

# WHO e-Prequalification System (ePQS)

**Learning materials**WHO Immunization Devices (IMD-PQS)
2025





Vaccines & Immunization Devices Assessment Team (VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

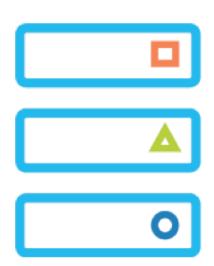
## Key access links (for reference)

WHO ePQS Portal landing page:

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

ePQS login link:

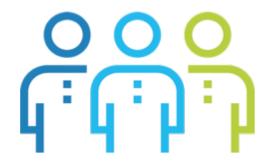
https://who.lightning.force.com/lightning



## 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 intended as comprehensive resources to support users gain necessary competence and autonomy in using the features and functions of ePQS. These learning materials concern Immunization Devices (IMD-PQS) users. The deck:

ePQS Portal

- 1. Explains the role(s) of ePQS in the IMD-PQS prequalification process
- 2. Introduces the ePQS navigation
- Guides PQ Holders and new applicants through the ePQS prequalification and post-prequalification applications
- 4. Introduces key concepts and terminology
- 5. Provides links to all detailed technical guidance

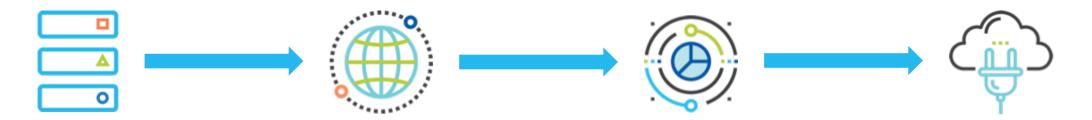




Q&A / coaching sessions with the IMD-PQS ePQS support team may be scheduled subsequent to this self-training.

## 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 procedures

#### **SECTION D – SUPPORT**

Additional and forthcoming technical support

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## 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:

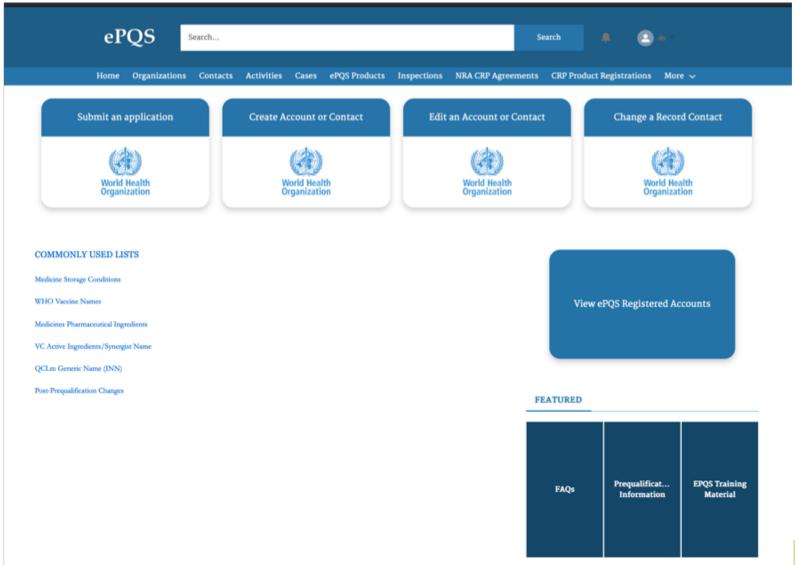
- submit & manage prequalification applications & post-PQ variations
- follow the site inspections process
- view records relevant to them
- submit required changes to account, contact & product information
- upload and download <u>documents</u> securely
- view and monitor <u>notifications for pending 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, PQ Holders and the WHO PQ** 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 Immunization Devices (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:
  - the ePQS application wizard,
  - the ePQS integrated email agent & file-sharing (cloud)
  - o the downloadable request forms on the ePQS home page, and
  - the up/download of documents to the relevant "External Communications" folder within each user's account, or the users ePQS personal folder.

# 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.

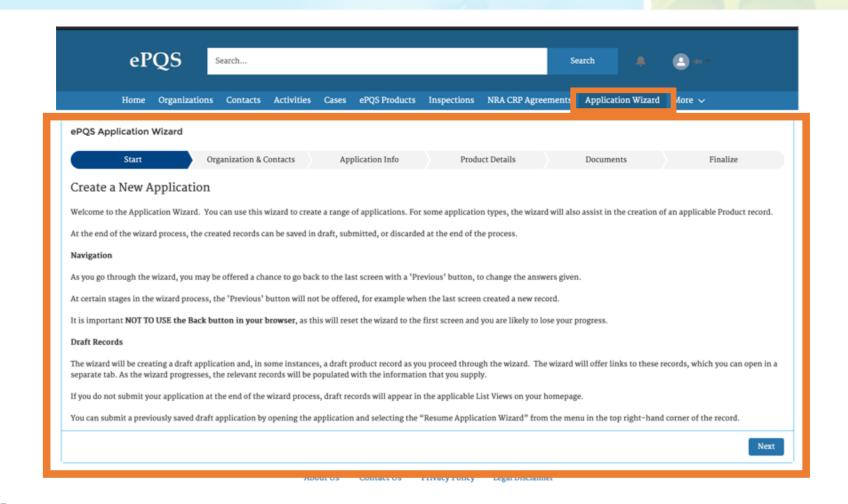


#### Cloud file-sharing facility ("Box")

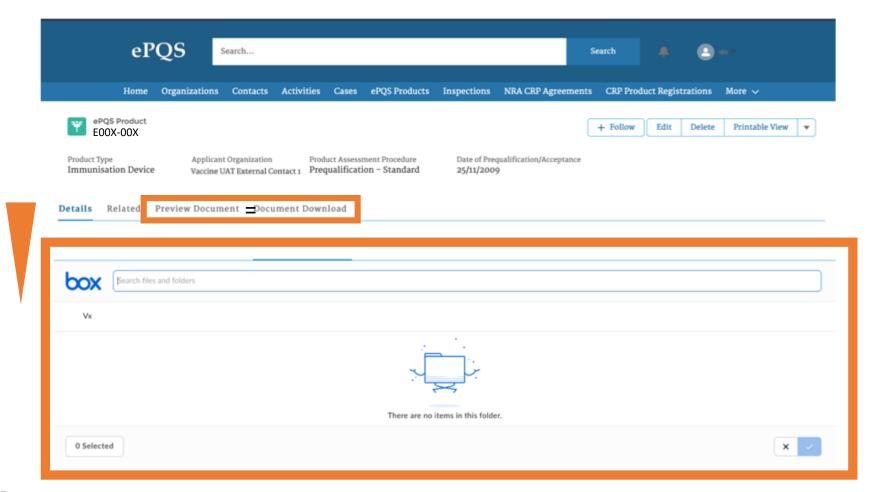
A cloud file-sharing facility manages the uploading, storage and sharing of documents between external applicants, WHO prequalification divisions and external experts. (The name of this cloud file-sharing facility is "Box".) File-sharing takes place via an "External Correspondence" folder, accessible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



# 1. ePQS Introduction Quick view - Application Wizard

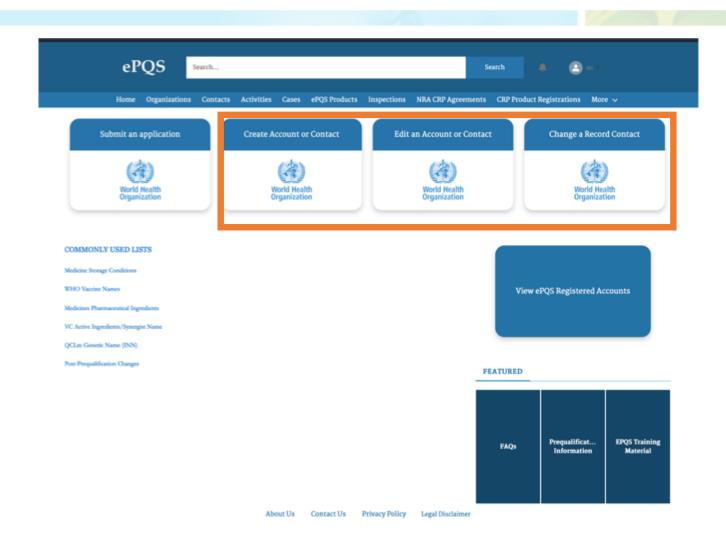


# 1. ePQS Introduction Quick view - Document up/download



#### 1. ePQS Introduction

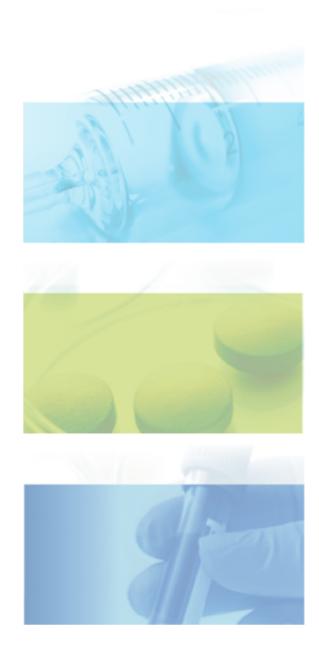
## Quick view - Data change request forms



## 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 for major record types	❖ Contacts & accounts				
❖ 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.
- 3. Contacts need to "register" to gain access to the the system.

Registration is via the:

"External Form - New ePQS User" linked here:

https://who.my.salesforce.com/sfc/p/#3X000005AZtm/a/NN000001rmcH/.Kqqi2wVzq1TliizyfrvIoi 0D5v 7CmXUozH01 Ke0

Each new user / registration request must complete:

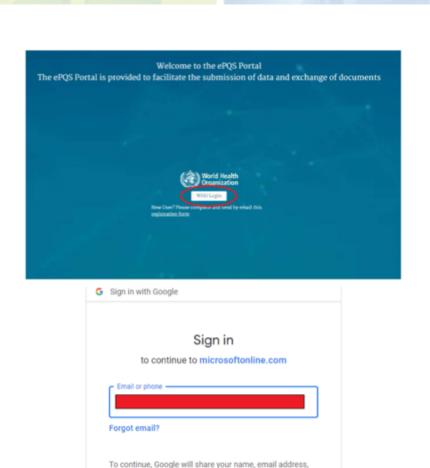
- Section 1 (Declaration),
- Section 3 (New User) and
- Section 4 (New Account)
- 5. Return the form to <a href="mailto:vaccprequalification@who.int">vaccprequalification@who.int</a>, with the IMD-PQS Secretariat in copy.

Updated: September 2025

#### 2. Access

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

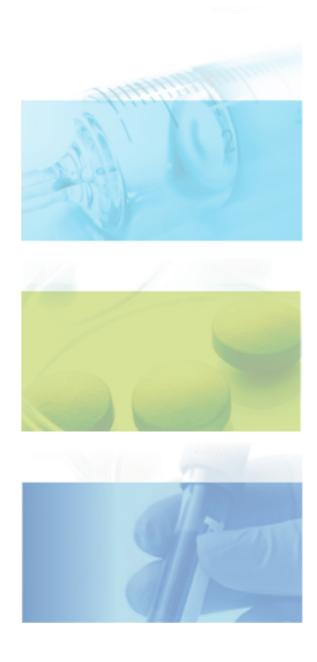
- Accessing the link: <u>https://who.my.site.com/ePQS/s/login/</u>
- 2. EITHER clicking the "WHO Login" button. The user will be directed to WHO Microsoft identity platform where they will be required to enter their username and click on the "Next" button.
- **3. OR** depending on which authentication 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.



language preference, and profile picture with

Create account





# 3 Concepts & terminology

## 3. Concepts & terminology



This section of the learning materials provides key terms that users will encounter whilst using ePQS.

It is intended as an ongoing reference guide throughout the training and your ePQS use.

## 3. Concepts & terminology – two critical terms

#### "Records" and "Cases"

Record

A single instance of object data. Records types include:

- Product record (basic information about a product),
- Product Variant record (detailed product specification data),
- Contact record (individual user),
- Account record (PQ Holder organisation),
- Case record (record of a prequalification-related application in ePQS).

Case

Every prequalification (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 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 ID**Once opened, each case will be assigned an ID in the format

"PQ-IMD-YEAR-XXXX".



#### Terms related to applications

**Application** New application for product prequalification, post-PQ change

(variation) or Reassessment. Submitted via the Application Wizard.

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

prequalification change.

**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.



#### IMD-PQS-specific application 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 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, 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 ID**Subsequent to a successful application for prequalification, WHO IMD-

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

Product number": "E0XX-XXX".

**Product Site**Location and facility at which a product is manufactured.





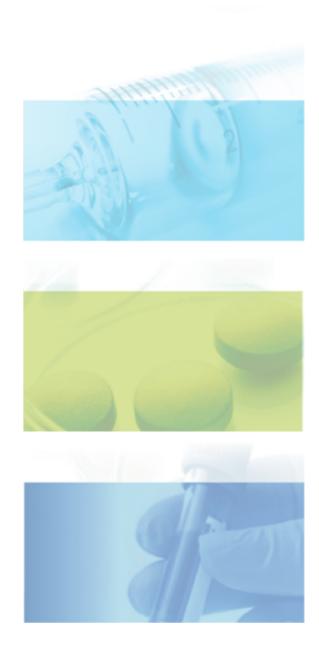
## SECTION B - DISCOVERY

## ePQS navigation & features - Discovery



This "discovery" section of the learning materials guides users through the different features and functions of ePQS and where they can be found.

