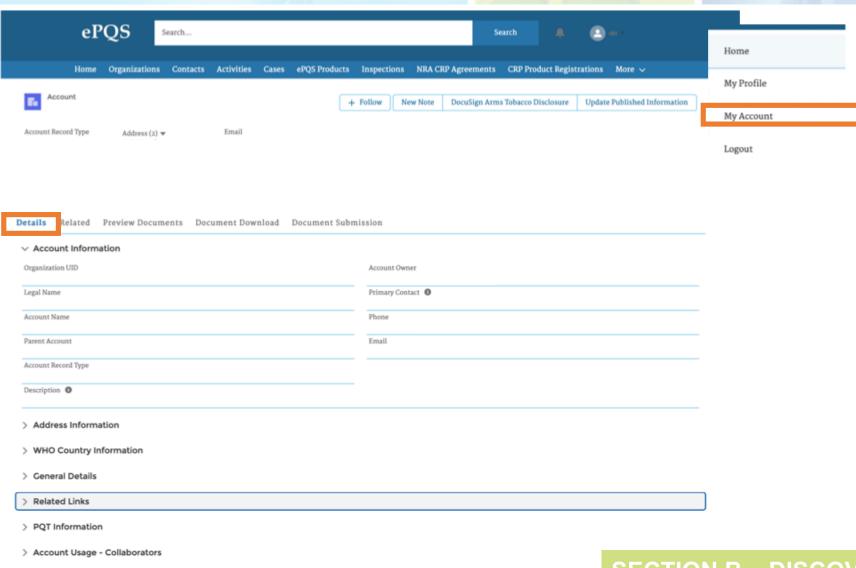
> System Information



"My account" appearance.

5 sub-tabs appear:
Details; Related;
Preview documents;
Document download;
Download submission.

"Details" displays the information that is stored in ePQS related to the manufacturing company (or other supplier entity) you are linked to.



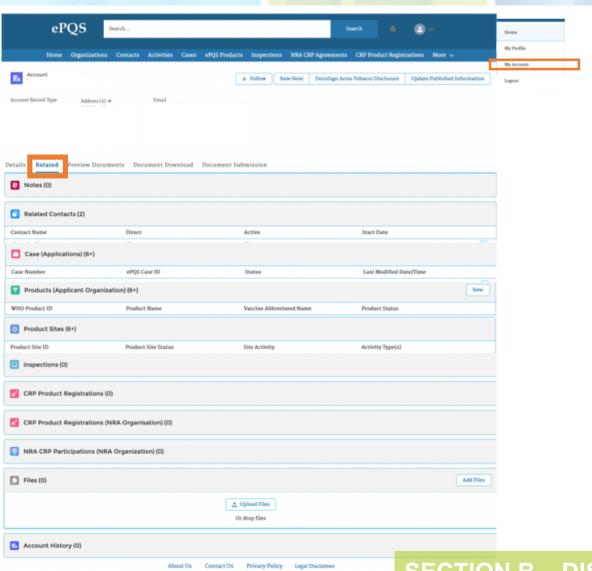
4. ePQS navigation – Related



"Related" provides a list of all records in ePQS related to your account.

This includes:

- contacts;
- accounts;
- products;
- product sites;
- inspections;
- files; and
- account history.

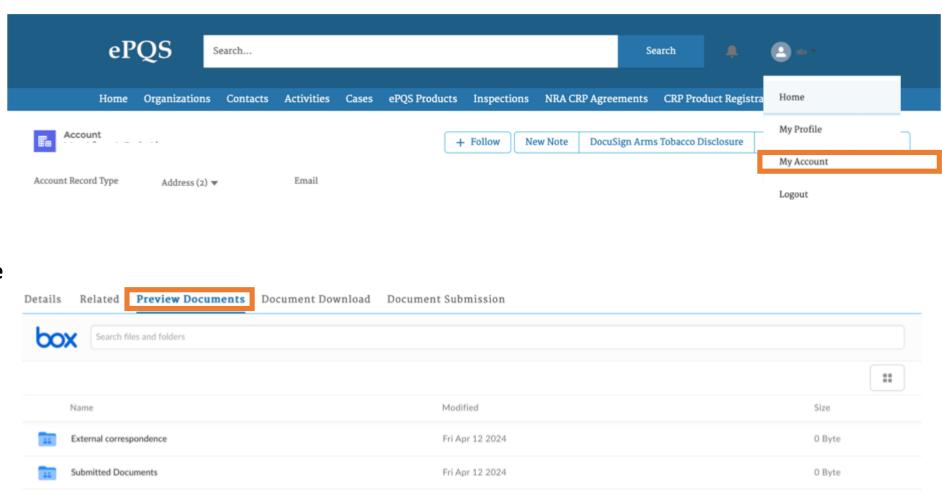




"Preview documents" is a reference library of all documents related to your account.

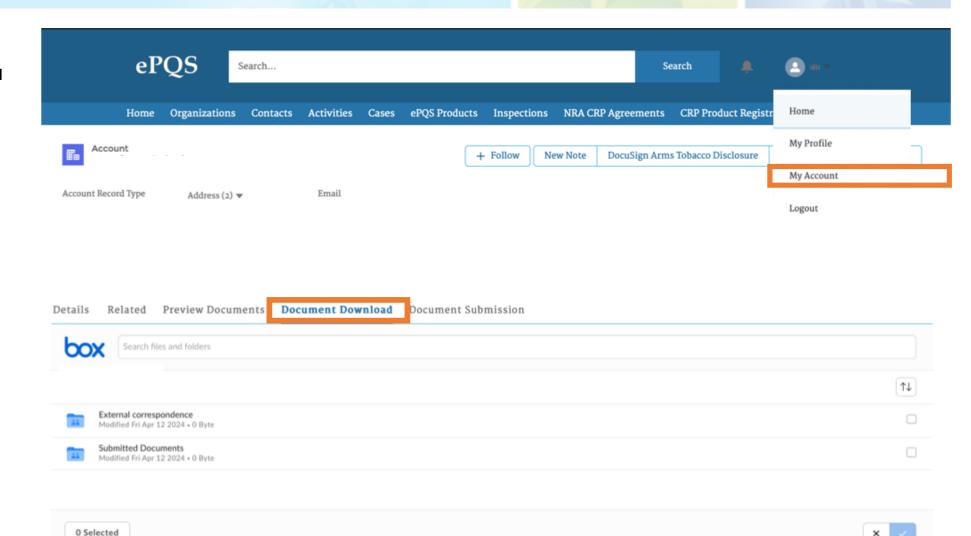
"External correspondence" contains the documents you have submitted as correspondence with the IMD-PQS Secretariat.

'Submitted documents' contains the documents uploaded to the account or as part of an application wizard process.





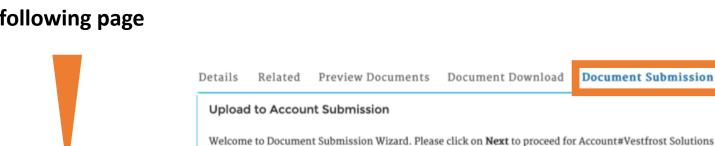
"Download documents" allows you to download and save locally all the documents related to your account.

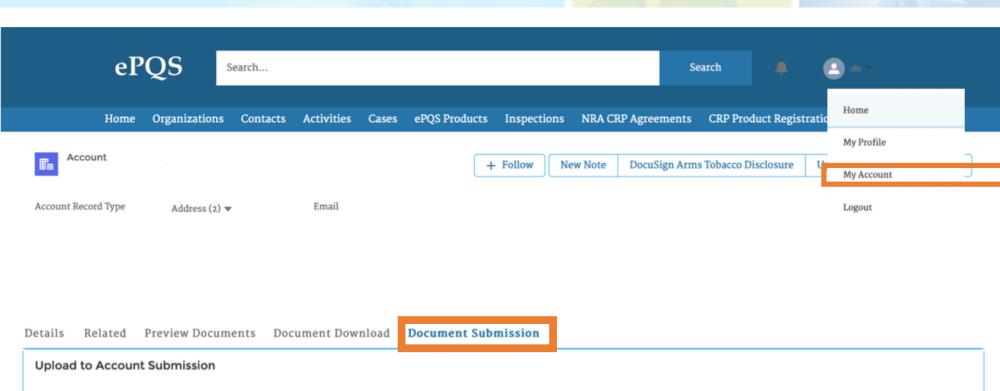




"Document submission" enables you to upload documents to your account.

Instructions on following page





Privacy Policy

Legal Disclaimer

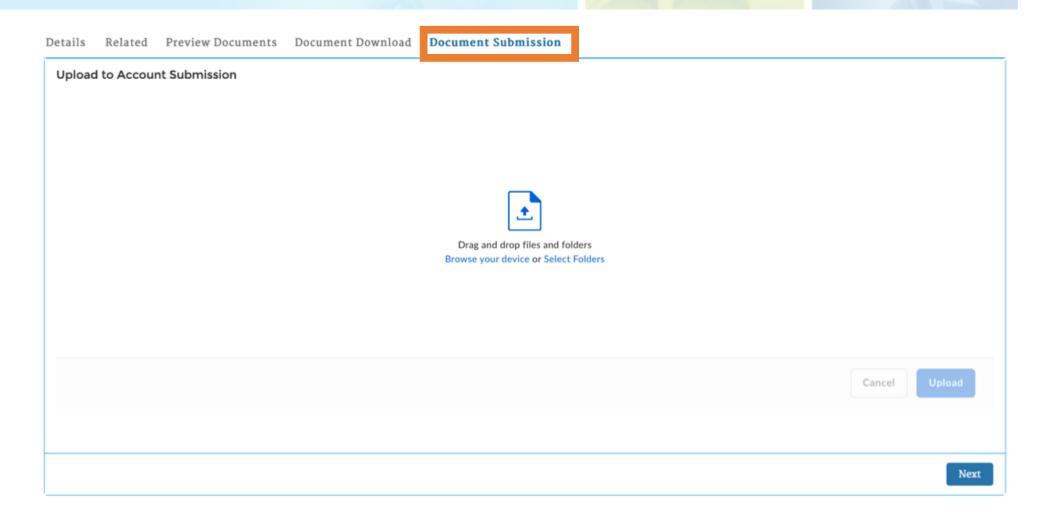
About Us

Contact Us

Next



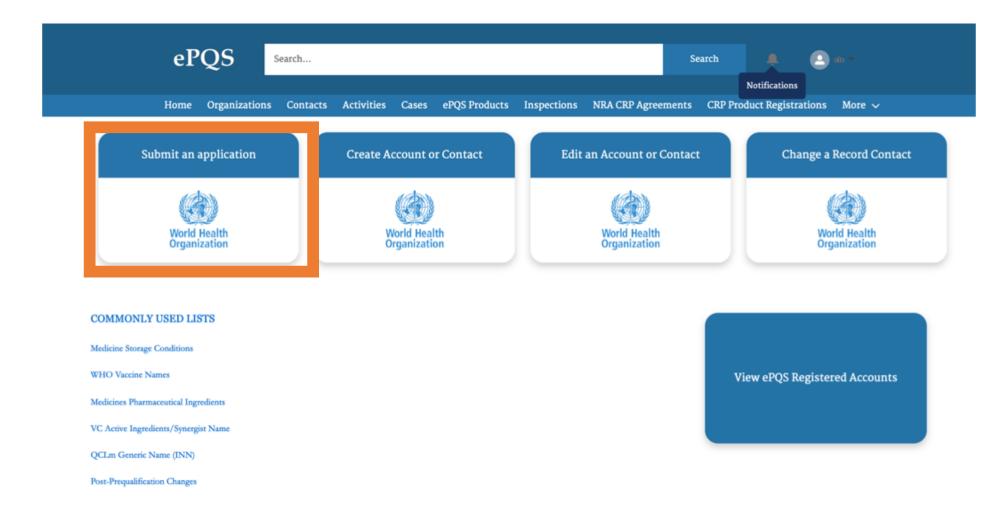
"Document submission" interface.



