

# WHO e-Prequalification System (ePQS)

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



**Prequalification Applicants**  
**Prequalification Holders**



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)

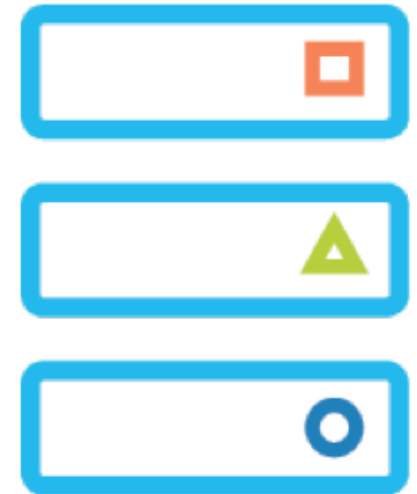
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WHO ePQS Portal landing page:

<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



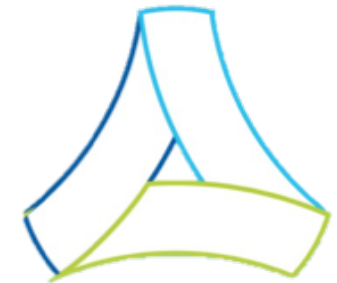
Learning materials are intended as comprehensive resources to support users gain necessary competence and autonomy in using the features and functions of ePQS. **These learning materials concern Immunization Devices (IMD-PQS) users. The deck:**

1. Explains the role(s) of ePQS in the IMD-PQS prequalification process
2. Introduces the ePQS navigation
3. 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.**

## ePQS Portal



# 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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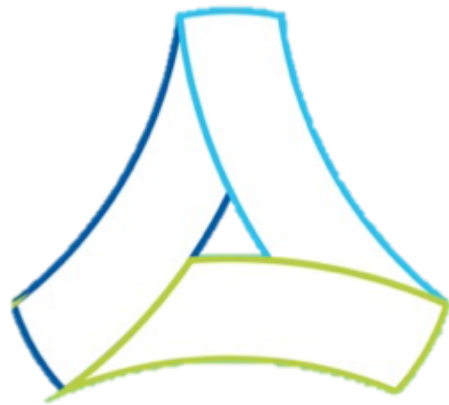
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## SECTION A – SET-UP



# 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:

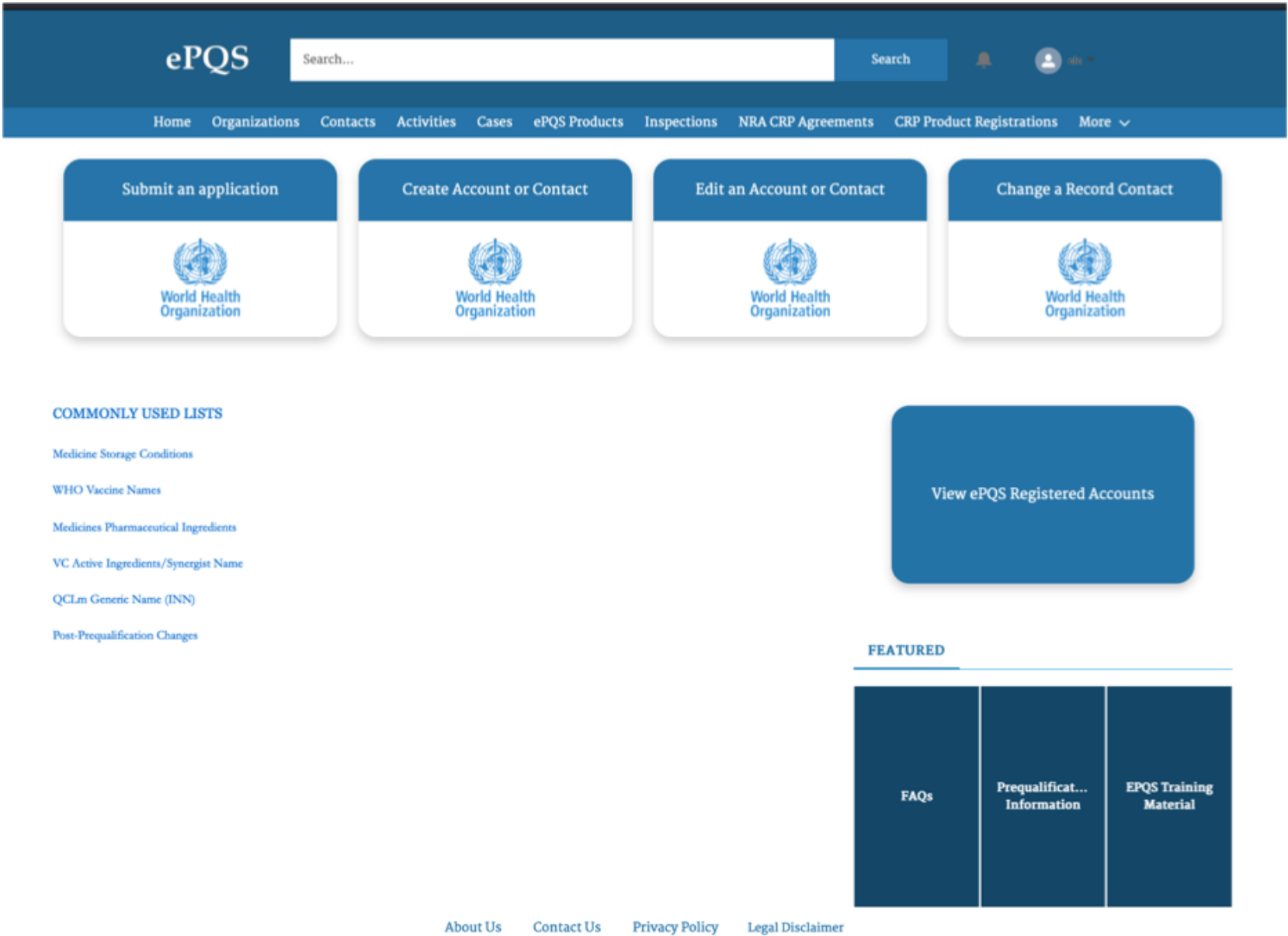
- submit & manage [prequalification applications & post-PQ variations](#)
- follow the [site inspections](#) process
- [view records](#) relevant to them
- submit required changes to account, contact & product information
- upload and download [documents](#) securely
- view and monitor [notifications for pending activities](#)