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

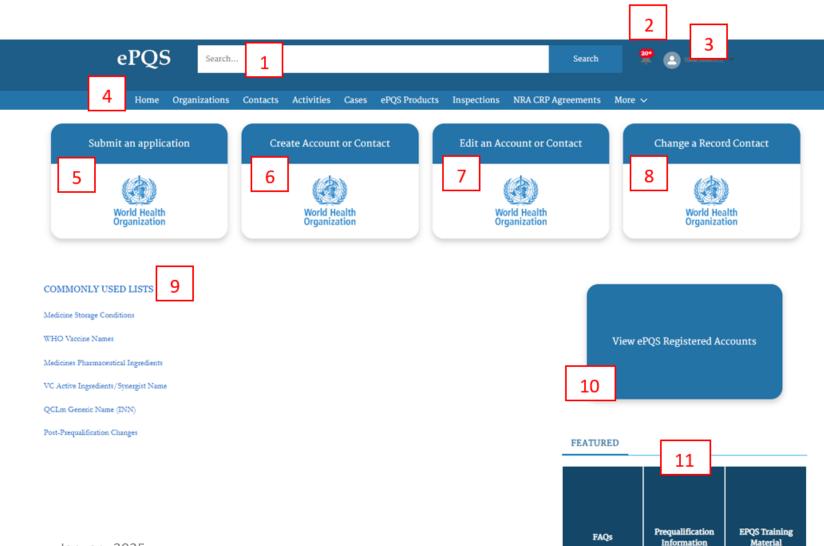


4

## 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.

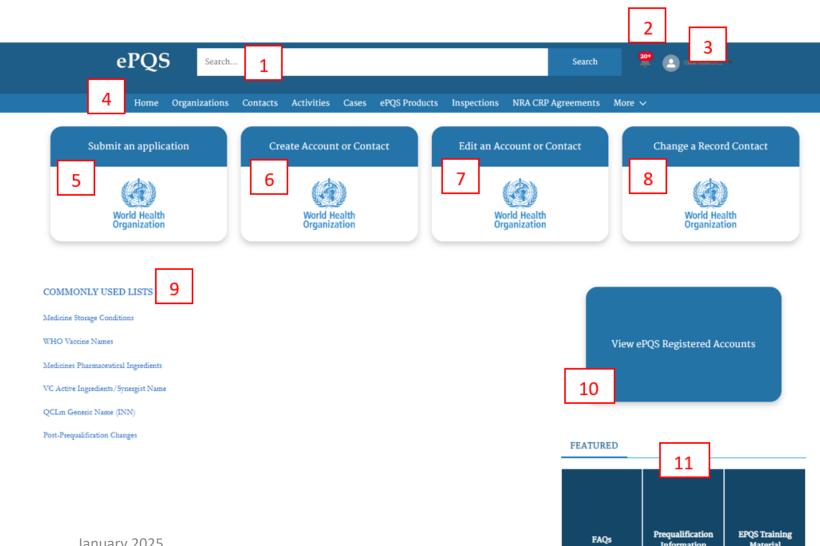
#### 5) Application wizard

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 Agreements	CRP Pro	duct Registra	Home
Name							Manager				My Profile
_											My Account
Title							Company N	ame			Logout
							Active				
							Contact				
							P1				
Email							Phone				
Address							Mobile				

## 4. ePQS navigation – My account



The "My account" icon provides users with access to most actions.

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



## 4. ePQS navigation – My account

> System Information

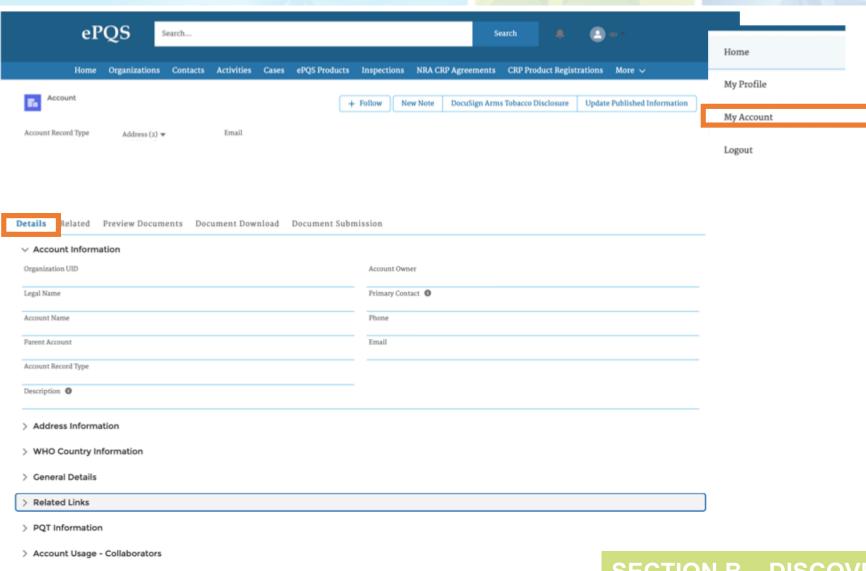


"My account" appearance.

#### 5 sub-tabs appear:

- Details;
- Related;
- Preview documents;
- Document download;
- Download submission.

"Details" displays the information that is stored in ePQS related to the PQ Holder (or other supplier entity) that a user is linked to.



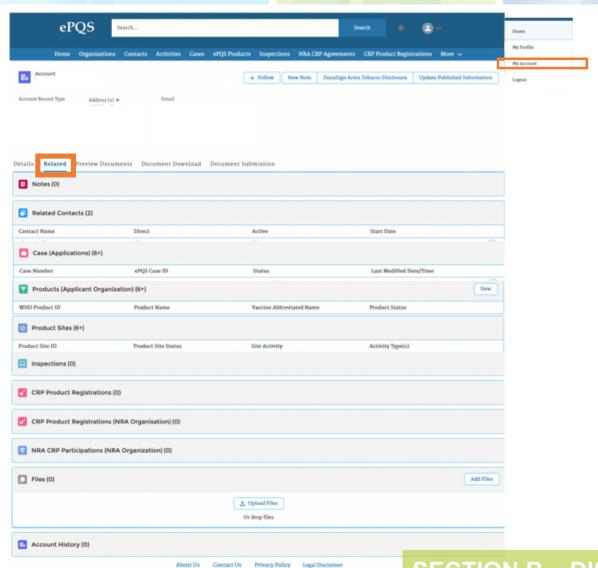
## 4. ePQS navigation – Related



"Related" provides a list of all records in ePQS related to a user's account.

#### This includes:

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

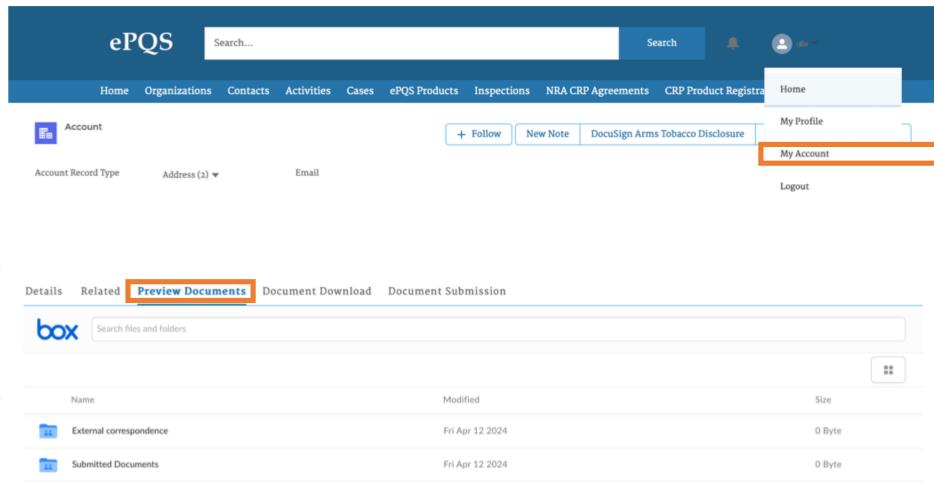




"Preview documents" is a reference library of all documents related to a user's account.

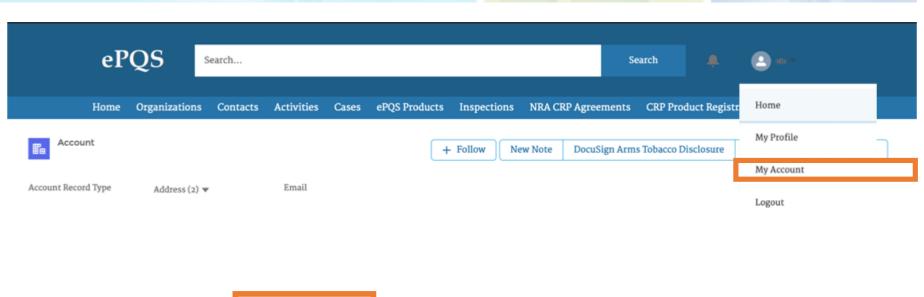
"External correspondence" contains the documents users have submitted as correspondence with the IMD-PQS Secretariat.

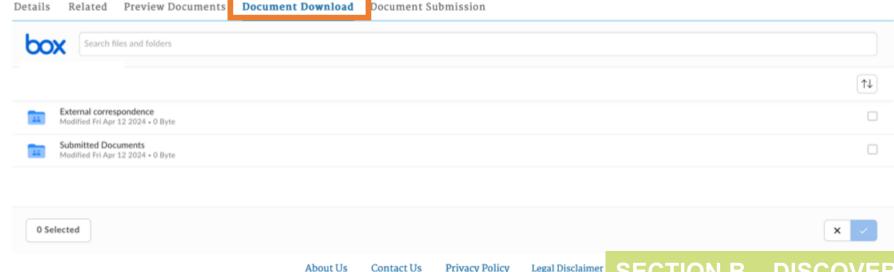
"Submitted documents" contains the documents uploaded to the account, or as part of an application wizard process.





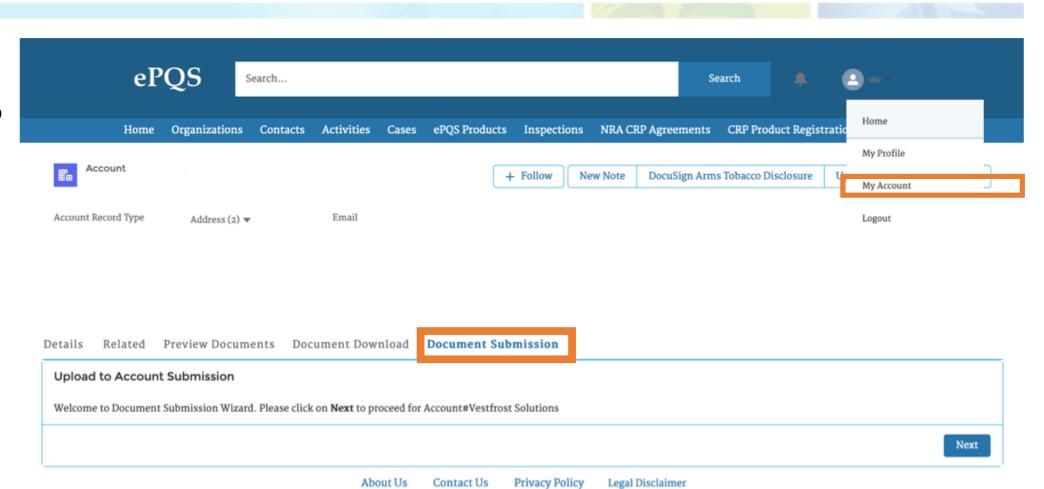
"Download documents" allows users to download and save locally all the documents related to their account.





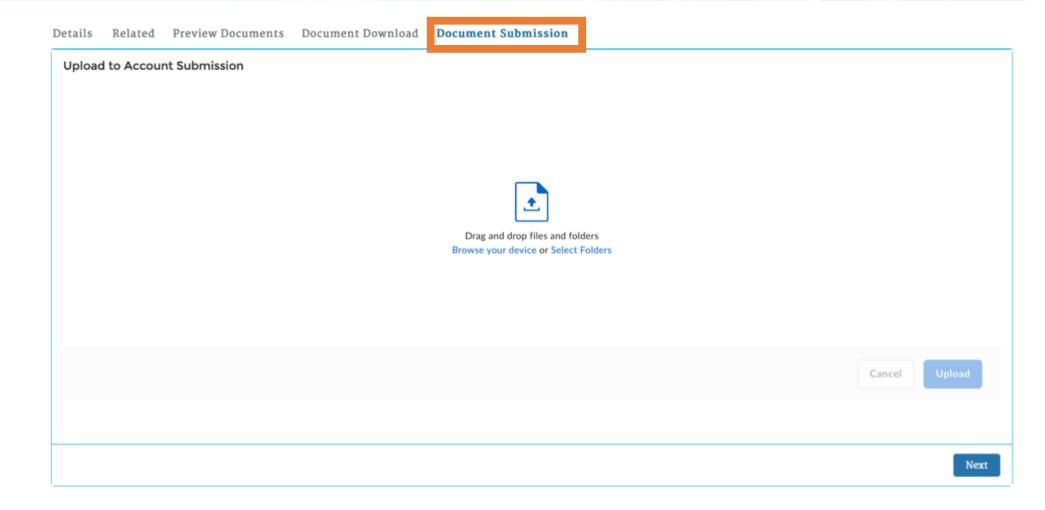


"Document submission" enables users to upload documents to their account.