4. ePQS navigation – Wizard



The "Submit an application" tab provides access to the "Application Wizard", for prequalification applications and post-PQ variations submissions.



4. ePQS navigation – Forms



The three other tabs on the homepage provide access to application forms to request the creation or editing of your account or associated contact details.



Medicine Storage Conditions WHO Vaccine Names Medicines Pharmaceutical Ingredients VC Active Ingredients/Synergist Name QCLm Generic Name (INN) Post-Prequalification Changes

COMMONLY USED LISTS

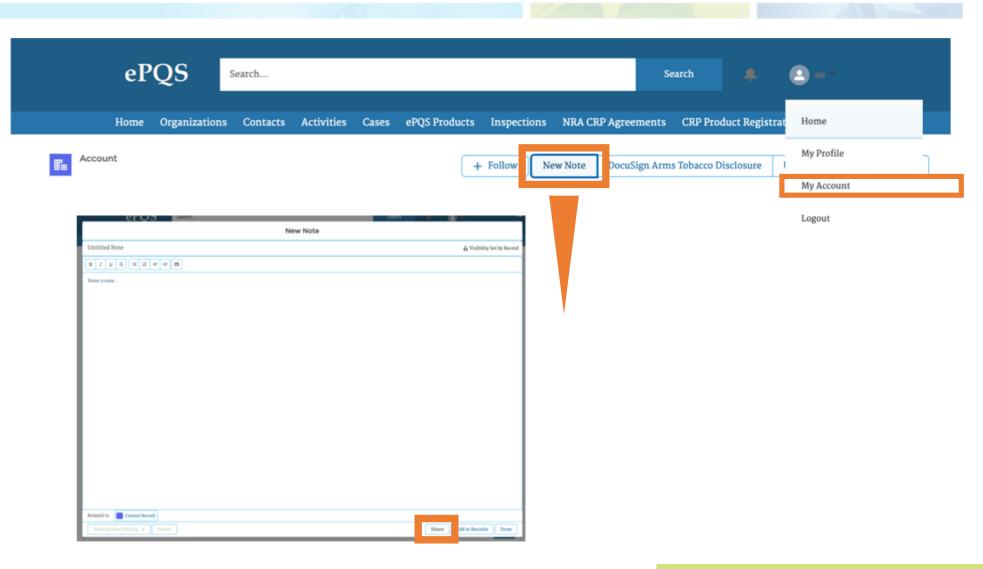


4. ePQS navigation – Notes



Under your "account" interface, you may also create "notes".

Notes may also be shared with others (your contacts or internal / WHO users).

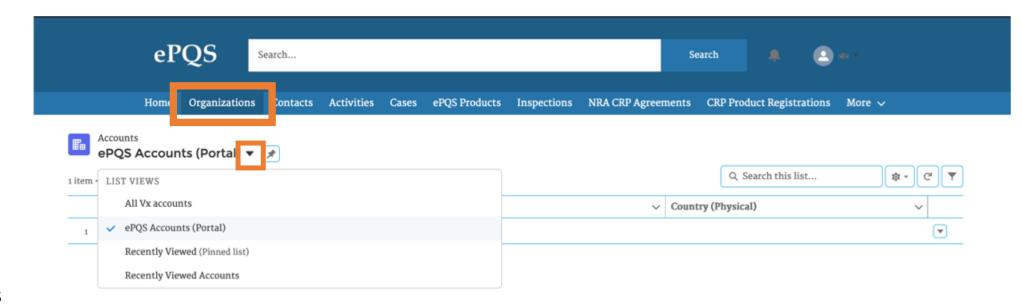


4. ePQS navigation – Organisations



Via the main tab "Organisations" you can access a list of all organisation accounts associated with your own.

Various list views are available using the inverted arrow; including "all" and "recently viewed"

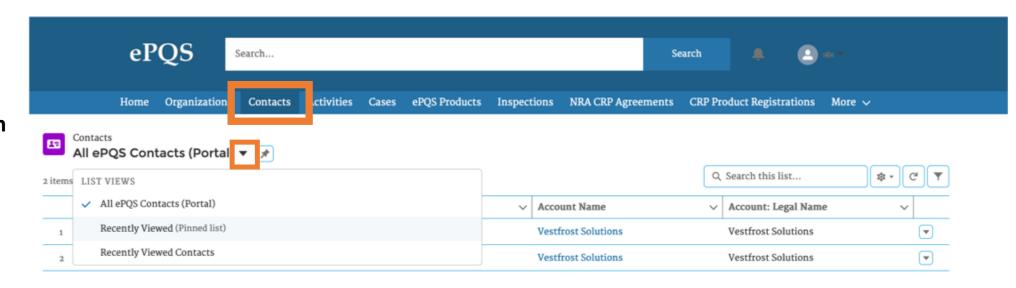


4. ePQS navigation – Contacts



Via the main tab
"Contacts" you
can access a list
of all organisation
accounts
associated with
your own.

Various list views are available; including "all" and "recently viewed"

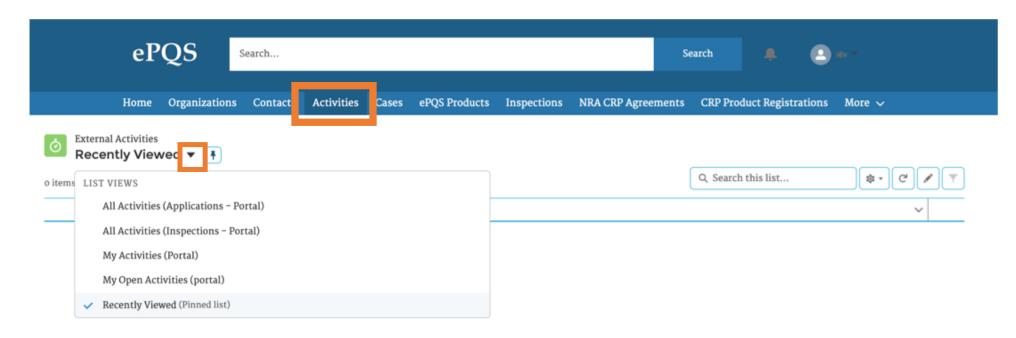


4. ePQS navigation – Activities



Via the main tab
"Activities" you
can access a list of
all the "external
activities" related
to your account.
This includes
applications, postPQ variants and
inspections.

Various list views are available; including "My activities" and "recently viewed"

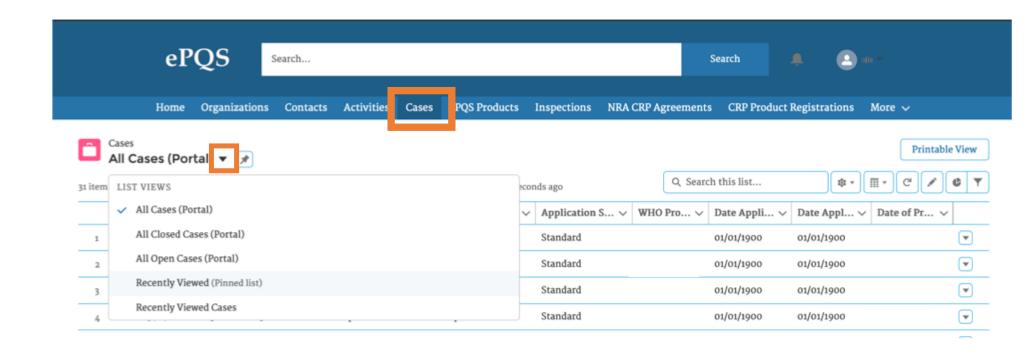


4. ePQS navigation – Cases



Likewise, a list of all "cases" relevant to your account is available via the main tab.

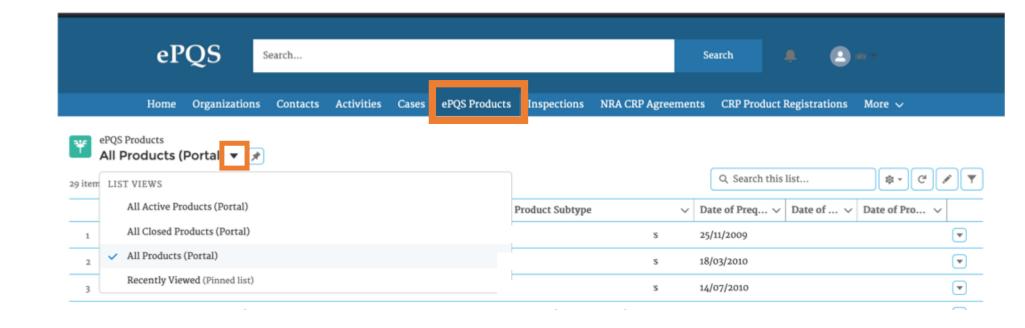
Available list views include "Open cases", "closed cases", "all" and "recently viewed".



4. ePQS navigation – Products



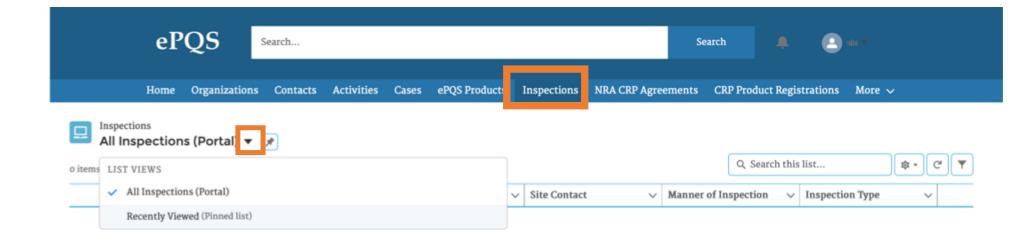
Likewise, a list of all "products" related to your account is available via the main tab.



4. ePQS navigation – Inspections



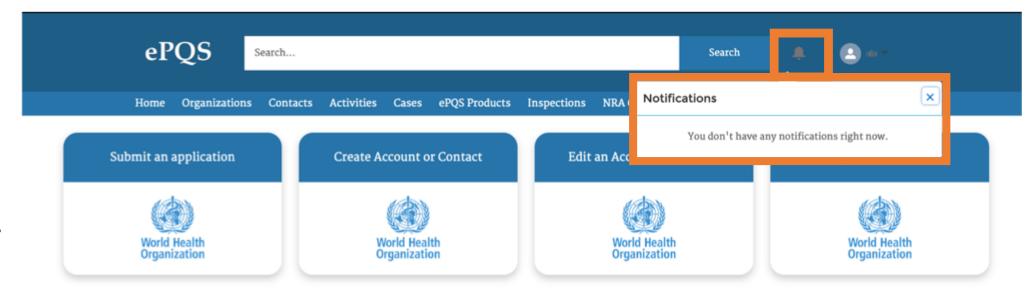
And a list of all "Inspections" related to your product sites is available via the main tab.



4. ePQS navigation – Bell

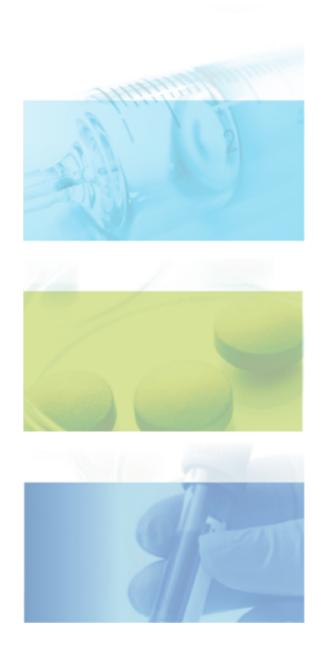


And finally, the bell notification provides an overview of all the outstanding notifications and actions relevant to your account.





SECTION C - APPLICATION PROCEDURES



5 Step-by-step guide

5. Step-by-step guide



ePQS activities that will be required to set-up your account and to process application submissions are:

- a. Verification of product data sheets
- b. Access, accounts and contact details
- Correct record visibility and correct product list visibility
- d. Access and functionality of personal user folder
- e. Application submission (if applicable)
- f. Post-PQ variation submission (if applicable)
- g. Uploading of documents (related to the submission)
- h. Downloading of documents shared with the applicant
- i. Assignment of activities to applicants
- i. Bell and email notifications associations with actions





5a

Verification of product data sheets



TASK

Once registraton and access is obtained, PQ Holders and new applicants must first verify that all data is correct on each of their product data sheets.





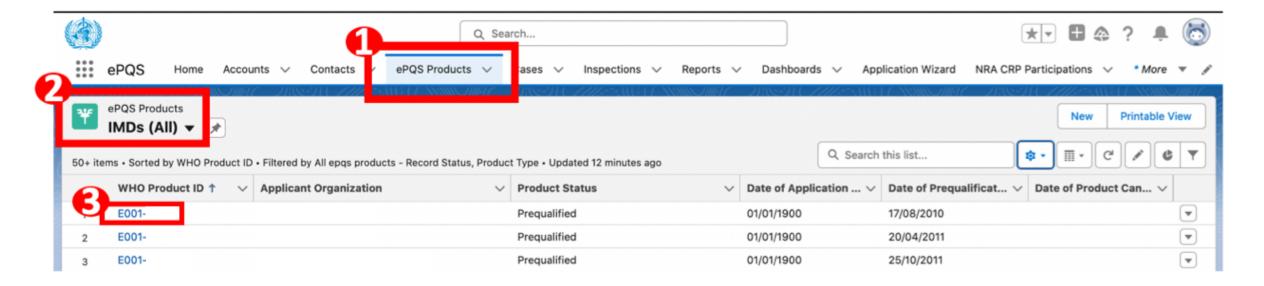
Communicate any omissions or errors to: pqsinfo@who.int & huckerbyg@who.int





Where to find your product data sheets for verification:

- 1. On the ePQS homepage, select the "ePQS Products" tab.
- 2. In "list view" select "IMDs (All)"
- 3. In this view you can select individual prequalified products

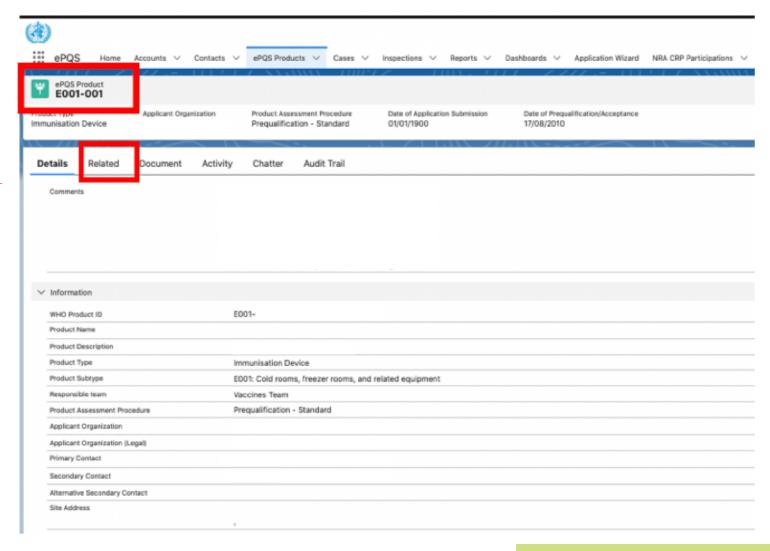




When you click on the product, you will see this "Product page" for the one product selected.

However you need to go to the "Product Variant page" to specifications.

So, click on the "Related" sub-tab.

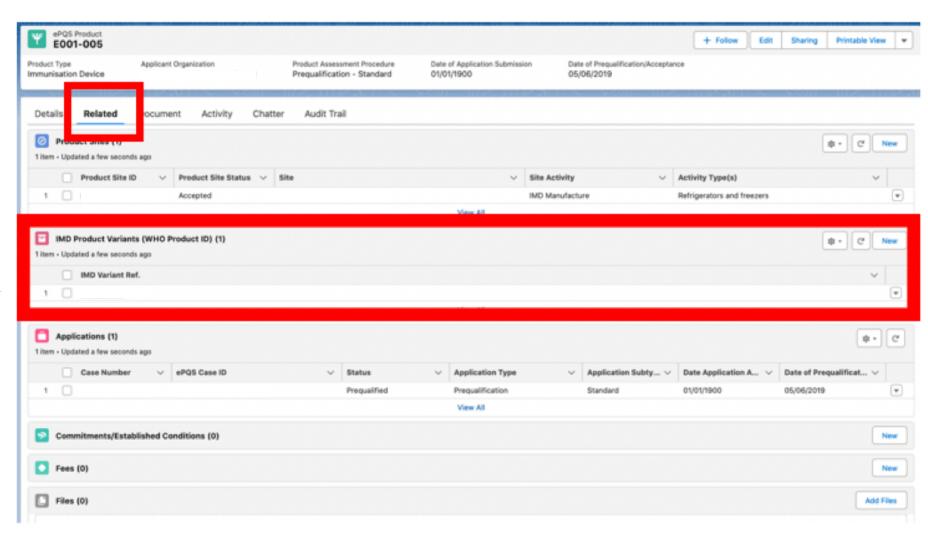




"Related" brings up a list of the record-types related to this one product.

Select the record displayed under "IMD Product Variant"







This brings you to the "product variant page" (eg here for E001)

With its organised data fields/values.

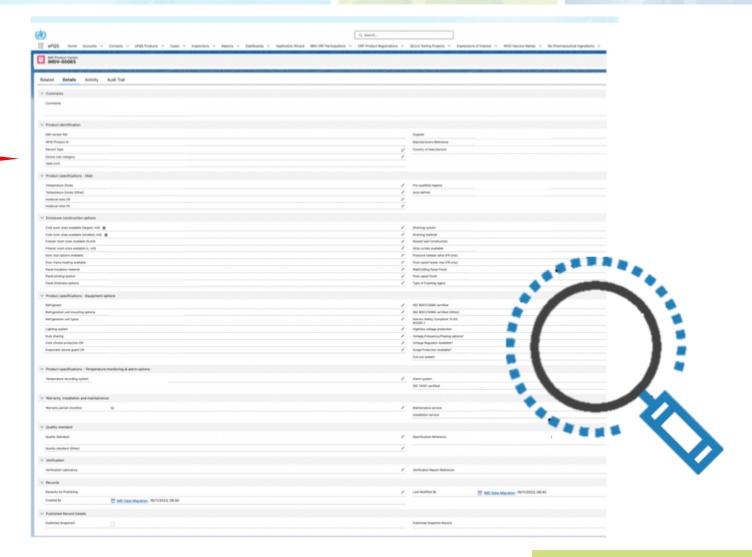


- Review all data fields
- Report any errors or issues to the IMD-PQS Secretariat:

pqsinfo@who.int

- To report issues please use the <u>templates</u> on the following slide.







Product Data Sheet feedback forms are available on the IMD-PQs website here:



https://extranet.who.int/prequal/immunization-devices/prequalification-guidance-applicants-prequalification-holders

There you will find a feedback forms for each category:

- IMD-PQS Data Sheet feedback form E001
- IMD-PQS Data Sheet feedback form E002
- IMD-PQS Data Sheet feedback form E003
- IMD-PQS Data Sheet feedback form E004
- IMD-PQS Data Sheet feedback form E005
- IMD-PQS Data Sheet feedback form E006

- IMD-PQS Data Sheet feedback form E007 Energy Harvest Control
- IMD-PQS Data Sheet feedback form E007 Voltage Stabilisers
- IMD-PQS Data Sheet feedback form E008
- IMD-PQS Data Sheet feedback form E010
- IMD-PQS Data Sheet feedback form E013



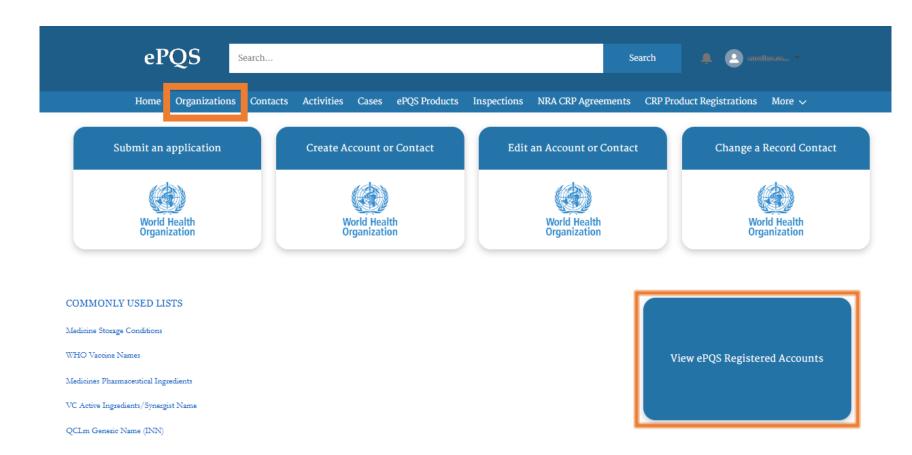
5b

Accessing registered accounts

5b. Accessing registered accounts



To access a list of all accounts related to your own, click either on "Organisations" or "View ePQS Registered Accounts".



5b. Accessing registered accounts



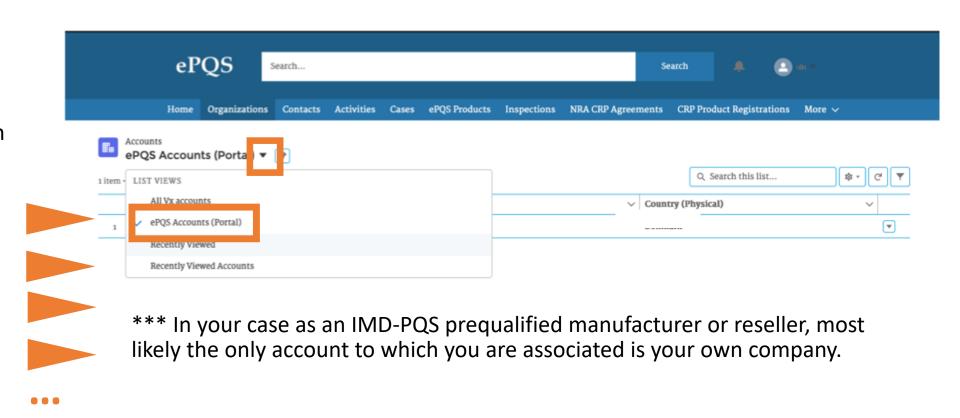
You may select different list views.

Recommended: "ePQS Accounts".