"Document submission" interface allow users to upload documents by drag-and)drop or browsing their device.

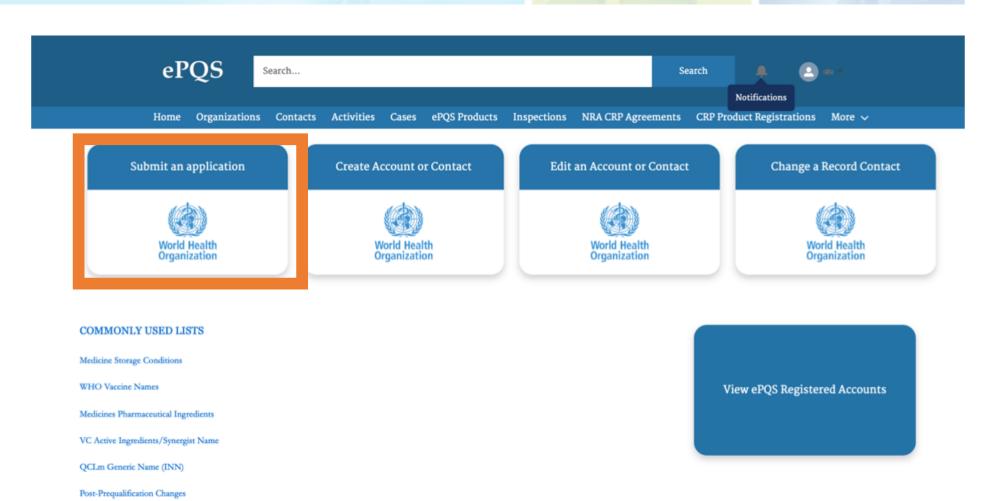


## 4. ePQS navigation – Wizard



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

to complete the Application Wizard IN FULL, including all product specification data, before submitting the applications.



## 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

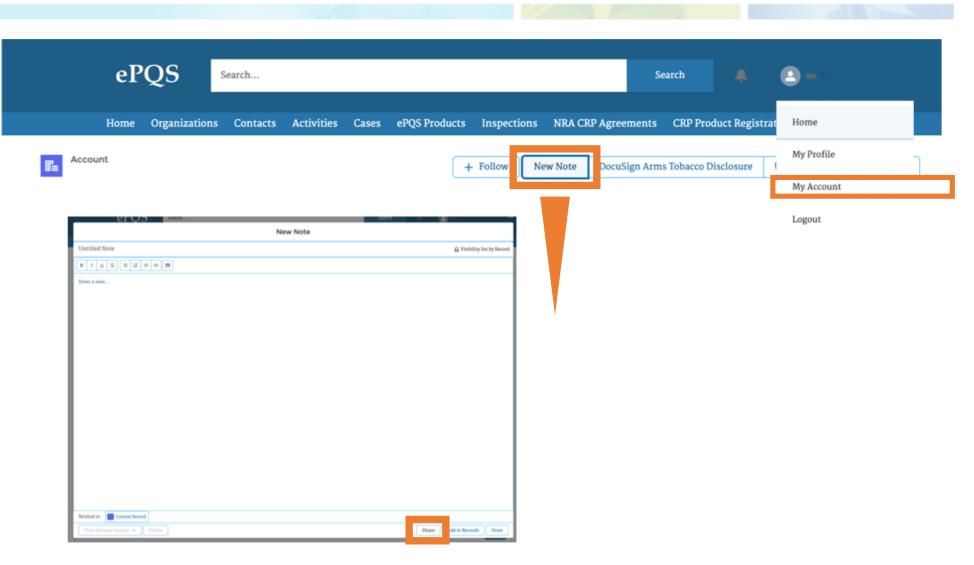


## 4. ePQS navigation – Notes



"account"
interface, users
may also create
"notes".

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

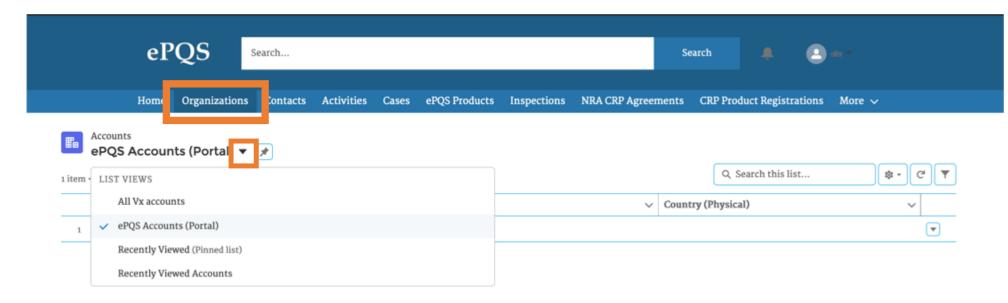


## 4. ePQS navigation – Organisations



Via the
"Organisations"
tab users can
access a list of all
organisation
accounts
associated with
their own.

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

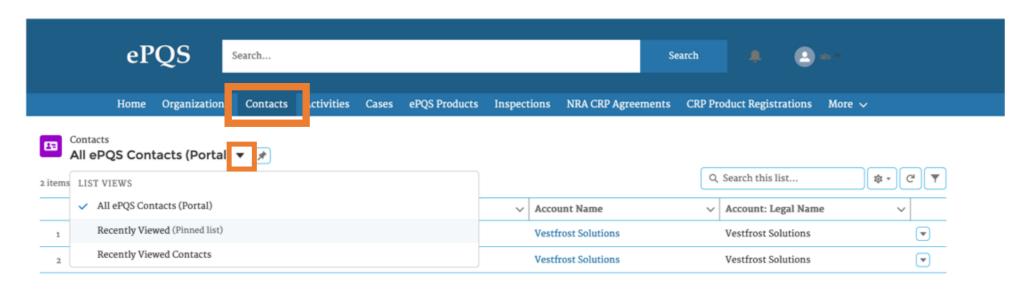


## 4. ePQS navigation – Contacts



Via the main
"Contacts" tab,
users can access a
list of all
organisation
accounts
associated with
their own.

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

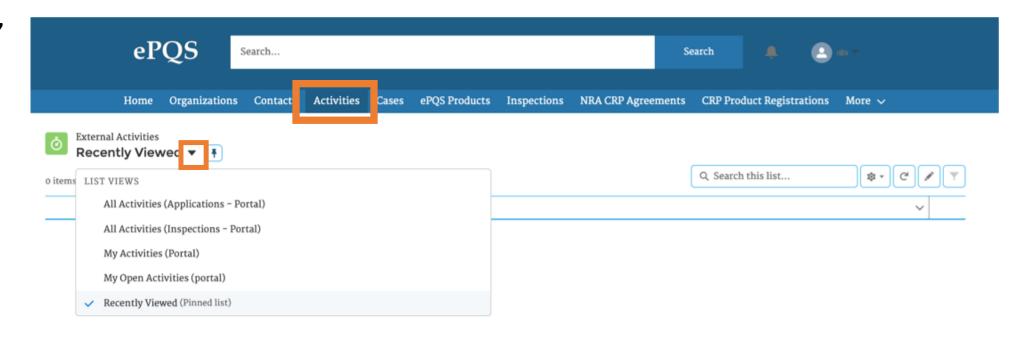


## 4. ePQS navigation – Activities



Via the "Activities" tab, users can access a list of all the "external activities" related to their account. This includes applications, post-PQ variants and inspections.

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

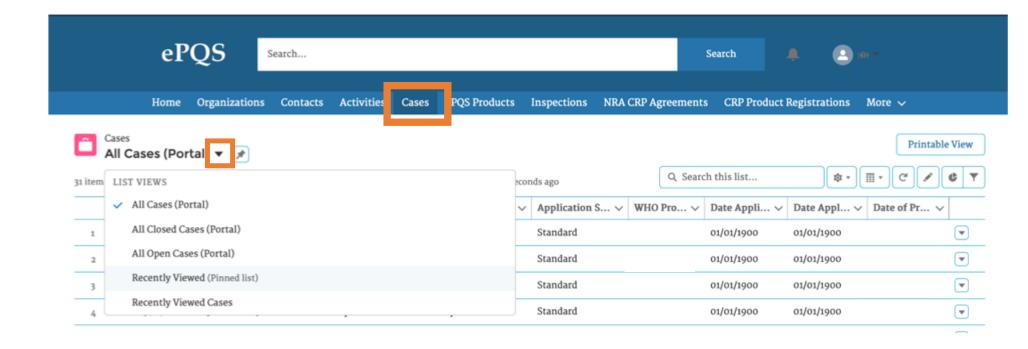


## 4. ePQS navigation – Cases



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

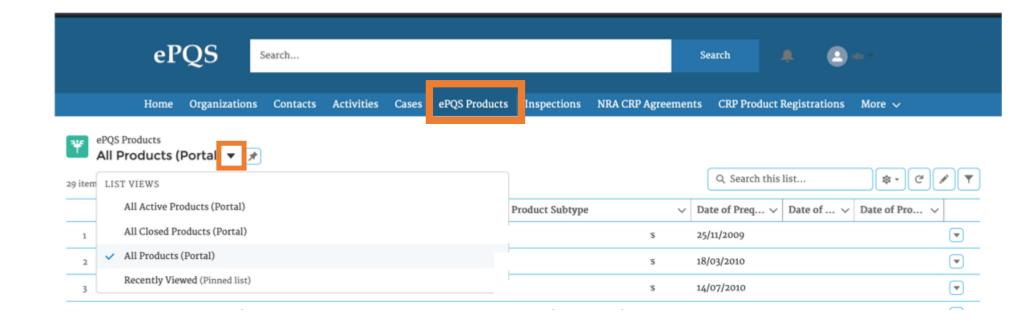
Available list
views include
"Open cases",
"Closed cases",
"All" and
"Recently
viewed".



## 4. ePQS navigation – Products



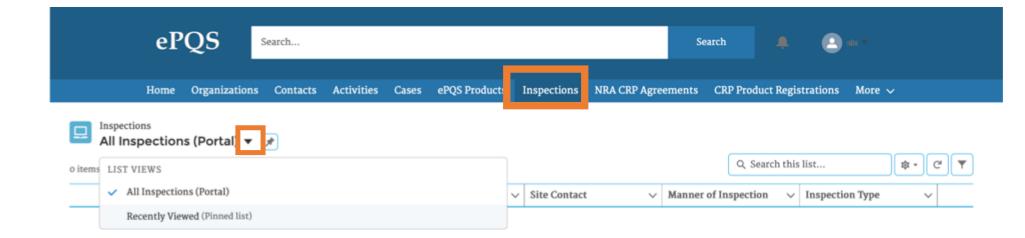
Likewise, a list of all "products" related to a user's account is available via the main tab.



## 4. ePQS navigation – Inspections



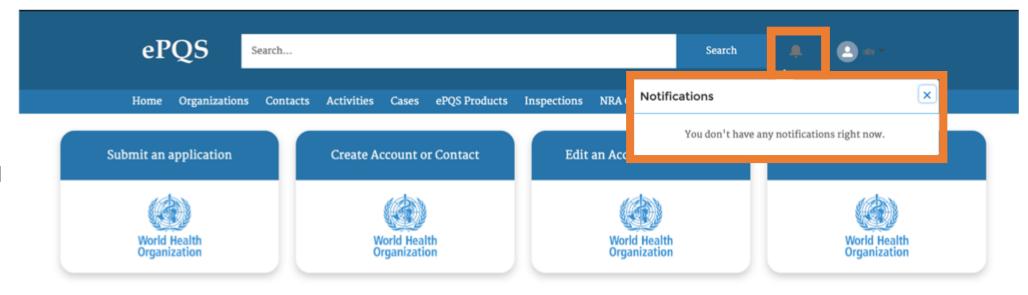
And a list of all "Inspections" related to a user's product sites is available via the main tab.



## 4. ePQS navigation – Bell

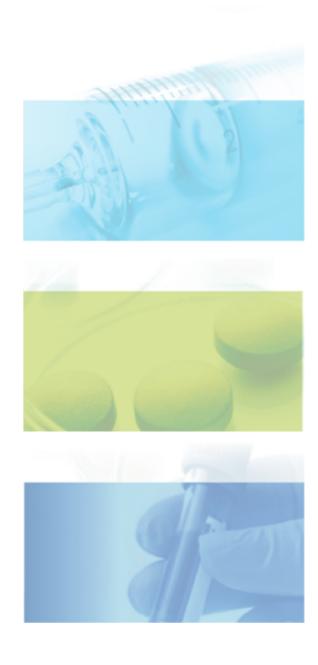


The bell notification provides an overview of all the outstanding notifications and actions relevant to a user's account.