Then please review each record that appears in the list:

Account types include:

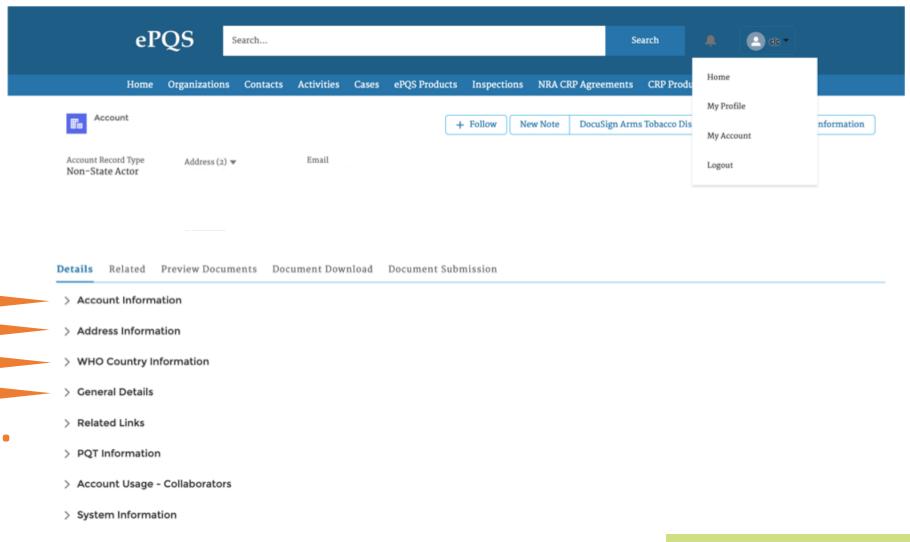
- Non-State actors (private sector)
- Government institutions
- Institution
- Committee



5b. Accessing registered accounts



Inside each account record, open each drop down section ("Account information", "Address information" etc.) and verify that the data and information contained inside each is correct.



Legal Disclaimer



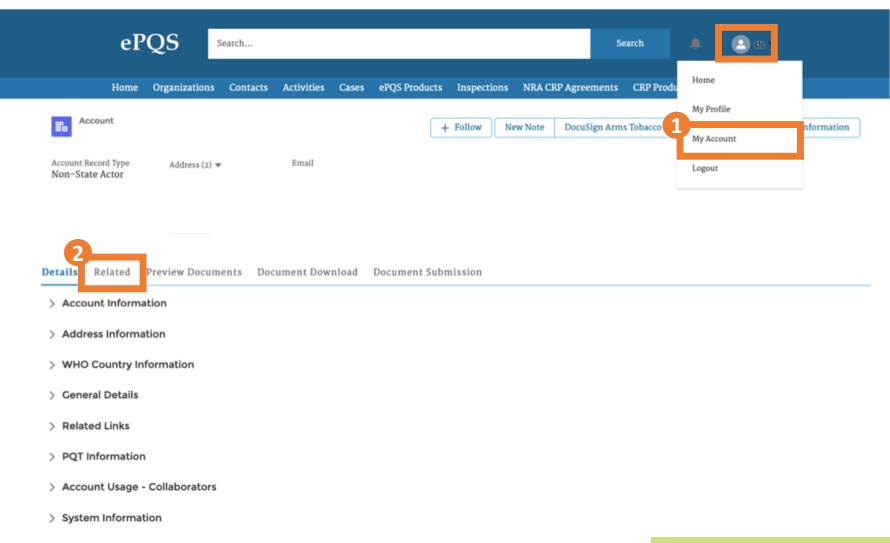
5C

Correct record visibility

5ci. Correct record visibility



- 1. Click on your profile icon, and select "My Account".
- 2. Then click on the "Related" sub-tab.



5ci. Correct record visibility

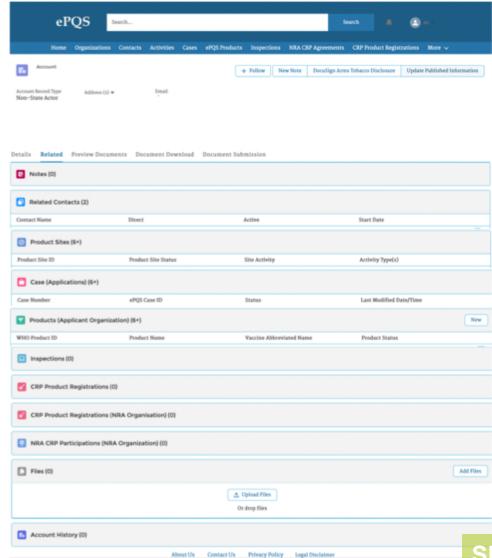


The "Related" sub-tab displays all records of all types related to your account.

Open and view each type of record.

Ensure that each of the follwoing types of records are visible:

- Notes
- Related contacts
- Product sites
- Case
- Products
- Files
- Account history

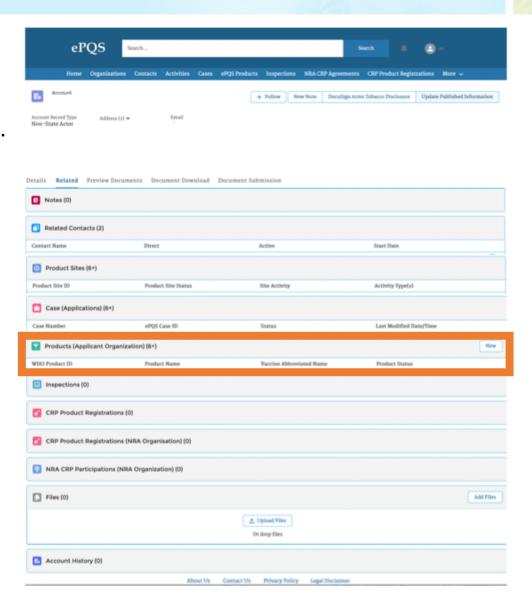


5cii. Correct record visibility - Products



Products

Expand or click directly on the Products sub-tab.



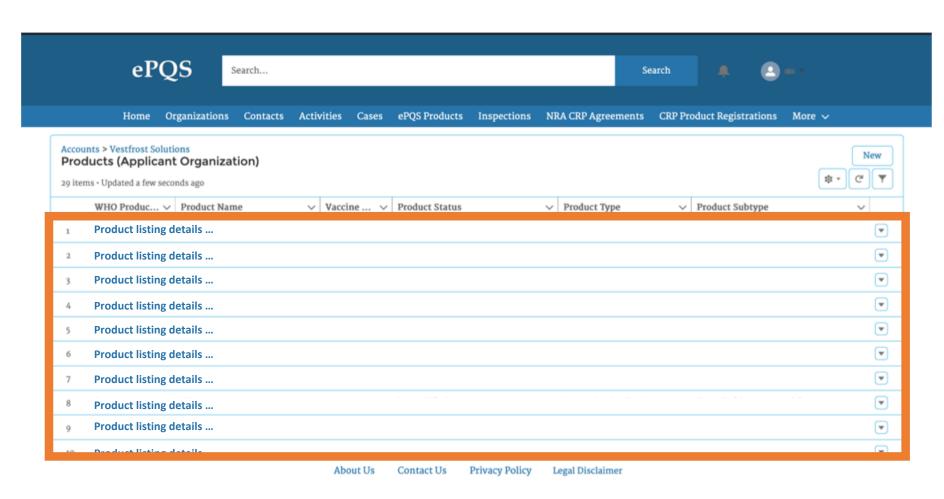
5cii. Correct record visibility - Products



Products

Please review the list of products that is displayed:

- 1. Verify that ALL of your previously and currently prequalified products, and/or products currently under review are present in the list.
- 2. Verify that your account displays ONLY products from your organisation and NOT products of any other organisation.





50

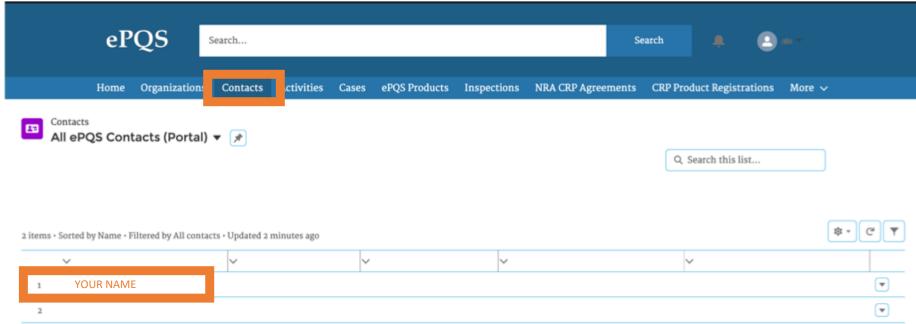
Personal use folder

5d. Personal use folder



ePQS offers external users a "Personal folder", in which you may upload/house documents you are working on, before submitting them or sharing them with internal users.

To access the personal use folder go to "Contacts" and choose yourself from the list of contacts.

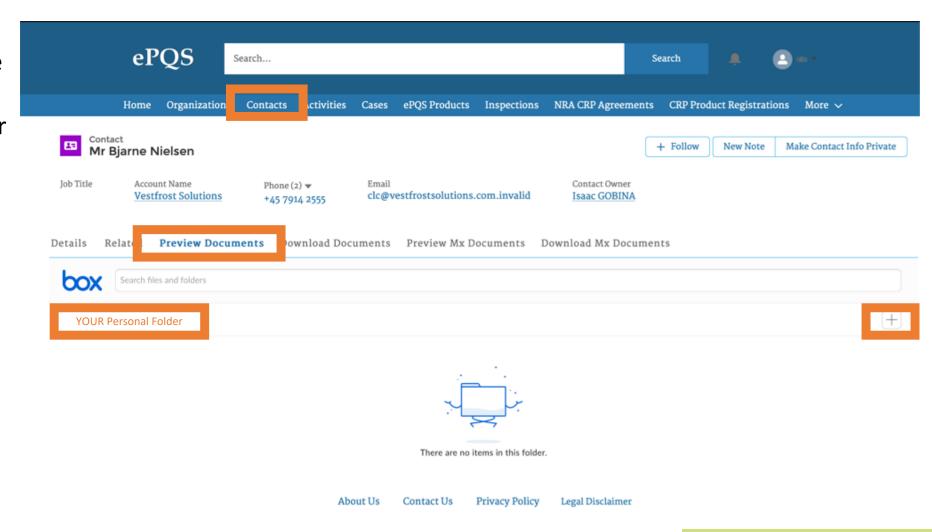


5d. Personal use folder



Once inside your own contact record, click the "Preview Documents" tab. You will see a folder with name conventions (YourName) "PersonalFolder". Upload documents by clicking on the "+" icon.

IMPORTANT – personal folders are <u>not private</u>. Internal users (IMD-PQS) can view all external user Personal Folders.





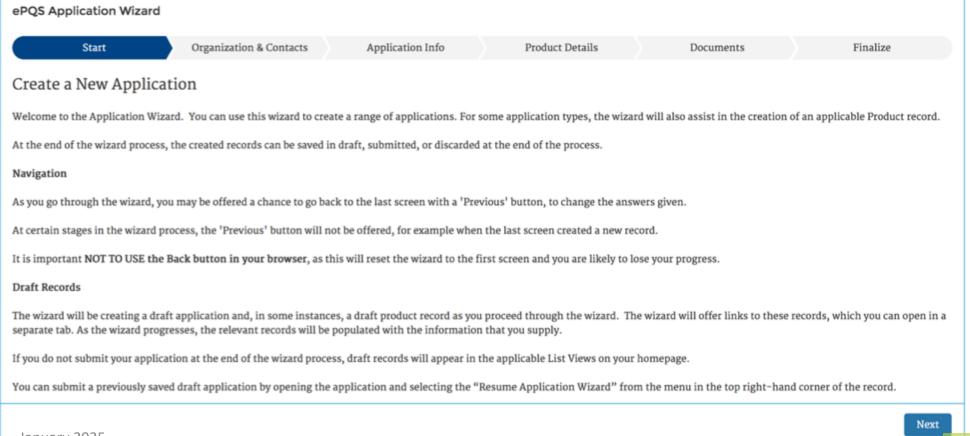
5e

Application submission procedure

5e. Application submission procedure



The "Application Wizard" tool provides step-by-step instructions for how to complete the application. The wizard welcome page provides an overview of the process:







Applicants will first be prompted to select the relevant contacts (yourself or your colleagues):

ePQS Application Wizard								
Organization & Contacts	Application Info	Product Details	Documents	Finalize				
Choose Contact								
Choose Applicant Primary Contact Nominate a primary contact for this applicat	tion who is an employee of Vaccine	UAT External Test Account 1, and also i	ndicate if there are other secondary peo	pple involved.				
*Primary Contact								
Vaccine UAT External Contact 1								
Optionally Choose Secondary Contacts If needed you can optionally choose a secondary and an alternative secondary contact, or leave the selection as "None".								
* Secondary Contact								
None				‡				
* Alternative Secondary Contact Choice								
None								
				Previous Next				

5e. Application submission procedure



Next, select "Immunization Device" as the product type:

ePQS Application Wizard								
Organization & Contacts Application Info Product Deta	ils Documents	Finalize						
Choose Product Type								
Select the product area to narrow down the list of application types.								
* Product Type Active Pharmaceutical Ingredient Active Pharmaceutical Ingredient Master File Finished Pharmaceutical Product Finished Vaccine Product IMD Evaluating Laboratory Immunisation Device In Vitro Diagnostic Male Circumcision Device Quality Control Laboratory Vector Control Active Ingredient Vector Control Product WHO Prequalification Evaluating Laboratory								
		Previous						





Next, select "Prequalification" as the application type:

ePQS Application Wizard				
Organization & Contacts	Application Info	Product Details	Documents	Finalize
Choose Application Type				
Based on the product type, here is the lis	t of application types available.			
*Application Type Prequalification Post-PQ Change Reassessment				
				Previous

5e. Application submission procedure



The Wizard will ask for confirmation of the application details:

Note: WHO-IMD applications are classified as "Vx IMD" (Vaccines – Immunization Devices) within the ePQS system.

ePQS Application Wizard							
Organization & Contacts	Application Info	Product Details	Documents	Finalize			
Confirm Application Details By proceeding to the next step you will be creating a draft Vx IMD Application. This draft application will be available in your List View of Cases.							
Application Type: Prequalification Product Type: Immunisation Device	ecteating a draft vx IMD Application. This d	itali application will be available i	in your list view of cases.				
Organization: Vaccine UAT External Test Account 1 Primary Contact: Vaccine UAT External Contact 1							
				Previous			





The Wizard will provide you with your case number. Make a note of this reference number:

ePQS Application Wizard							
Organization & Contacts Application	Info Product Details	Documents	Finalize				
Continue Application							
A draft application has been created.							
For reference the new application has the case number PQ-IMD-2023-0040. You can view the draft application details by following the link.							
			Next				





Next, select the "Product Subtype" (the IMD-PQS Product Category) to which you wish to submit your product for prequalification assessment:

ePQS Application Wizard						
Organization & Contacts Appl	lication Info	Product Details	Documents	Finalize		
Additional Application Info						
*Product Subtype VE001: Cold rooms, freezer rooms, and related equipment E003: Refrigerators and freezers E004: Cold boxes and vaccine carriers E005: Coolant-packs E006: Temperature monitoring devices E007 EHC: Cold chain accessories E007 VS: Cold chain accessories E008: Injection devices for immunization E010: Waste management equipment E013: Injection devices for therapeutic purposes						





The Wizard will provide you with your application number (which is the same as your case number):







Input a product name of your choice, a description, and the type of appliance (free text):

ePQS Application Wizard						
Organization & Contacts	\rangle	~	Product Details	\rightarrow	Documents	Finalize
Create a Product						
Further Vx IMD Details (Please fill out all required fields)						
* Product Name						
Product Description						
						li,
Type of Appliance						
						Next

5e. Application submission procedure



The following section of the application requires the input of the full product specifications (called the "IMD Product Variant" page).

ePQS Application Wizard								
Organization & Contacts	~	Product Details	Documents	Finalize				
Create IMD Product Variants								
Variant Information Details Screen 1 (Please fill out all required fields. For picklist fields,None should be selected if the answer is not available.)								
Range of cold room sizes available small (smallest, m	3)							
Range of cold room sizes available large (largest, m ₃)								
Freezer room sizes (smallest, m3)								
Freezer room sizes (largest, m3)								
*Pre-qualified regions				A				
None				ţ				
*ISO 9001/13485 certified								
None								
* ISO 14001 certified								
None January 2025				;				

**All fields are required unless not applicable for your product. There are multiple 'Variant Information Detail Screens' for each category of product.





Once the Variant Information Detail Screens are completed, the wizard will provide the "IMD Product Variant Ref.". Make a note of this reference number:

ePQS Application Wizard					
Organization & Contacts Create IMD Product Varia		~	Product Details	Documents	Finalize
Success IMD Product Variant Ref. IMDV-00033 cr	reated.				
					Next





Next, you have the choice to provide information about the "product site" (the site of product manufacture). Please select "Product Site" if your product is being manufactured on a site that is different from the site already registered in ePQS (accessible under \rightarrow Related \rightarrow Product sites)

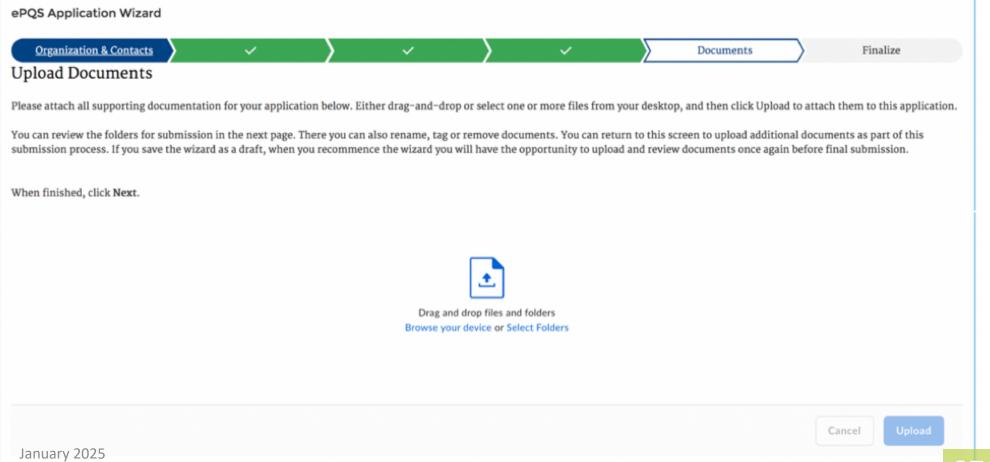
Otherwise, select "I don't want to add any more product related information at this time":

ePQS Application Wizard								
Organization & Contacts	>	>	Product-Related Info	Documents	Finalize			
Add Product Related Information								
*Choose Product Related Information to Add to Application Product Site I don't want to add any more product related information at this time								
					Previous			

5e. Application submission procedure



The final stage of the Wizard allows applicants to upload the (mandatory) documents.



See next slide for information related to what documents to submit:

5e. Application submission procedure



List of mandatory documents.

The IMD-PQS Secretariat has provided you with a detailed list of application requirements, including mandatory documents, in their positive reply to your "Pre-submission" form.

In addition, you may refer to <u>Section 3.4.3</u> of the <u>IMD-PQS Prequalfication Holder Guidelines</u> for a generic list of the documentation that must be provided for a complete application within each category.

Link in full: https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-holders





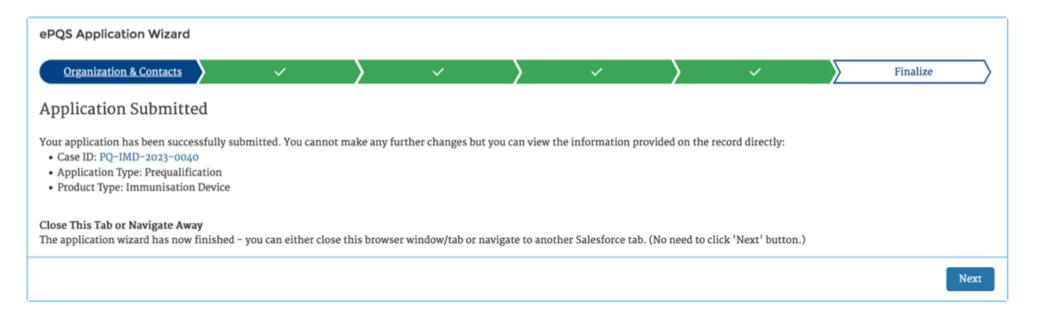
Once the complete documentation has been uploaded to the submission, the Wizard will provide the option to submit, save draft or discard draft:

ePQS Application Wizard								
Organization & Contacts	~	>	>	>	Finalize			
Review Application								
It is important that you review your application prior to submission. Use the link provided to open it in a new tab and look at the information entered, and also review the related records (click on the Related sub-tab) of which you should be able to open those records too.								
Case ID: PQ-IMD-2023-0040								
Product or Laboratory ID: P-15764								
Submit, Save or Discard Please choose whether you are ready to submit this application, if you need more time then save the existing draft, or discard if made in error.								
*Ready to submit?								
Yes								
 No, save existing draft application and product (if applicable) No, discard this draft application and product (if applicable) 								
o No, discard this draft application	and product (if applicable)							
					Previous Next			

5e. Application submission procedure



Once "submit" has been selected, the Wizard will confirm your Case ID. Your application is complete. The IMD-PQS Secretariat will contact you via the ePQS "Box" cloud file-sharing system with any further requests for information and with information about next steps.



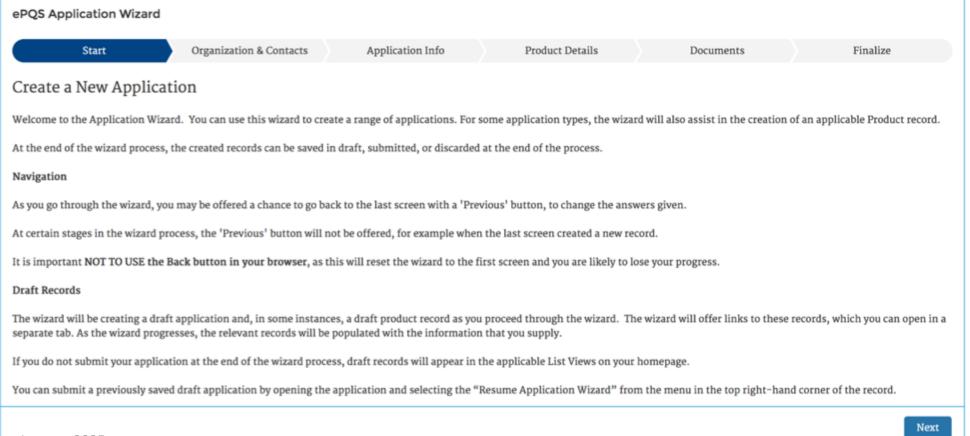


6f

Post-PQ variation submission



The "Application Wizard" tool provides step-by-step instructions for how to complete the application. The wizard welcome page provides an overview of the process:





Applicants will first be prompted to select the relevant contacts:

ePQS Application Wizard								
Organization & Contacts	Application Info	Product Details	Documents	Finalize				
Choose Contact								
Choose Applicant Primary Contact Nominate a primary contact for this application who is an employee of Vaccine UAT External Test Account 1, and also indicate if there are other secondary people involved.								
* Primary Contact								
Vaccine UAT External Contact 1								
Optionally Choose Secondary Contacts If needed you can optionally choose a secondary and an alternative secondary contact, or leave the selection as "None".								
* Secondary Contact								
None				^				
* Alternative Secondary Contact Choice								
None								
				Previous				