## SECTION C - APPLICATION PROCEDURES



## 5 Step-by-step guide

## 5. Step-by-step guide



ePQS activities required of a user to set-up their account and to process applications and associated processes include:

- a. Verifying product data records
- b. Verifying access, accounts and contact details
- c. Verifying correct record visibility and correct product list visibility
- d. Accessing and verifying functionality of personal user folder
- e. Submitting applications (if applicable)
- f. Submitting post-PQ variation submission (if applicable)
- g. Uploading documents (related to the submission)
- h. Downloading documents shared with the applicant
- i. Assigning activities to applicants
- j. Verifying bell and email notifications associated with actions





## **5**a

# Verification of product data sheets



#### **TASK**

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





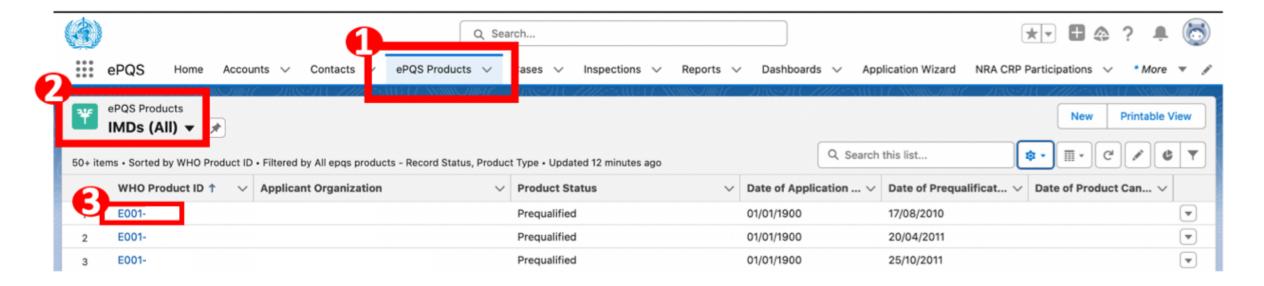
Communicate any omissions or errors to: <a href="mailto:pqsinfo@who.int">pqsinfo@who.int</a> & <a href="mailto:huckerbyg@who.int">huckerbyg@who.int</a> using the relevant change request form linked on slide 60 of this deck.





Registered users may find their product data records for verification:

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



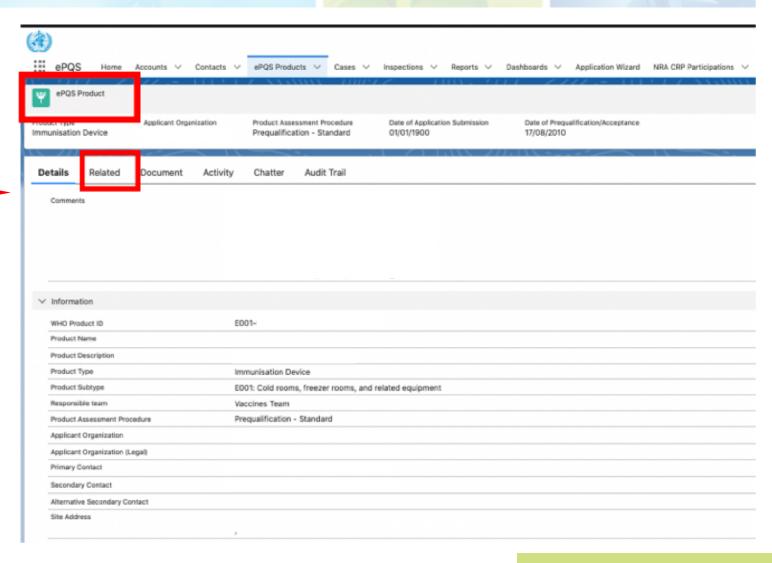


Users should click on the product code "E00X-XXX" to view the relevant "Product page".

Important: users need to progress further to the "<u>Product</u> <u>Variant page</u>" to see product's technical specifications.

Users should click on the

"Related" sub-tab.

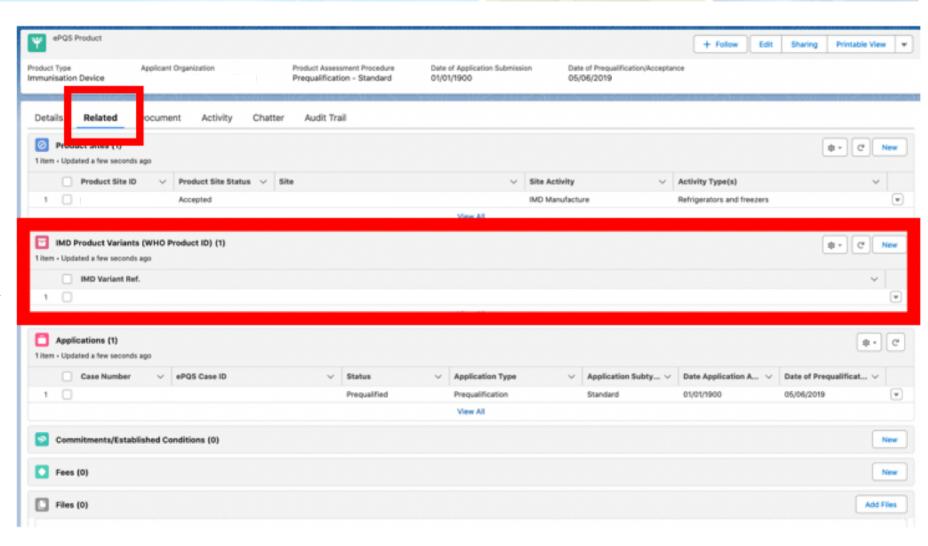




"Related" brings up a list of the record-types related to this specific product.

Select the record displayed under "IMD Product Variant"







This brings the user to the "product variant page" (e.g. here for E001)

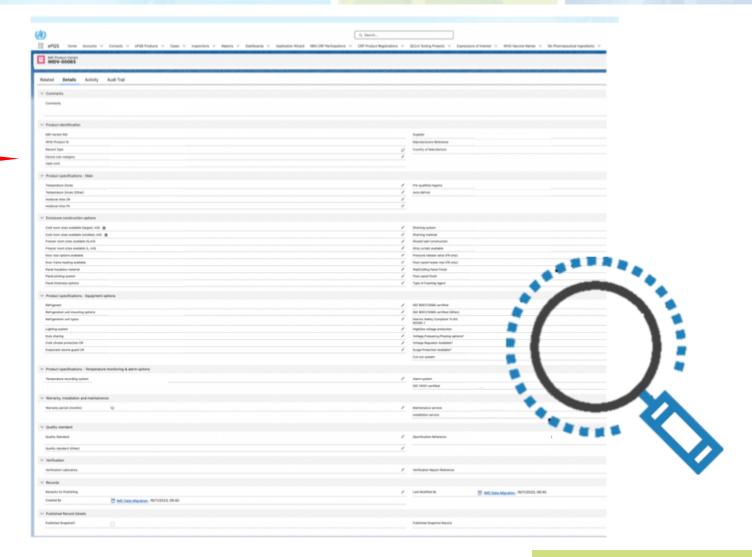
#### USER TASK →

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

pqsinfo@who.int & huckerbyg@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, users will find a feedback form 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



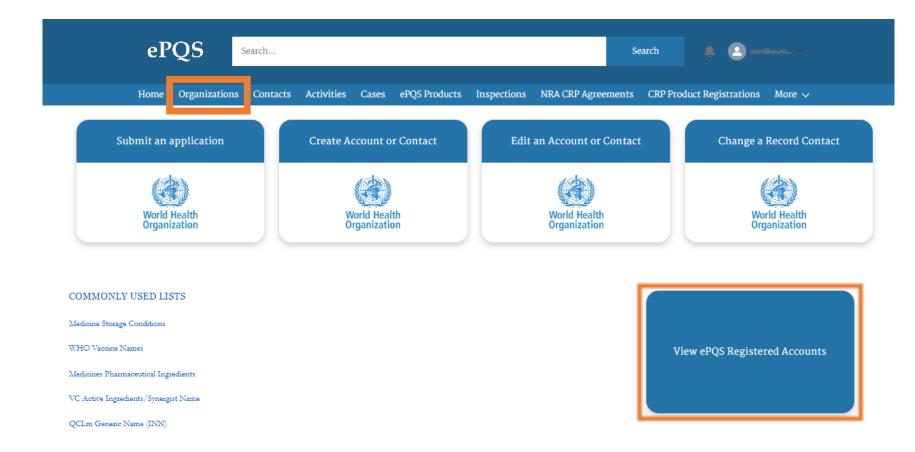
## **5**b

# Accessing registered accounts

## 5b. Accessing registered accounts



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



## 5b. Accessing registered accounts



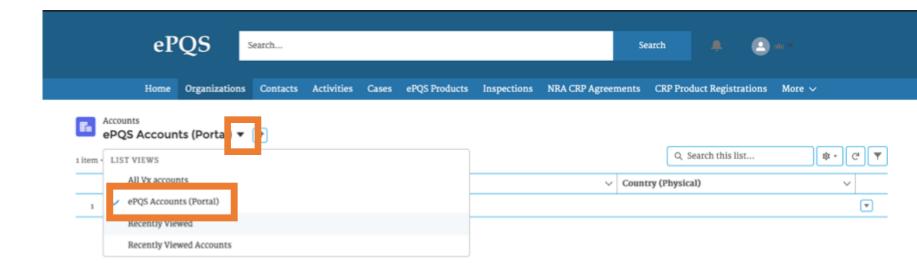
Users may select different **list views**.

Recommended: "ePQS Accounts".

Users should review each record that appears in the list:

#### Account types include:

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



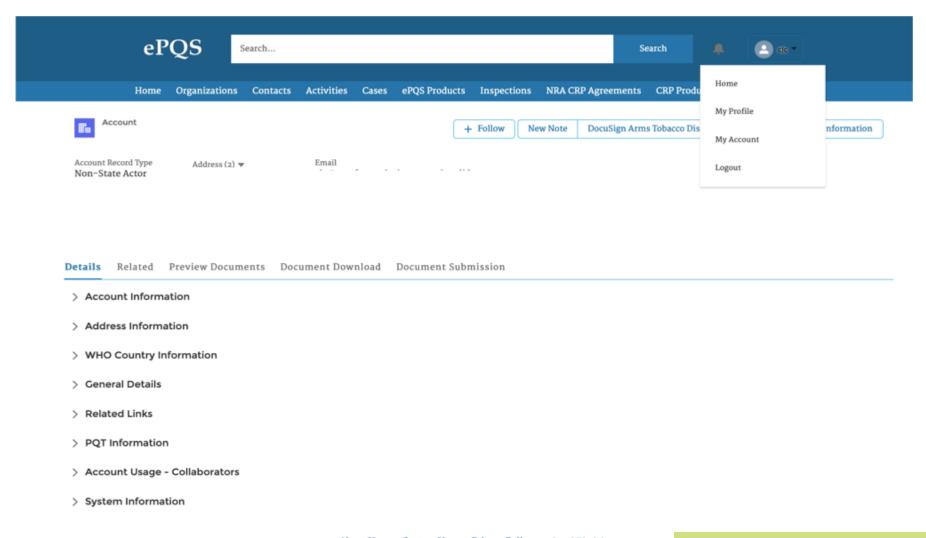
\*\*\* As an IMD-PQS prequalified manufacturer or reseller, the only account to which a user is associated is their own company.

### 5b. Accessing registered accounts



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

 Report any errors or issues to the IMD-PQS Secretariat: <a href="mailto:pqsinfo@who.int">pqsinfo@who.int</a> & huckerbyg@who.int





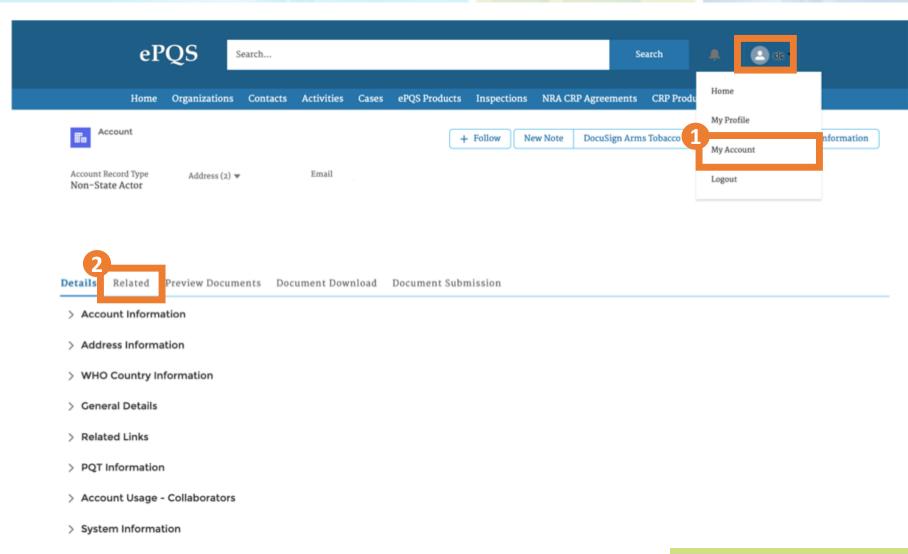
## **5**C

## Correct record visibility

### 5ci. Correct record visibility



- 1. Users should click on their profile icon, and select "My Account".
- 2. Then, click on the sub-tab "Related".