Next, select "Immunization Device" as the product type:

ePQS Application Wizard		
Organization & Contacts Application Info Product Details	Documents	Finalize
Choose Product Type		
Select the product area to narrow down the list of application types.		
 Product Type Active Pharmaceutical Ingredient Active Pharmaceutical Ingredient Master File Finished Pharmaceutical Product Finished Vaccine Product IMD Evaluating Laboratory Immunisation Device In Vitro Diagnostic Male Circumcision Device Quality Control Laboratory Vector Control Active Ingredient Vector Control Product WHO Prequalification Evaluating Laboratory 		
		Previous Next



Select "Post-PQ Change" as the application type:

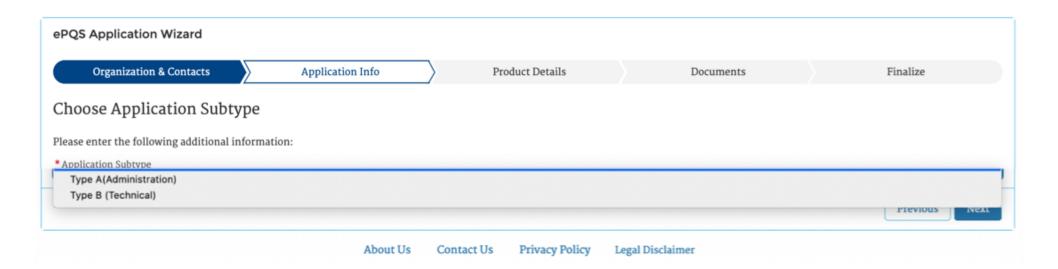
ePQS Application Wizard			
Organization & Contacts Application Info	Product Details	Documents	Finalize
Choose Application Type			
Based on the product type, here is the list of application types available.			
*Application Type Prequalification			
Post-PQ Change Reassessment			
			Previous Next
About He Co	ontact He Drive av Delica	Logal Disalaiman	



Next, you have a choice between two types of post-PQ variations:

- Type A Administration -> Select for administrative variations that do not impact product specifications
- Type $B Technical \rightarrow$ Select for administrative variations that do not impact product specifications

NOTE – the following sequence of screens are the same for both of these options.



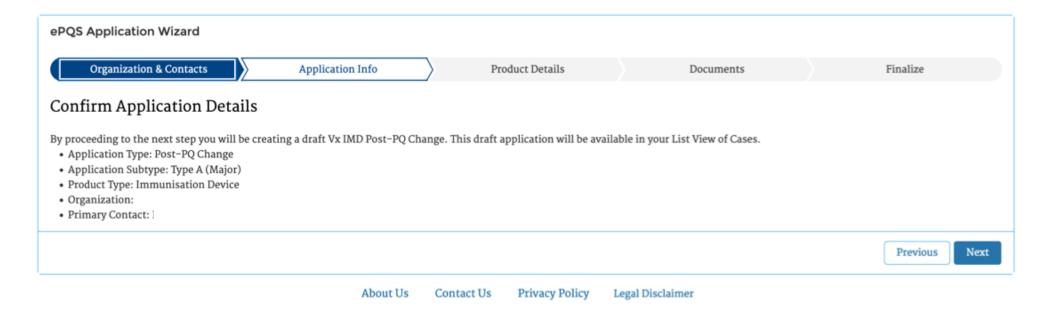


The next screen advises that you will asked to select the product for which you wish to report the variation. The selection happens on the later screen.

ePQS Application Wizard							
Organization & Contacts Application Info	Pro	oduct Details	Documents	Finalize			
Relevant Products Found							
For the specific product type selected, matching relevant prequalified or acceptable status products have been successfully found. You will be asked to link one to this application shortly.							
				Previous Next			
About Us	Contact Us	Privacy Policy	Legal Disclaimer				



The next screen summarizes the application details you have inputted so far, and asks you to confirm them.





Then the application informs you that the draft application has now been created and asks you to confirm your wish to continue.

It provides you with an application case number. It is recommended to make a note of this "offline", for your records.

ePQS Application Wizard							
Organization & Contacts Application Info	Product Details	Documents	Finalize				
Continue Application							
A draft application has been created.							
For reference the new application has the case number PQC-IMD-2024-0007. You can view the draft application details by following the link.							
			Next				
About Us Con	ntact Us Privacy Policy	Legal Disclaimer					



The next screen "Add Change Information" is a recurring screen in the remaining part of the application. It reappears until you have selected each of these options in sequence, starting here with "Add products...". Later you will loop back and need to select "Add one or more pieces of information...", and finally "No more at this time".

At this stage, select "Add products..."

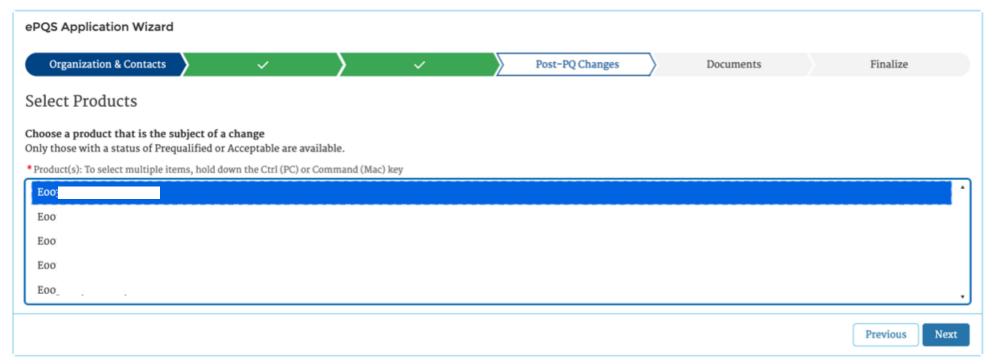
ePQS Application Wizard									
Organization & Contacts	>	> ~		Post-PQ Changes	Documents	Finalize			
Add Change Information									
You will need to list the products	that are being changed, and als	o record the change types that a	pply						
Either Add products that are the subject of post-prequalification changes Add one or more pieces of information about the change, including the type No more at this time									
						Next			

About Us Contact Us Privacy Policy Legal Disclaimer



The application will provide you with a list of products currently related to your account. Select the product for which you wish to submit a post-PQ variation.

Note – you may only select one product for each round on this screen. If you wish to submit a variation for multiple products, you may add other products the next time this screen appears.





The next slide confirms your product selection.

ePQS Application Wizard									
Organization & Contacts	·	〉	~	Po	st-PQ Changes	\rangle	Documents) 1	Finalize
Add Products									
Success The following product(s) have been linked with your PQC-IMD-2024-0007 application: E00									
									Next
		About Us	Contact Us	Privacy Pol	cv Legal Discla	imer			



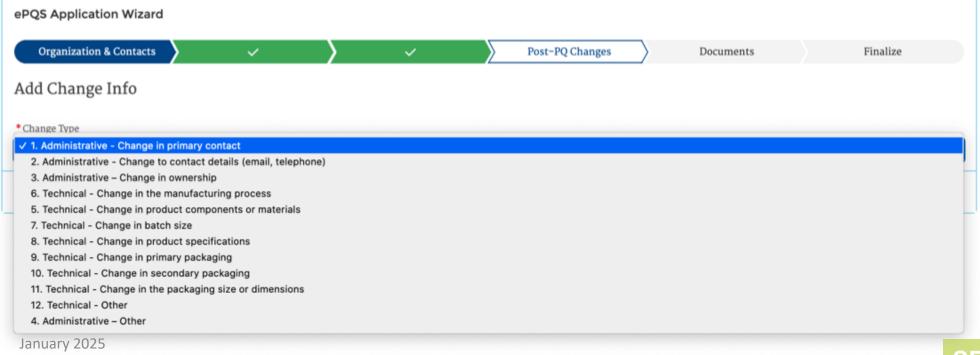
Next, you are presented for a second time the "Add Change Information" screen. This time, select "Add one or more pieces of information..."

ePQS Application Wizard								
Organization & Contacts	~	〉	Post-Po) Changes	Documents	Finalize		
Add Change Information								
You will need to list the products that are being changed, and also record the change types that apply Either Add products that are the subject of post-prequalification changes Add one or more pieces of information about the change, including the type No more at this time								
						Next		
	A	About Us Contact U	Js Privacy Policy	Legal Disclaime	r			



Here you are asked to select the precise type of variation (change) you wish to submit Select one type of change (variation) from the list.

Note – This same list will appear irrespective of whether you selected "Type A Administrative" or "Type B Technical" change types at the start.



SECTION C - PILOT



Here you are asked to provide the detailed information related to the required change. It is very important that you provide the complete set of information here, as described in the text on the screen. If the complete information is not provided the application will be returned to you for your further input.

ePQS Application Wizard									
Organization & Contacts	~	,	Post-PQ Changes	Documents	Finalize				
Add Change Info									
Please provide: 1. an explanation or rationale for the change; 2. the data currently retained in the prequalified product record (the PQS Data Sheet), related to this information type; 3. the change required (provide the NEW data to be used to update the prequalified product record (PQS Data Sheet) related to this type of information); Lastly, please describe the evidence to verify the change, and upload the relavant documentation on the following screen.									
Change Description									
					Previous Next				

Legal Disclaimer



On this screen the application confirms that your change information has been linked with the product you selected.

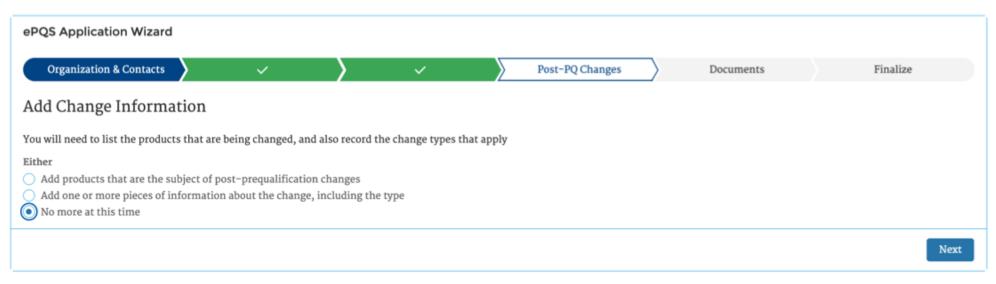
ePQS Application Wizard									
Organization & Contacts	~	>	~	Post-l	Q Changes	D	ocuments	I	Finalize
Add Change Info									
Success The change of type "1. Administrative - Change in primary contact" has been linked with your PQC-IMD-2024-0007 application.									
									Next
	,	About Us	Contact Us	Privacy Policy	Legal Disclain	ner			



Next you are linked back to the "Add change information" screen for a third time.

Note - If you wish to report changes to additional products, you may begin to add the additional or next product(s) here by re-selecting the second option. You will be prompted to add the change details for that additional product on the screen that follow.

If you do not wish to add additional products, select "No more at this time".



About Us Contact Us Privacy Policy Legal Disclaimer



Assuming you have selected "No more at this time", you will be moved onto the start of the document upload procedure. Click "Next".

ePQS Application Wizard	
You are uploading documents to Case#PQC-IMD-2024-0007	
	Previous

About Us Contact Us Privacy Policy Legal Disclaimer



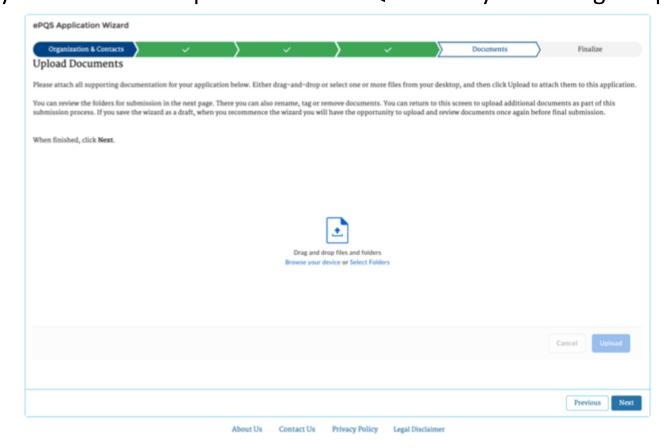
Select the type of document you will upload (CTD or eCTD).

WHO requirements and guidance on eCTD documents can be found here: https://extranet.who.int/prequal/ectd-portal

ePQS Application Wizard				
* Select Document Type eCTD Non-eCTD				
				Previous Next
	Alta con TTa	 D. I D. W	I and Diadainan	



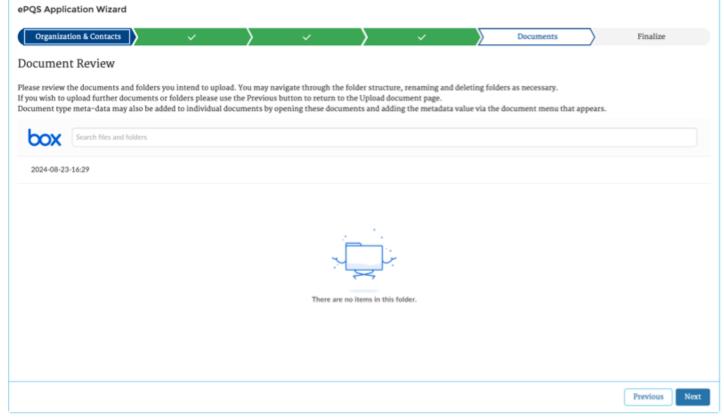
On this screen upload ALL the documents related to the change (variation) request, specifically the evidence required for IMD-PQS to verify the change requested.





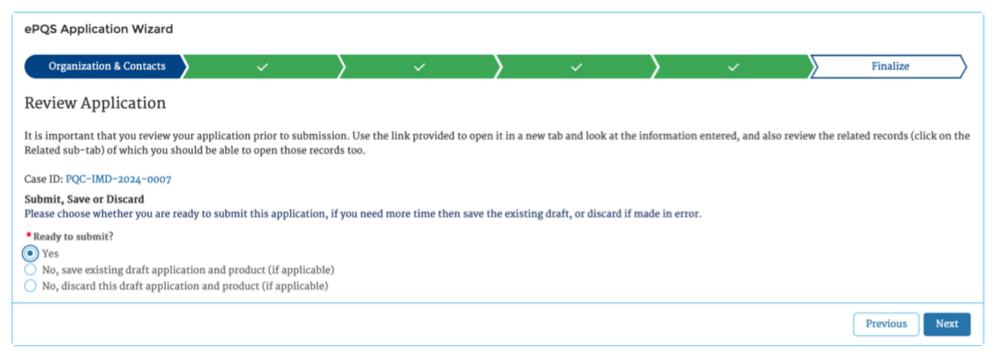
On the subsequent screen you will see a display list of all the documents you have

uploaded.



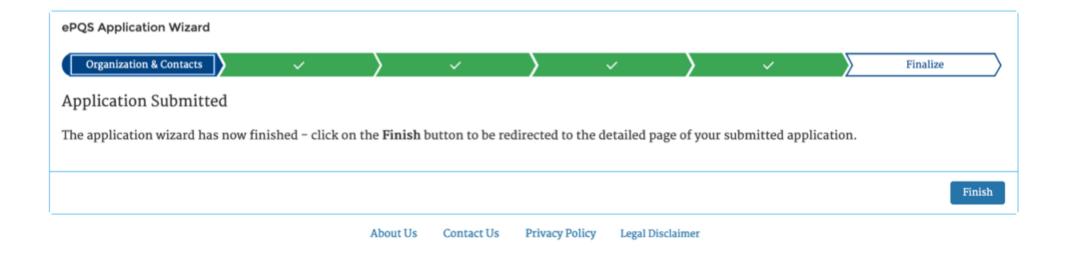


You are now at the review and submit stage. On this screen you can opt to use the generated <u>ePQS case number</u> or link provided earlier to review the application. Otherwise, select "Yes" to submit, or else "No save draft" if you wish to come back later to complete or update the submissions, or "No discard".





The Wizard will confirm your application has been submitted. Click "Finish" to be taken to the appearance of your change application.

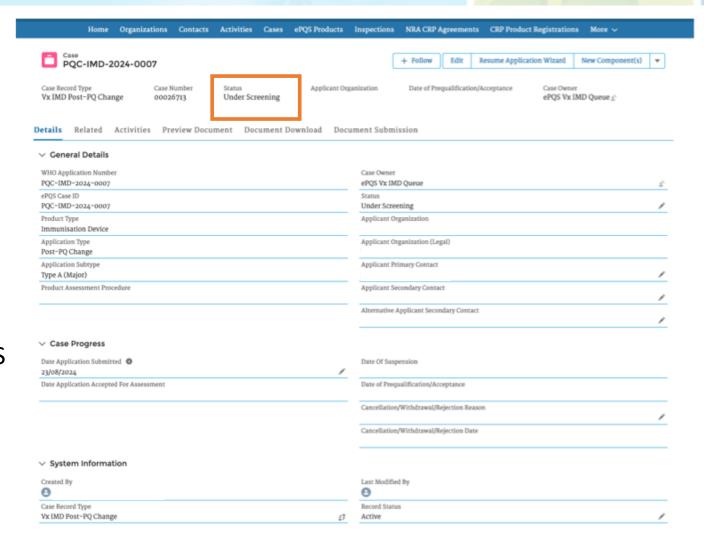




This screen displays the case information related to the change (variation) submission.

The status will be listed as "Under Screening".

A "Required action" notification will be delivered to the IMD-PQS Secretariat and Technical Specialists responsible for reviewing the change request and information submitted.



Contact Us

Privacy Policy

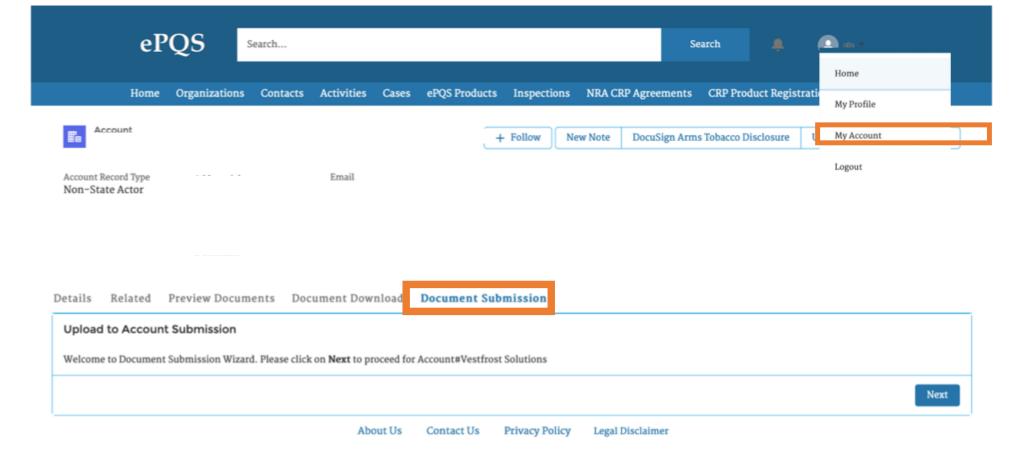


5G Uploading of documents

5g. Uploading of documents – account / organisation



Under "My
Account" /
"Document
Submission"
you may upload
documents

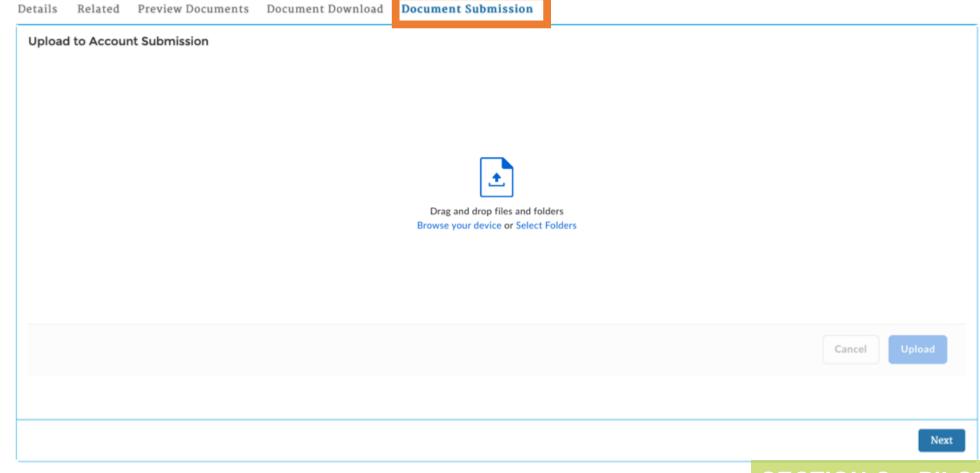


5g. Uploading of documents – account / organisation



Document submission interface →

Once documents are uploaded you can view them in "Preview".



5g. Uploading of documents - cases



Documenst related to cases (i.e. product applications) are available under the cases tab.

ePQS Search... Search Home Organizations Contacts Activities Cases PQS Products Inspections NRA CRP Agreements CRP Product Registrations More 🗸 Printable View All Cases (Portal) ▼ 🖈 Q Search this list... 31 item LIST VIEWS conds ago All Cases (Portal) ∨ Application S... ∨ WHO Pro... ∨ Date Appli... ∨ Date Appl... ∨ Date of Pr... ∨ All Closed Cases (Portal) Standard 01/01/1900 01/01/1900 All Open Cases (Portal) Standard 01/01/1900 01/01/1900 Recently Viewed (Pinned list) Standard 01/01/1900 01/01/1900 Recently Viewed Cases Standard 01/01/1900 01/01/1900

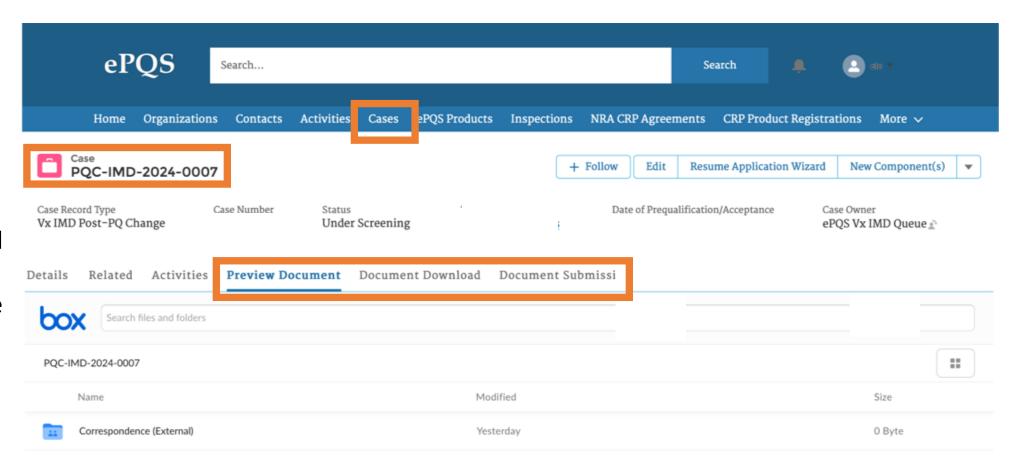
5g. Uploading of documents - cases



The "Preview",
"Download" and
"Submission"
functionalities
work in the same
way.