Legal Disclaimer

## 5ci. Correct record visibility

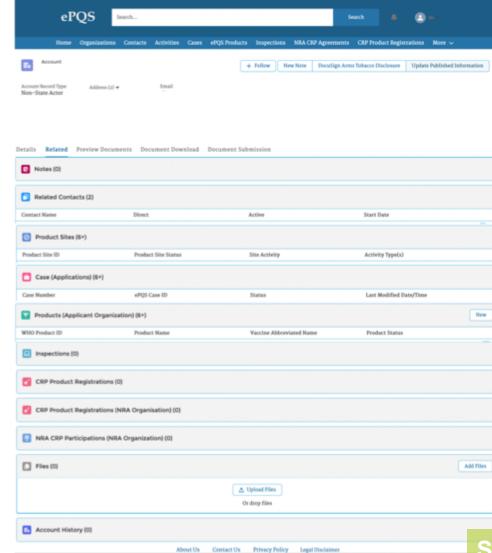


The "Related" sub-tab displays all records, of all types, related to a user's account.

Users should **open and view** each type of record.

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

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

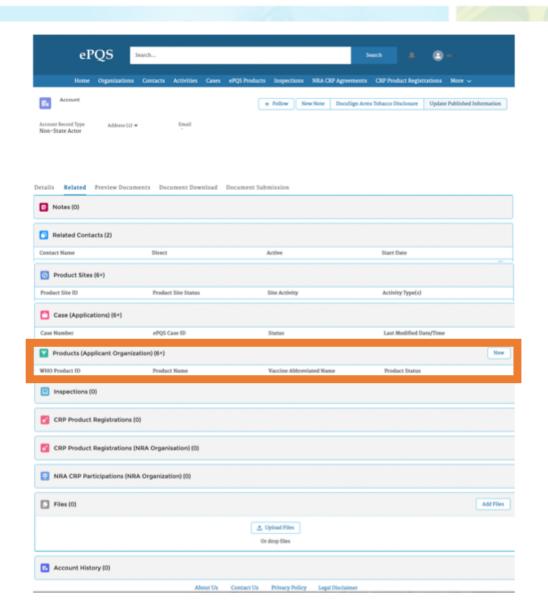


## 5cii. Correct record visibility - Products



#### **Products**

Expand or click directly on the Products sub-tab.



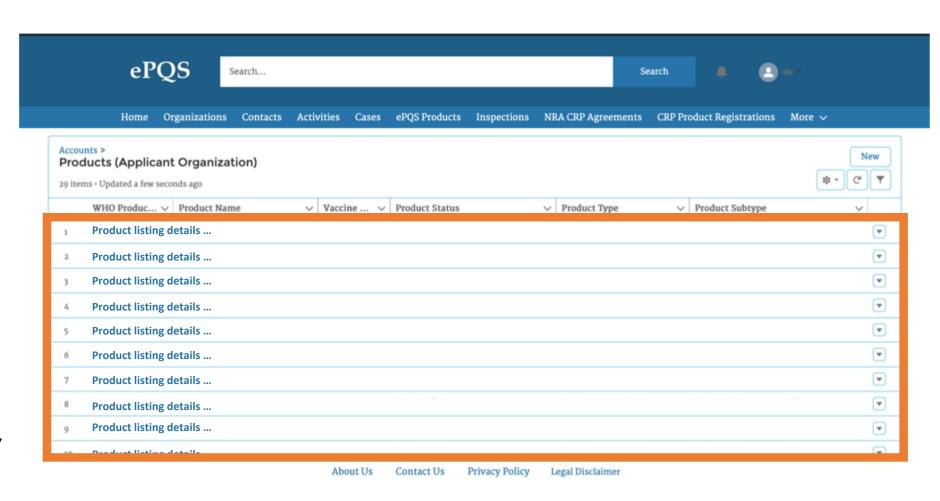
## 5cii. Correct record visibility - Products



#### **Products**

Users should **review the list of products** that is displayed:

- 1. Users should verify that ALL of their previously and currently prequalified products, and/or products currently under review are visible in the list.
- 2. Users should also verify that their account displays ONLY products from their organisation and NOT products of any other organisation.





## **5**0

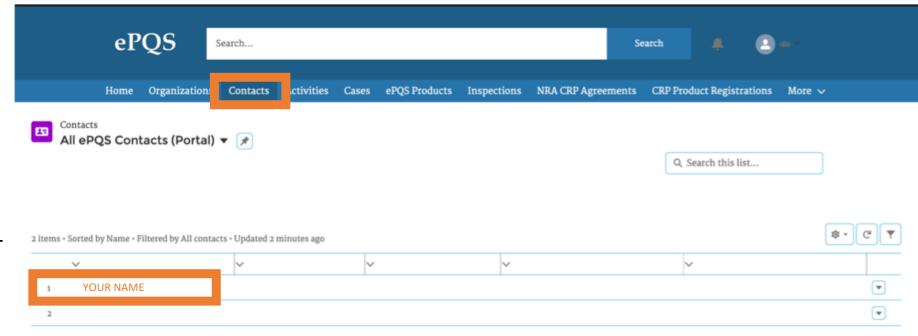
## Personal use folder

### 5d. Personal use folder



ePQS provides external users a "Personal folder", in which they may upload/store documents they are working on, before submitting them or sharing them with IMD-PQS.

To access the personal use folder, users should go to "Contacts" and choose themselves from the list of contacts.

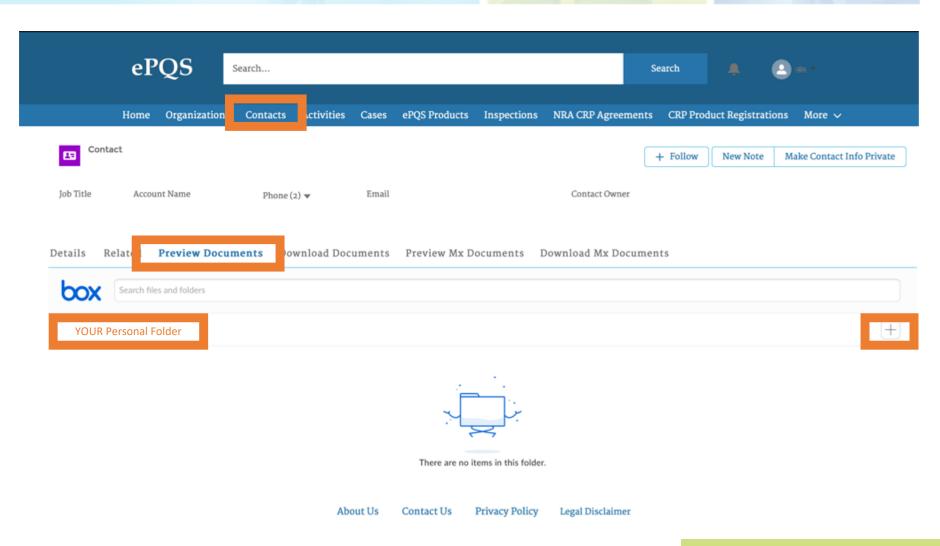


### 5d. Personal use folder



Once inside their own contact record, users should click the "Preview Documents" tab. Users will see a folder: (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.



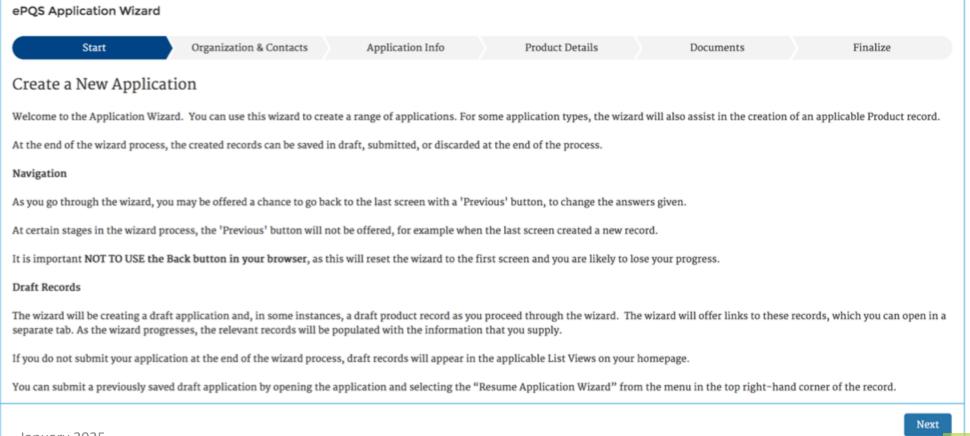


## **5e**

# Application submission procedure



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:





#### **VERY IMPORTANT INFORMATION:**

- You MUST complete the full Application Wizard, **including the "PRODUCT VARIANT" section**, for your application to be considered by the WHO IMD team. Please do not click "submit" on your application until you have completed the full Application Wizard, including the "PRODUCT VARIANT" section.
  - It is NOT possible to return to a submitted application to complete the Application Wizard.
  - If you submit an application without completing the Application Wizard, the application will be discarded and you will need to submit a new application.
  - (You CAN return to an already-submitted application to submit documents or additional documents however, using the "Additional Documents Wizard" tool.)

Kindly also avoid pausing your application during the creation of the "<u>product record</u>" and/or the "<u>product variant record</u>" at the current time, as there is a risk of subsequent Wizard sections being omitted once you restart the application. You may however safely pause before or after these stages in the wizard.





Applicants will first be prompted to select the relevant **contacts** (themselves, their 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 it	ndicate if there are other secondary peo	pple involved.
*Primary Contact				
Vaccine UAT External Contact 1				<b>‡</b>
Optionally Choose Secondary Contacts If needed you can optionally choose a second	dary and an alternative secondary c	contact, or leave the selection as "Non	e".	
* Secondary Contact				
None				<b>‡</b>
* Alternative Secondary Contact Choice				
None				<b>‡</b>
				Previous Next



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.		
<ul> <li>Product Type</li> <li>Active Pharmaceutical Ingredient</li> <li>Active Pharmaceutical Ingredient Master File</li> <li>Finished Pharmaceutical Product</li> <li>Finished Vaccine Product</li> <li>IMD Evaluating Laboratory</li> <li>Immunisation Device</li> <li>In Vitro Diagnostic</li> <li>Male Circumcision Device</li> <li>Quality Control Laboratory</li> <li>Vector Control Active Ingredient</li> <li>Vector Control Product</li> <li>WHO Prequalification Evaluating Laboratory</li> </ul>		
		Previous Next





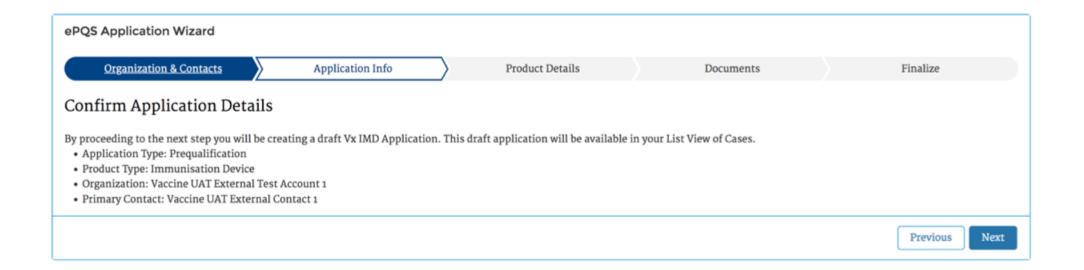
Next, select "Prequalification" as the application type:

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



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.







The Wizard will provide the your **case number**. Make a physical 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 num er PQ-IMD-2023-0040. You	n view the draft application details	s by following the link.	
			Next





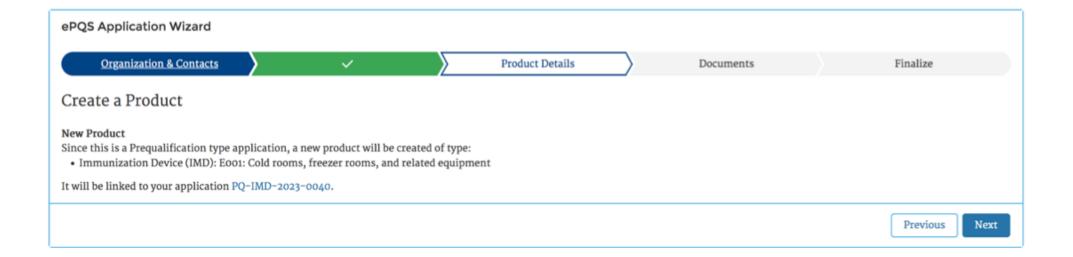
Next, select the "Product Subtype" (the IMD-PQS Product Category):

ePQS Application Wizard	
Organization & Contacts Application Info Product De	etails 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 the **application number** (which is the same as the case number shown previously):







Input a **product name** – the manufacturer product reference. A **description**, and the **type of appliance** (free text) are also useful, but not mandatory:

ePQS Application Wizard				
Organization & Contacts	<b>&gt;</b>	Product Details	Documents	Finalize
Create a Product				
Further Vx IMD Details (Please fill out all required fields)				
* Product Name				
Product Description				
				fis.
Type of Appliance				
				Next



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 fie	elds,None should be selecte	d if the answer is not available.)		
Range of cold room sizes available small (smallest,	m3)			
Range of cold room sizes available large (largest, m	3)			
December of the form that was				
Freezer room sizes (smallest, m3)				
Freezer room sizes (largest, m3)				
*Pre-qualified regions				
None				<b>‡</b>
* ISO 9001/13485 certified				
None				÷
* ISO 14001 certified				
None January 2025				÷

\*\*All fields are
required unless
not applicable
for a product.
There are
multiple such
pages to
complete for
each category of
product.