Only an "External correspondence" folder is available for cases.

Ensure you are able to upload documents and visualise them afterwards.





5h

Downloadingof documents

5h. Downloading of documents



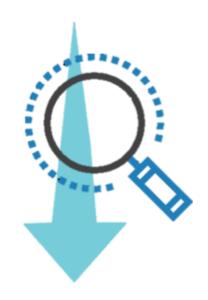
TASK

Test-download documents from your "External correspondence" folder and "Submitted documents folder" and any other folders that appear on your account

Report any issues.



Communicate any omissions or errors via: pqsinfo@who.int & huckerbyg@who.int

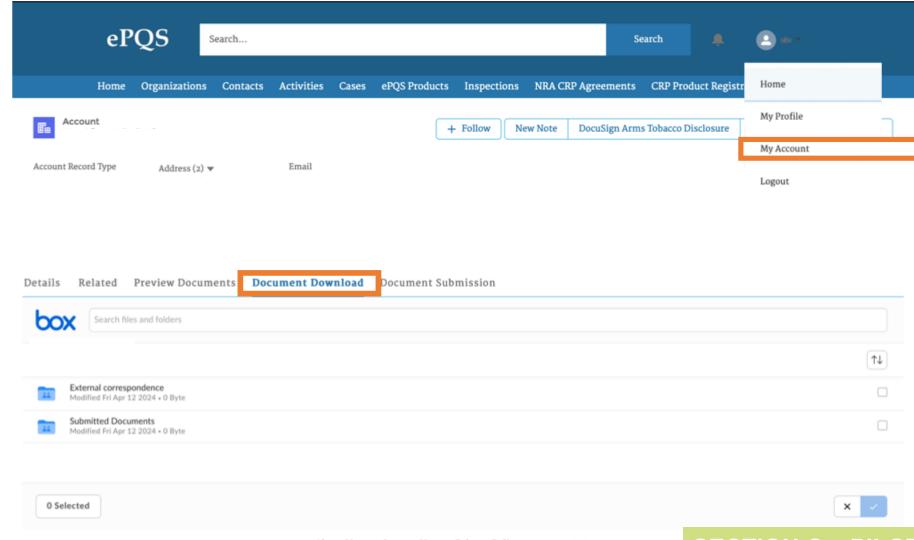


5h. Downloading of documents



Under "My Account" /
"Document
Download" at least
two folders should
appear: "External
correspondence"
folder and "Submitted
documents".

Once you have submitted an application, open the folders and test-download the contents.



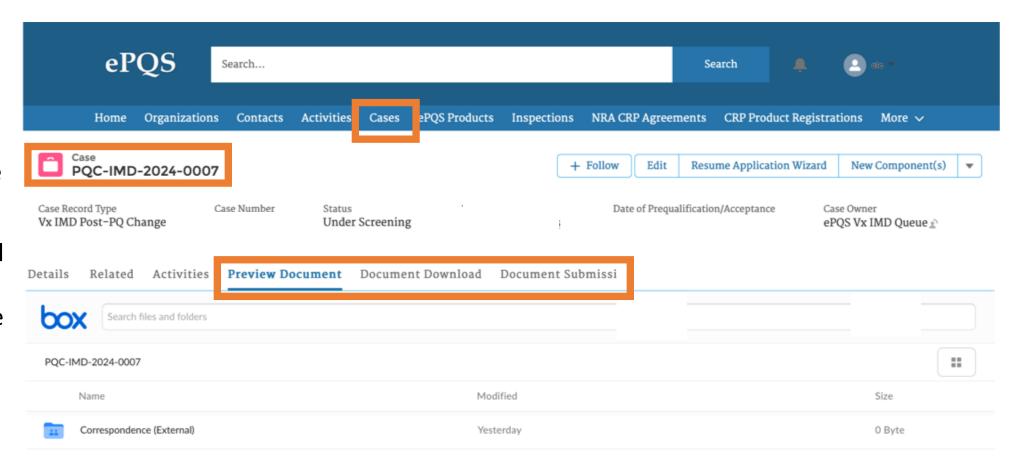
5h. Uploading of documents - cases



The "Preview",
"Download" and
"Submission"
functionalities
work in the same
way.

Only an "External correspondence" folder is available for cases.

Ensure you can download documents from this location.





5

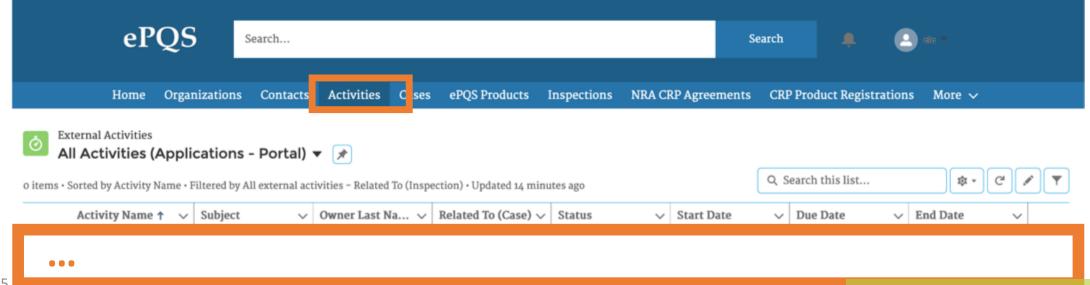
Viewing assigned activities

5i. Viewing of assigned activities



Clicking on the "Activities" tab will display a list of all pending activities related to your account. Clicking on each list item will take you to the detailed instructions / requirements of each task. It is also useful to know that you will automatically receive an email (via your contact-registered email address) each time a new activity is assigned to you.

Tasks might be the upload/transmission of further information, providing a response to a specific question, or a request to schedule a meeting.





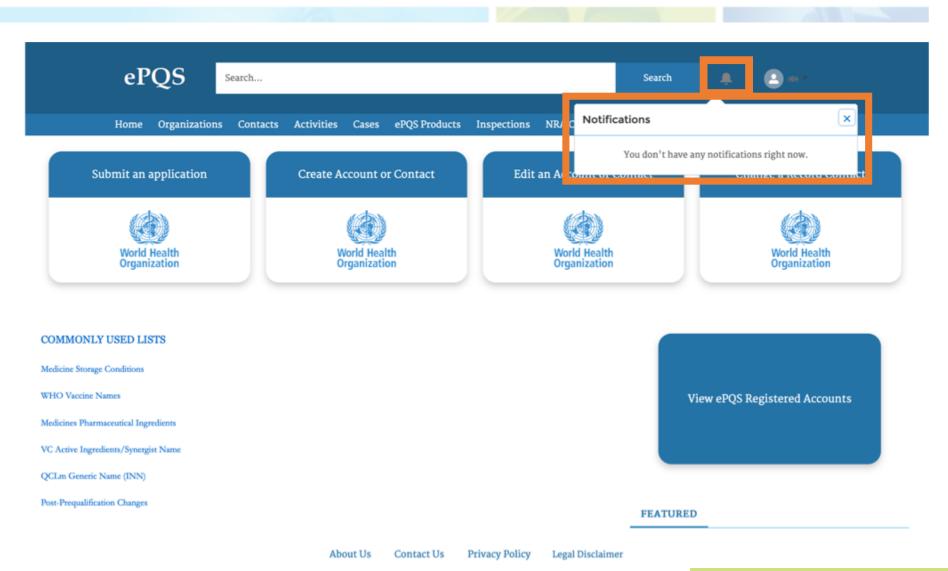
5

Bell and email notifications & associations with actions

5j. Assignment of activities to applicants

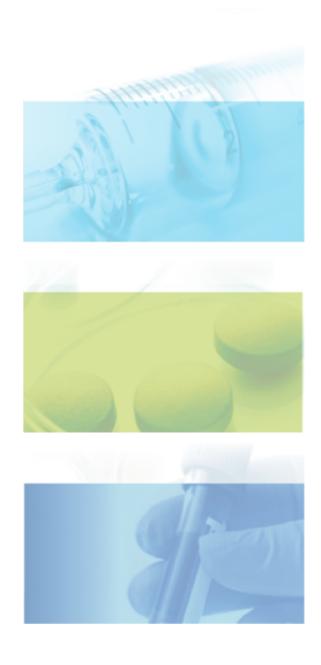


You will find a list of any pending activities via the bell notification.





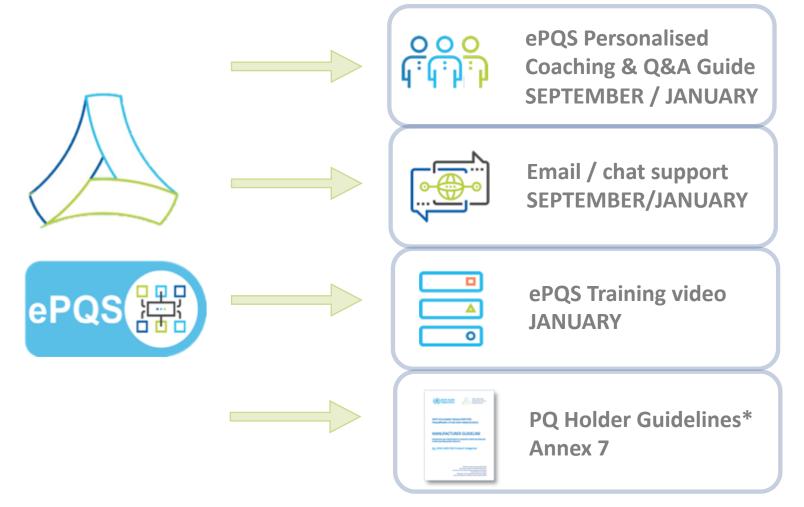
SECTION D – TECHNICAL SUPPORT



6 **Additional** technical support

6i. IMD-PQS Technical support

IMD-PQS will provide the following additional support to pilot participants and on through the universal launch.



^{*} LINK: https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-applicants-prequalification-holders

6ii. General user guidance – specific training

General guidance is available on the ePQS landing page:

Link: https://extranet.who.int/prequal/epqs-portal

General Portal Information

ePQS - Accounts Contacts Users and Record Visibility

ePQS - Creating or editing a Contact or Account

ePQS - Portal Introduction and Features

ePQS - Terms and Conditions of use (4 October 2023)

ePQS - User Registration and accessing the ePQS Portal

ePQS Portal



The ePQS Portal is the externally-facing Salesforce Community site of the WHO Prequalification Unit's new ePQS system. ePQS is a platform for the processing of Prequalification information for medicines, diagnostics, vector control products, vaccines, immunization devices, quality control laboratories and inspections.

Within the portal, users will have the ability to:

- View Salesforce records relevant to the user
- · Submit applications
- . Upload and download documents securely
- · View and monitor notifications for pending activities

Portal Opening: Final preparations are being made to open the portal. It is anticipated that the portal will go live in the second quarter 2024. Further more specific updates will be provided as timelines become clarified

Registered users will be able to access the Portal at this link: https://who.my.site.com/ePQS/s/login/

Guidance notes related to the features of the portal, processes around applications, document submissions, and many other topics will be progressively posted to this webcase.

Weblears will be ensounced soon and regular clinics will be held post-go live to support users, answer questions, and identify issues in order to make continuous

General Portal Information

ePQS - Accounts Contacts Users and Record Visibility

ePQS - Creating or editing a Contact or Account

ePQS - Portal Introduction and Featur

ePQS - Terms and Conditions of use (4 October 2023)

ePOS - User Registration and accessing the ePOS Portal