#### **IMPORTANT REMINDER:**

- You MUST complete the **"PRODUCT VARIANT" section** of the "Application Wizard", for your application to be considered by the WHO IMD team. Please do not click "submit" on your application until you have completed the full Application Wizard, including the "PRODUCT VARIANT" section.
  - It is NOT possible to return to a submitted application to complete the Application Wizard.
  - If you submit an application without completing the Application Wizard, the application will be discarded and you will need to submit a new application.

Kindly also avoid pausing your application during the creation of the "<u>product record</u>" and/or the "<u>product variant record</u>" at the current time, as there is a risk of subsequent Wizard sections being omitted once you restart the application. You may however safely pause before or after these stages in the wizard.





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

ePQS Application Wizard					
Organization & Contacts	<b>&gt;</b>	~	Product Details	Documents	Finalize
Create IMD Product Varia	ants				
Success IMD Product Varia t Ref. IMDV-00033 o	created.				
					Next



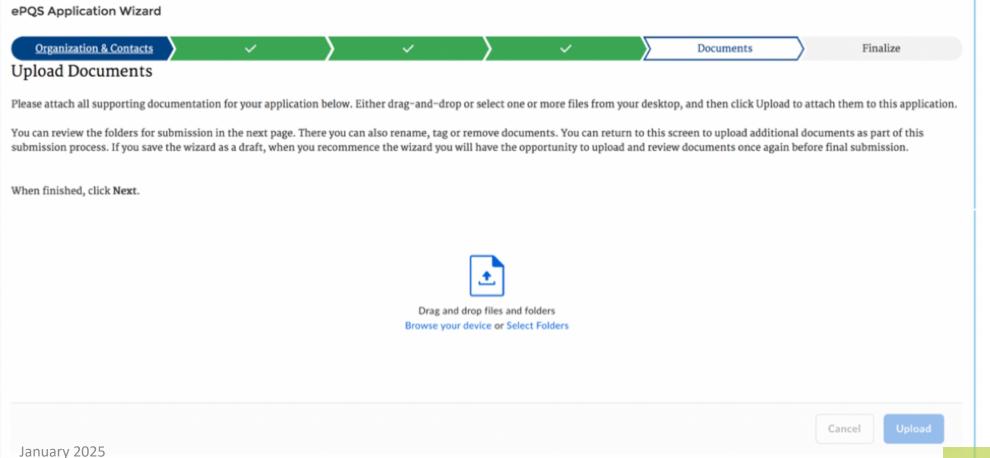
Next, please provide information about the "product site" (the actual site of product manufacture). This information is for the WHO Inspections team. Click on "Product Site" and select the product site option provided (which is related to your company).

- If the product site option provided is your office address and NOT the manufacturing site please contact <a href="mailto:Huckerbyg@who.int">Huckerbyg@who.int</a> and provide the manufacturing site address. The addresses will then be correctly assigned in ePQS.
- If your prequalified products are manufactured at MORE THAN ONE site, please contact <u>Huckerbyg@who.int</u> and provide the additional manufacturing site address.
   A new product site will be created and assigned to this product.





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



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



List of mandatory documents.

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

In addition, users 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 for each product category.

The Prequalification Guidelines can be downloaded from: <a href="https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-applicants-prequalification-holders">https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-applicants-prequalification-holders</a>

## **5e. Application submission procedure MANDATORY folder structure**



IMD PQS requires applicants to upload the application documents under the following folder structure.

A. INITIAL APPLICATION ROUND 1  A1. DOSSIER SUBMISSION INFORMATION  A1i. PRE-SUBMISSION APPLICATION  A2ii. DEVICE TECHNICAL SPECIFICATION  A3iii. LABORATORY/MANUFACTURER QUALITY CERTIFICATION(S)  A4iv. DEVICE MARKETING APPROVAL(S)	Upload the pre-submission you submitted previously to the IMD-PQS Secretariat (if relevant).  This is the Application Review Template provided
A2. COMPLETED APPLICATION REVIEW TEMPLATE  A3. SUBMISSION DATA  A3i. TEST REPORTS  A3ii. INSPECTION REPORTS  A4iii. USER-TESTING REPORTS  A5iv. RISK ANALYSIS	to you in the application guidance from the IMD-PQS Secretariat.
A4. EQUIPMENT CALIBRATION CERTIFICATES  A5. TEST PROTOCOLS  B. APPLICATION REVIEW ROUND 2  C. APPLICATION REVIEW ROUND 3	** Include the up-to-date, most recent version of the Application Review Template in every round of review.

- This folder structure is mandatory.
- However, applicants are only required to create & upload the folders & subfolders that are relevant & required for their application.
- Refer to the detailed list of application requirements provided to you by the WHO IMD-PQS Secretariat.
- CLICK HERE TO DOWNLOAD THIS
  FOLDER STRUCTURE IN PREFORMATTED .ZIP FORMAT:
  https://extranet.who.int/prequal/key
  -resources/documents/imd-pqsepqs-mandatory-folder-structure

Updated: September 2025

SECTION C — PILOT





Create the folder structure locally on your computer.

A. INITIAL APPLICATION ROUND 1

A1. DOSSIER SUBMISSION INFORMATION

A1I. PRE-SUBMISSION APPLICATION

A2II. DEVICE TECHNICAL SPECIFICATION

A3III. LABORATORY/MANUFACTURER QUALITY CERTIFICATION(S)

A4IV. DEVICE MARKETING APPROVAL(S)

A2. COMPLETED APPLICATION REVIEW TEMPLATE

A3. SUBMISSION DATA

A3I. TEST REPORTS

A3II. INSPECTION REPORTS

A4III. USER-TESTING REPORTS

A5IV. RISK ANALYSIS

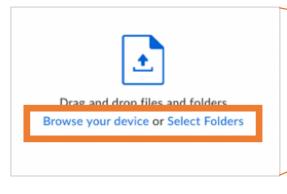
A4. EQUIPMENT CALIBRATION CERTIFICATES

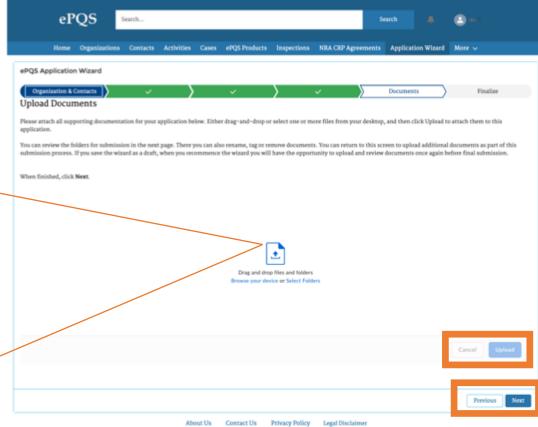
A5. TEST PROTOCOLS

B. APPLICATION REVIEW ROUND 2

C. APPLICATION REVIEW ROUND 3

Then, upload each folder and sub-folder to ePQS on the "Upload Documents" page. Keep the names and numeration as shown on this slide (even if not all folders are relevant).





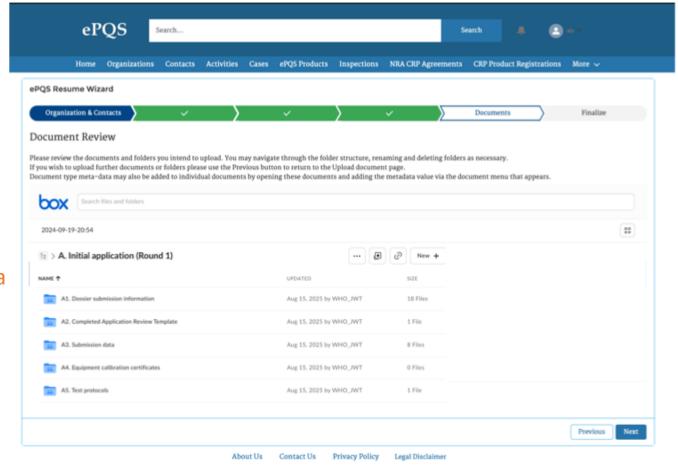




Once uploaded, Box will display the folder structure as shown here.

Once all documents are uploaded, click "next".

IMPORTANT: A folder will **not** upload if it does not contain a document. Only upload the folders / sub-folders if they contain at least one document.







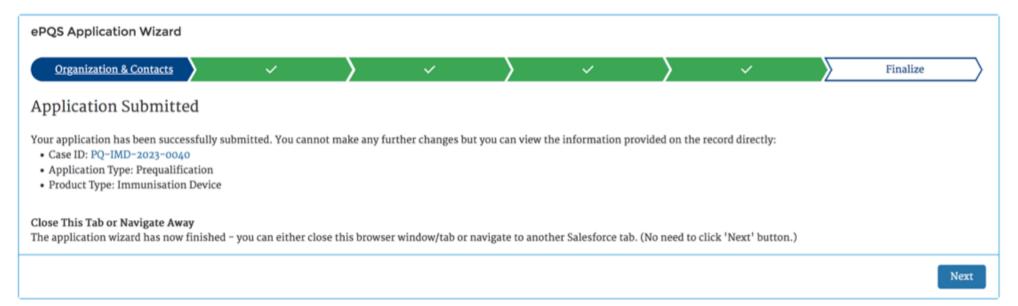
Once the complete documentation has been uploaded to the submission, the Wizard will provide the option to **submit**, **save draft** or **discard draft**:

ePQS Application Wizard					
Organization & Contacts	~	<b>&gt;</b>	<b>&gt;</b>	<b>&gt;</b> ~	Finalize
Review Application					
It is important that you review your a the Related sub-tab) of which you sho			it in a new tab and look at the	information entered, and also revi	ew the related records (click on
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 th	ne existing draft, or discard if	made in error.	
• Ready to submit?					
Yes					
No, save existing draft application					
No, discard this draft application a	and product (if applicable)				
					Previous





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



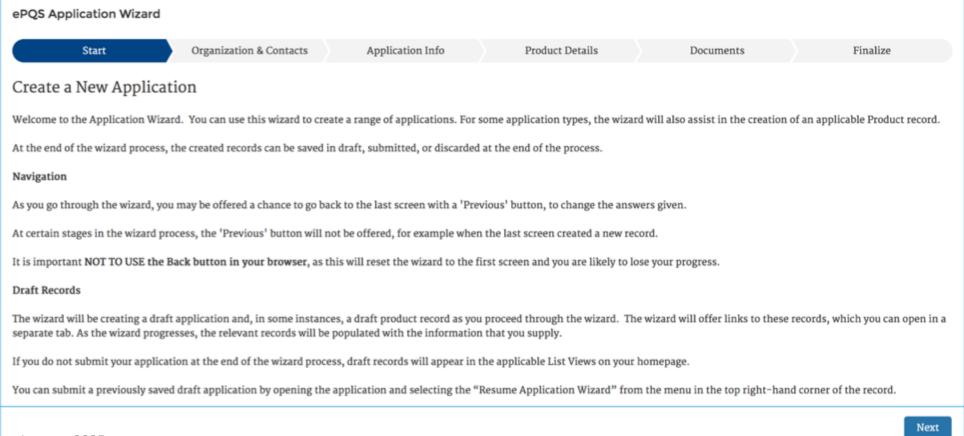


# 6f

# 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				<b>‡</b>			
*Alternative Secondary Contact Choice							
None				<b>‡</b>			
				Previous Next			



#### 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



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

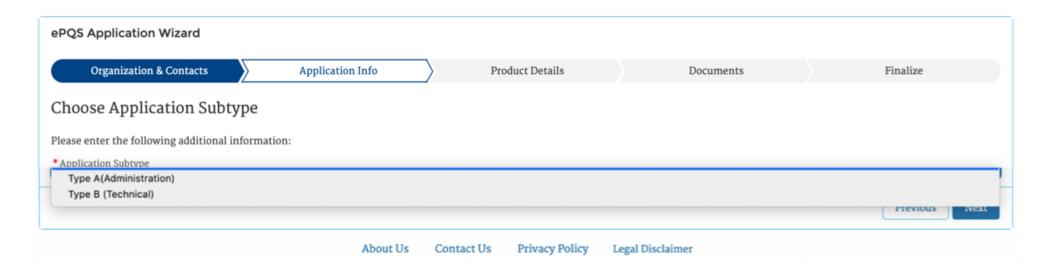
ePQS Application Wizard									
Organization & Contacts	Application Info	Product Details	Documents	Finalize					
Choose Application Type									
Based on the product type, here is the list of application types available.									
*Application Type  Prequalification									
Post-PQ Change									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



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

- Type A Administration → Select for ADMINISTRATIVE data changes.
- Type B Technical → Select for TECHNICAL variations that conncern product specifications

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



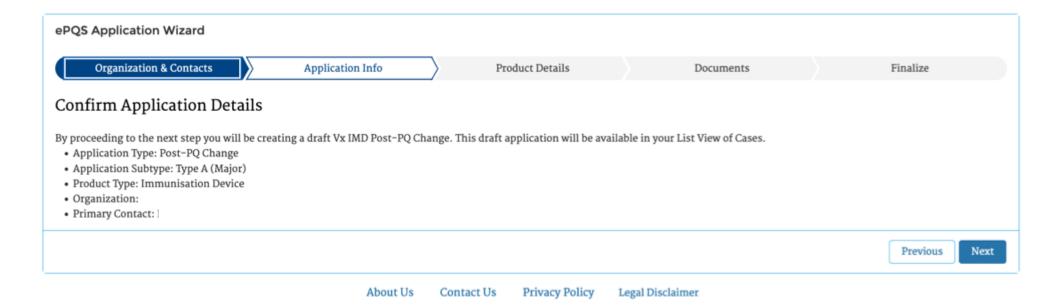


The next screen advises that users will be asked to select the product for which they wish to report the variation. The selection happens on the later screen.

ePQS Application Wizard							
Organization & Contacts Application Info	Product 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 Con	ntact Us Privacy Policy L	Legal Disclaimer					



The next screen summarizes the application details that the user has inputted so far, and asks for confirmation.





The draft application has now been created. This screen asks the user to confirm their wish to continue.

It provides an **application case number**. It is recommended to make a physical note of this 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 PQC-IMD-2024-0007. You can view the draft application	details by following the link.	
		Next
About Us Contact 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 the user has selected each of these options in sequence, starting here with "Add products...". (Later, the application will loop back and users will need to select "Add one or more pieces of information...", and finally "No more at this time".)

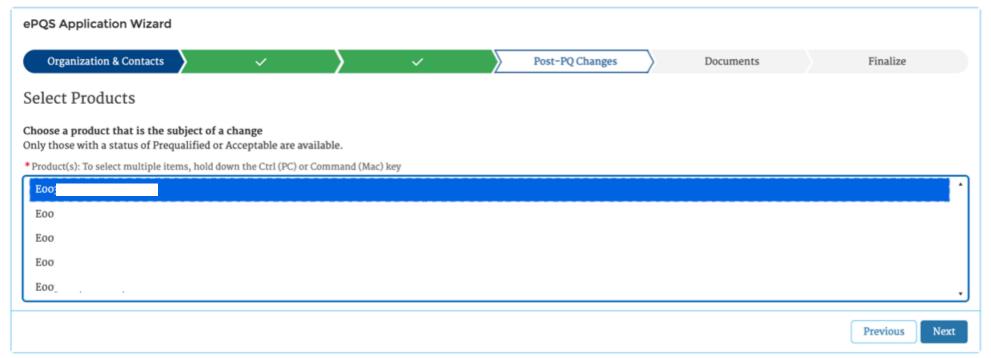
At this stage, select "Add products..."

ePQS Application Wizard								
Organization & Contacts	<b>&gt;</b>	<b>&gt;</b>	Post-PQ Changes	Documents	Finalize			
Add Change Informat	ion							
You will need to list the products	that are being changed, and also	record the change types that app	ly					
Either								
Add products that are the subject of post-prequalification changes     Add one or more pieces of information about the change, including the type								
O No more at this time								
					Next			



The Wizard will provide a list of products currently related to the user's account. Users should **select the product** for which they wish to submit a post-PQ variation.

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





The next slide confirms the product selection.

ePQS Application Wizard								
Organization & Contacts	· •	<b>〉</b>	~	Post-P	Q Changes	Documents	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 Policy	Legal Disclain	ner		



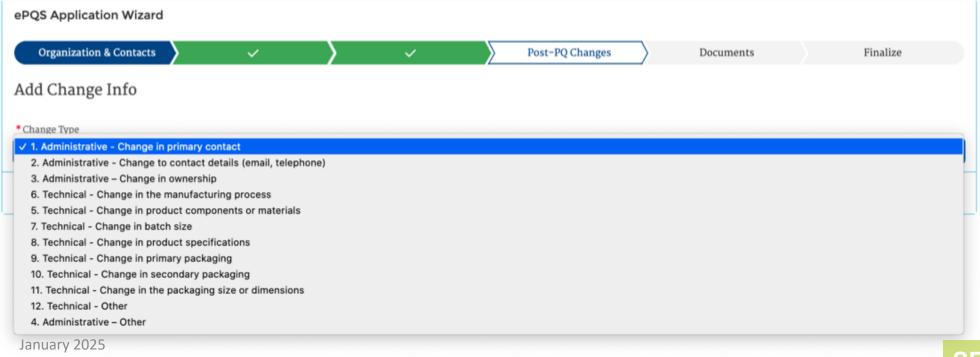
Next, users are presented for a second time the "Add Change Information" screen. This time, select "Add one or more pieces of information...".

ePQS Application Wizard								
Organization & Contacts	<b>&gt;</b>	<b>〉</b>	Post-P	Q Changes	Documents	Finalize		
Add Change Informati	ion							
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								
	,	About Us Con	tact Us Privacy Policy	Legal Disclaimer	r			



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

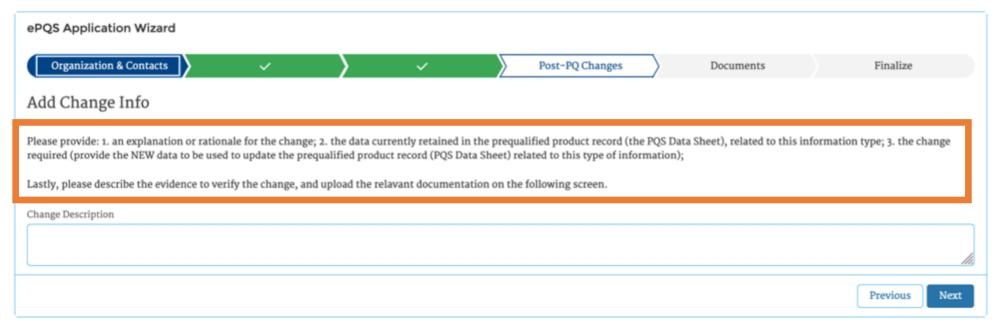
Note – This same list will appear irrespective of whether "Type A Administrative" or "Type B Technical" change types was selected at the start.



**SECTION C - PILOT** 



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





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

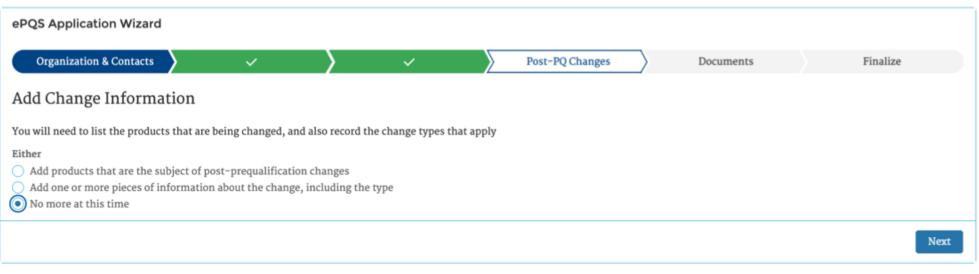
ePQS Application Wizard								
Organization & Contacts	·	<b>&gt;</b>	~	Post-F	Q Changes	Documents		Finalize
Add Change Info								
Success The change of type "1. Administrative - Change in primary contact" has been linked with your PQC-IMD-2024-0007 application.								
								Next
	1	About Us	Contact Us	Privacy Policy	Legal Disclair	mer		



Next the "Add change information" screen displays for a third time.

Note - If is wished to report changes to additional products, the user may begin to add the additional or next product(s) here by re-selecting the second option. The user will be prompted to add the change details for that additional product on the screen that follows.

If it NOT wished to add additional products, select "No more at this time".



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Assuming that "No more at this time" has been selected, the user 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 Next

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The user should select the type of document you will upload (CTD or eCTD).

WHO requirements and guidance on eCTD documents can be found here: <a href="https://extranet.who.int/prequal/ectd-portal">https://extranet.who.int/prequal/ectd-portal</a>

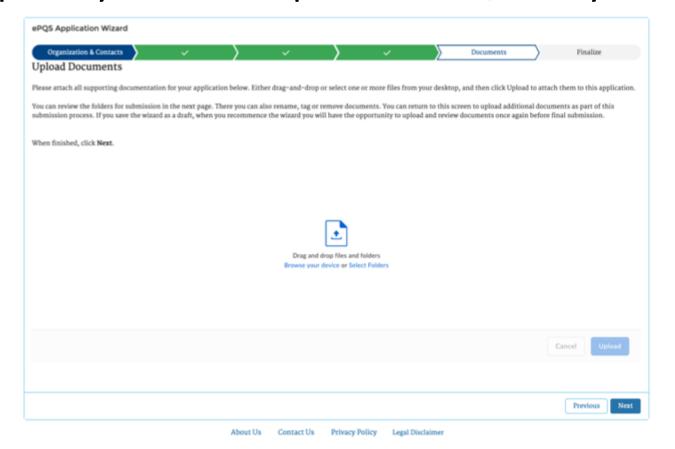
IMPORTANT – WHO IMD-PQS does NOT currently require eCTD documents. IMD-PQS PQ Holders should select "Non-eCTD".

ePQS Application Wizard	
* Select Document Type  eCTD  Non-eCTD	
	Previous Next

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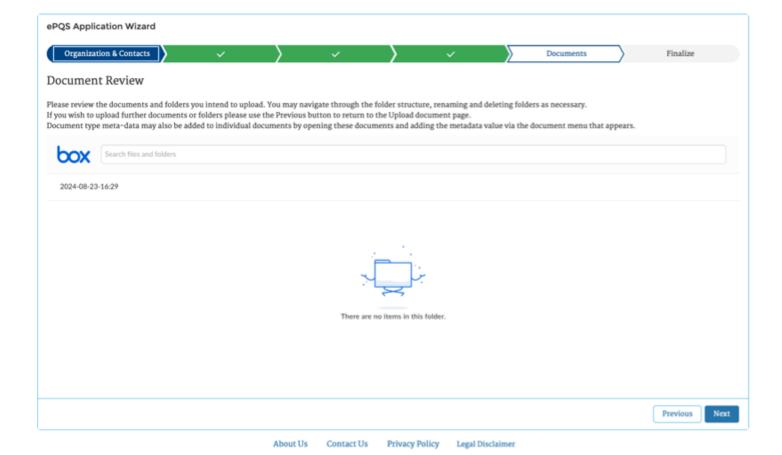
On this screen, users should upload ALL the documents related to the change (variation) request, specifically the evidence required for IMD-PQS to verify the change requested.





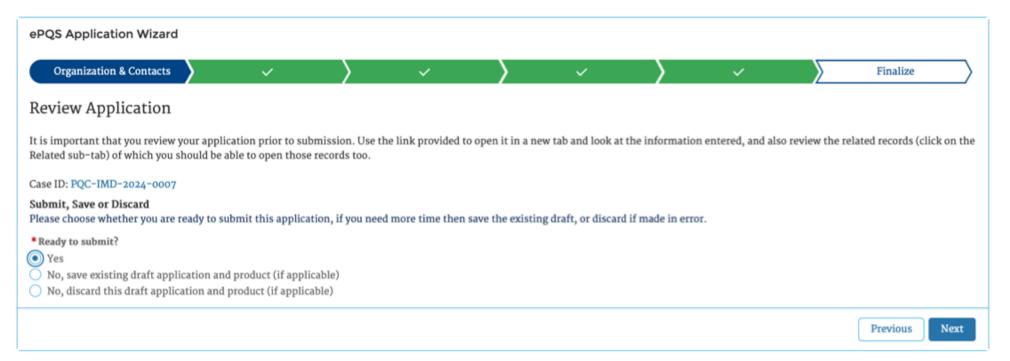
On the subsequent screen, users will see a display list of all the documents that have

been uploaded.





Users are now at the **review and submit stage**. On this screen, users may 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 it is wished to come back later to complete or update the submissions, or **"No, discard"**.





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

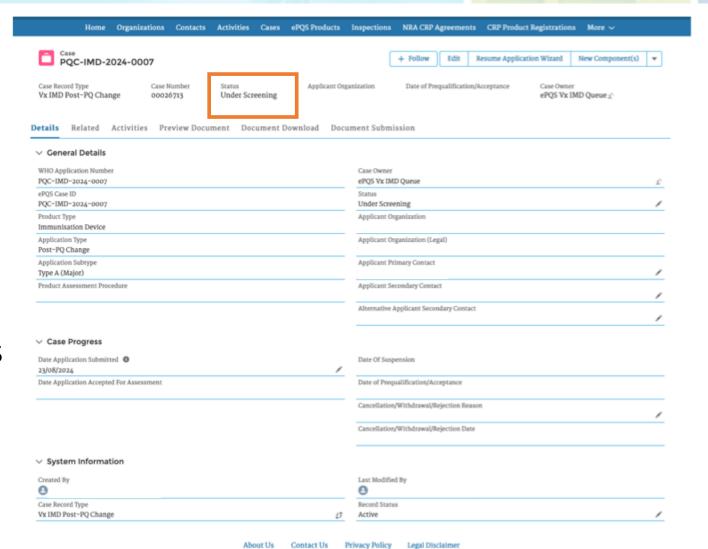
ePQS Application Wizard										
Organization & Contacts	· •	$\rangle$	<b>~</b>	$\rightarrow$	<b>~</b>	<b>〉</b>	<b>~</b>		Finalize	
Application Submitted	I									
The application wizard has now finished - click on the <b>Finish</b> button to be redirected to the detailed page of your submitted application.										
									F	inish
	ı	About Us	Contact Us	Privacy Policy	Legal Disclain	ner				



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.



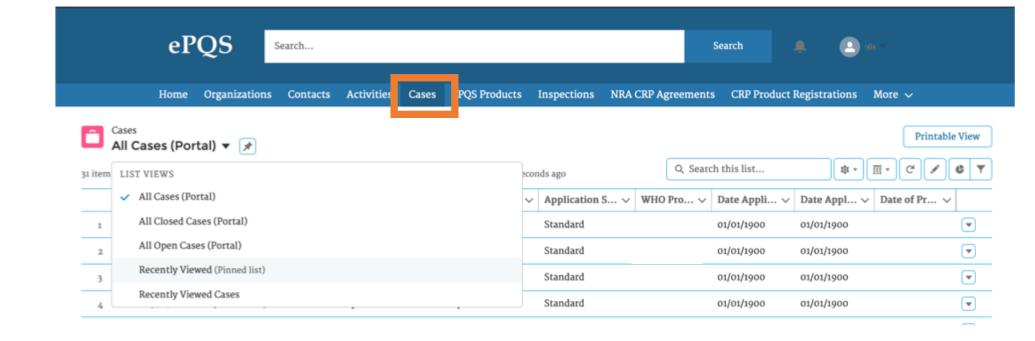


### 5G Up/downloading of documents



### 5g. Up/downloading of documents – Related to a PQ application (a "CASE")

Documents related to a "case" record - i.e. product applications - are available under the "Cases" tab.



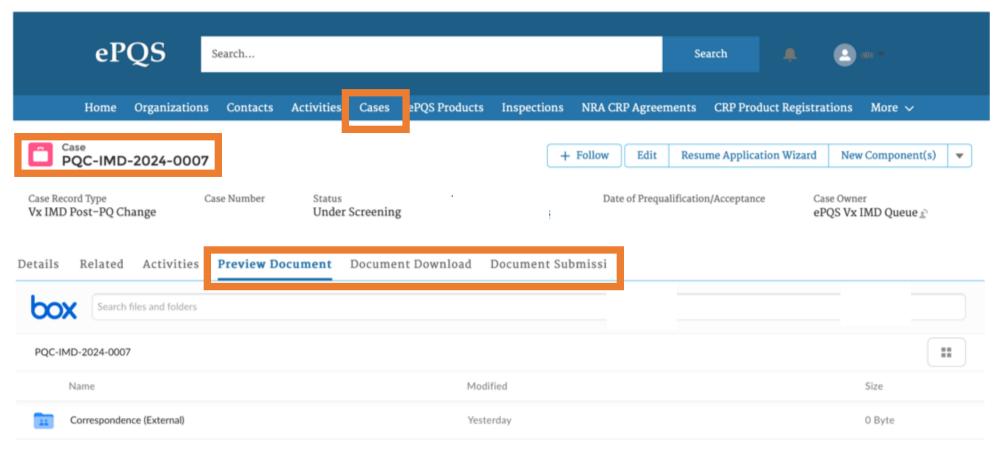


### 5g. Up/downloading of documents – Related to a PQ application (a "CASE")

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

The "Preview",
"Download" and
"Submission"
functions are
available.

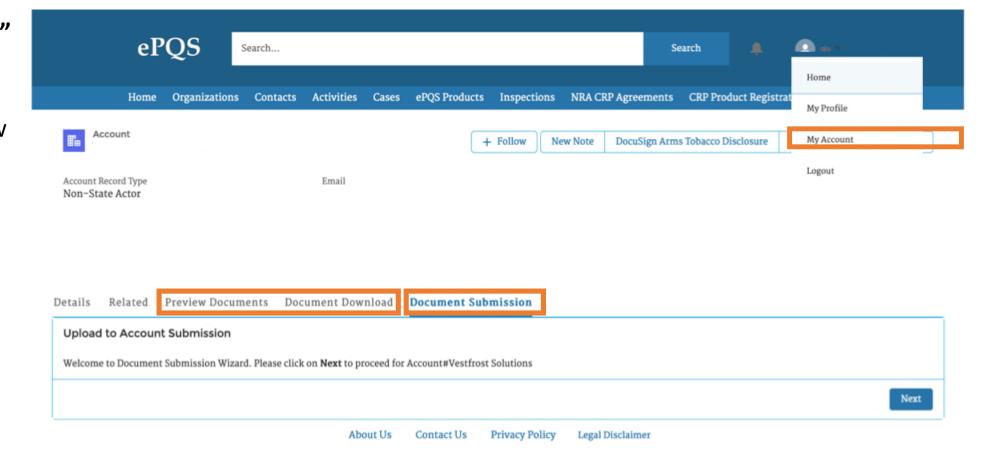
Users should ensure that they are able to upload documents & visualise them.



### 5g. Up/downloading of documents – Related to organisation ACCOUNT



Under "My Account" or "Document Submission", users may upload, preview and download documents related to their account or organisation (for example, certification and licencing).

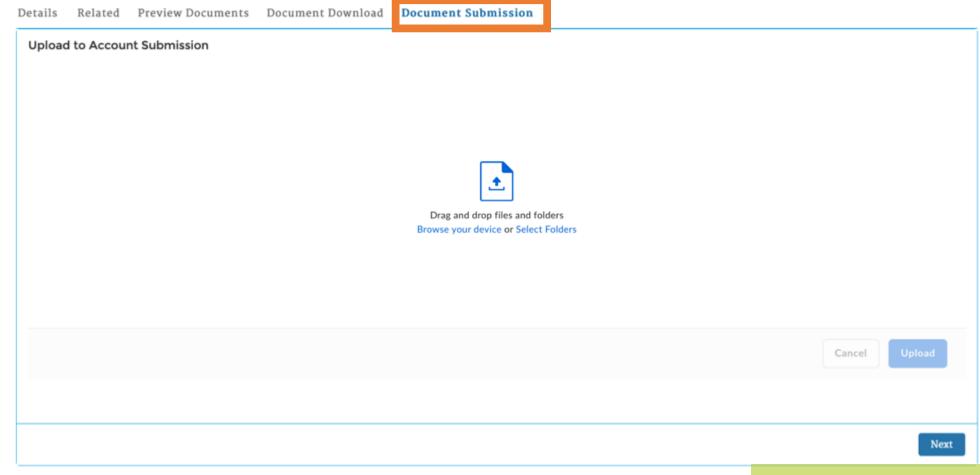


### 5g. Up/downloading of documents – Related to organisation ACCOUNT



Document submission interface →

Once documents are uploaded, users can view them in "Preview".





### 5h

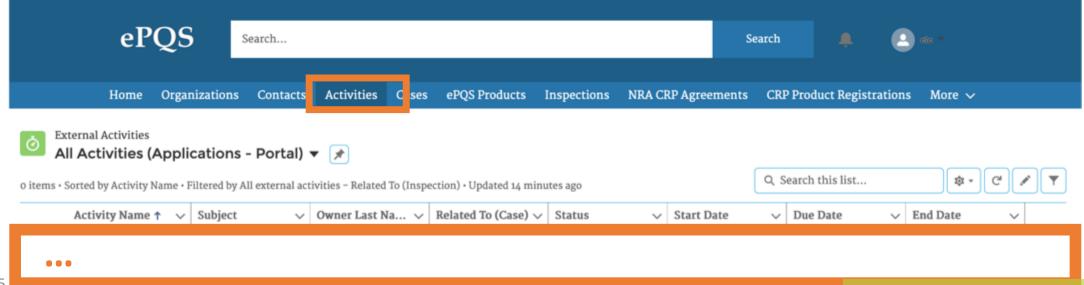
## Viewing assigned activities

#### 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. Users should note that they will automatically receive an email (via the contact-registered email address) each time a new activity is assigned.

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





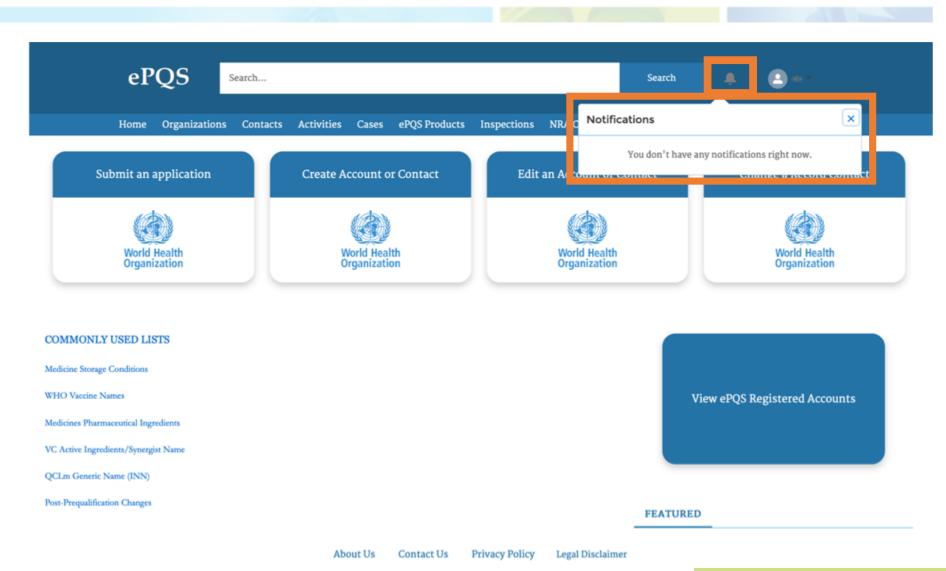
### **5**i

# Bell and email notifications & associations with actions

### 5j. Assignment of activities to applicants

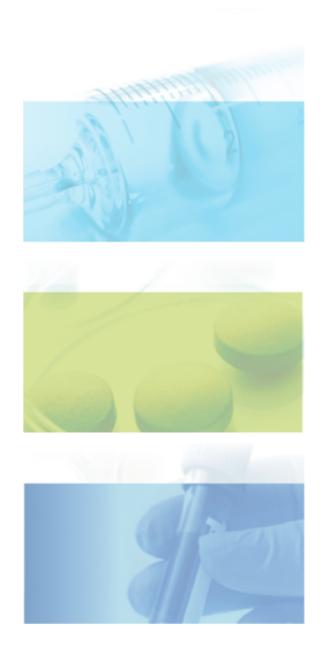


Users will find a list of any pending activities via the bell notification.





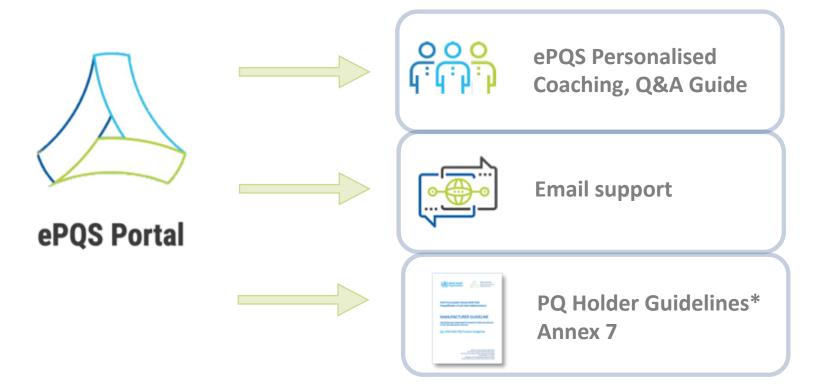
### SECTION D – TECHNICAL SUPPORT



6 **Additional** technical support

#### 6i. IMD-PQS Technical support

IMD-PQS will provide the following additional support to new users over 2025/6.



<sup>\*</sup> 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: <a href="https://extranet.who.int/prequal/epqs-portal">https://extranet.who.int/prequal/epqs-portal</a>

#### **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

ePOS - Creating or editing a Contact or Account

ePOS - Portal Introduction and Featur

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

ePOS - User Registration and accessing the ePOS Portal