[Product annual reassessment](#) (the IMD-PQS [Annual Review](#)) will be included in the ePQS system in future (2026/7).



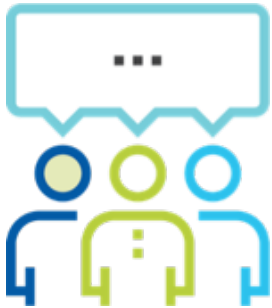
In addition to these processes, the ePQS platform **supports all communication between [applicants](#), [PQ Holders](#) and the WHO PQ** and external experts related to the workflows via a cloud file-sharing system integrated into ePQS system.

# 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)
  - 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 post-prequalification 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

ePQS

Search...

Search

Home Organizations Contacts Activities Cases ePQS Products Inspections NRA CRP Agreements **Application Wizard** More ▾

ePQS Application Wizard

Start Organization & Contacts Application Info Product Details Documents Finalize

### Create a New Application

Welcome to the Application Wizard. You can use this wizard to create a range of applications. For some application types, the wizard will also assist in the creation of an applicable Product record.

At the end of the wizard process, the created records can be saved in draft, submitted, or discarded at the end of the process.

#### Navigation

As you go through the wizard, you may be offered a chance to go back to the last screen with a 'Previous' button, to change the answers given.

At certain stages in the wizard process, the 'Previous' button will not be offered, for example when the last screen created a new record.

It is important **NOT TO USE the Back button in your browser**, as this will reset the wizard to the first screen and you are likely to lose your progress.

#### Draft Records

The wizard will be creating a draft application and, in some instances, a draft product record as you proceed through the wizard. The wizard will offer links to these records, which you can open in a separate tab. As the wizard progresses, the relevant records will be populated with the information that you supply.

If you do not submit your application at the end of the wizard process, draft records will appear in the applicable List Views on your homepage.

You can submit a previously saved draft application by opening the application and selecting the "Resume Application Wizard" from the menu in the top right-hand corner of the record.

Next

# 1. ePQS Introduction

## Quick view - Document up/download

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a 'Search' button. Below the header is a navigation menu with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows details for an 'ePQS Product' with ID 'E00X-00X'. It includes fields for Product Type (Immunisation Device), Applicant Organization (Vaccine UAT External Contact 1), Product Assessment Procedure (Prequalification - Standard), and Date of Prequalification/Acceptance (25/11/2009). Below these fields are tabs: Details, Related, Preview Document, and Document Download. The 'Document Download' tab is highlighted with an orange box. An orange arrow points from this tab to a large orange-bordered overlay window. This overlay is a Box file manager interface, showing a search bar, a folder icon, and the text 'There are no items in this folder.' at the bottom. The overlay also includes a '0 Selected' status and a close button.

ePQS

Search...

Search

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

ePQS Product  
E00X-00X

+ Follow Edit Delete Printable View

Product Type  
Immunisation Device

Applicant Organization  
Vaccine UAT External Contact 1

Product Assessment Procedure  
Prequalification - Standard

Date of Prequalification/Acceptance  
25/11/2009

Details Related Preview Document Document Download

box Search files and folders

Vx

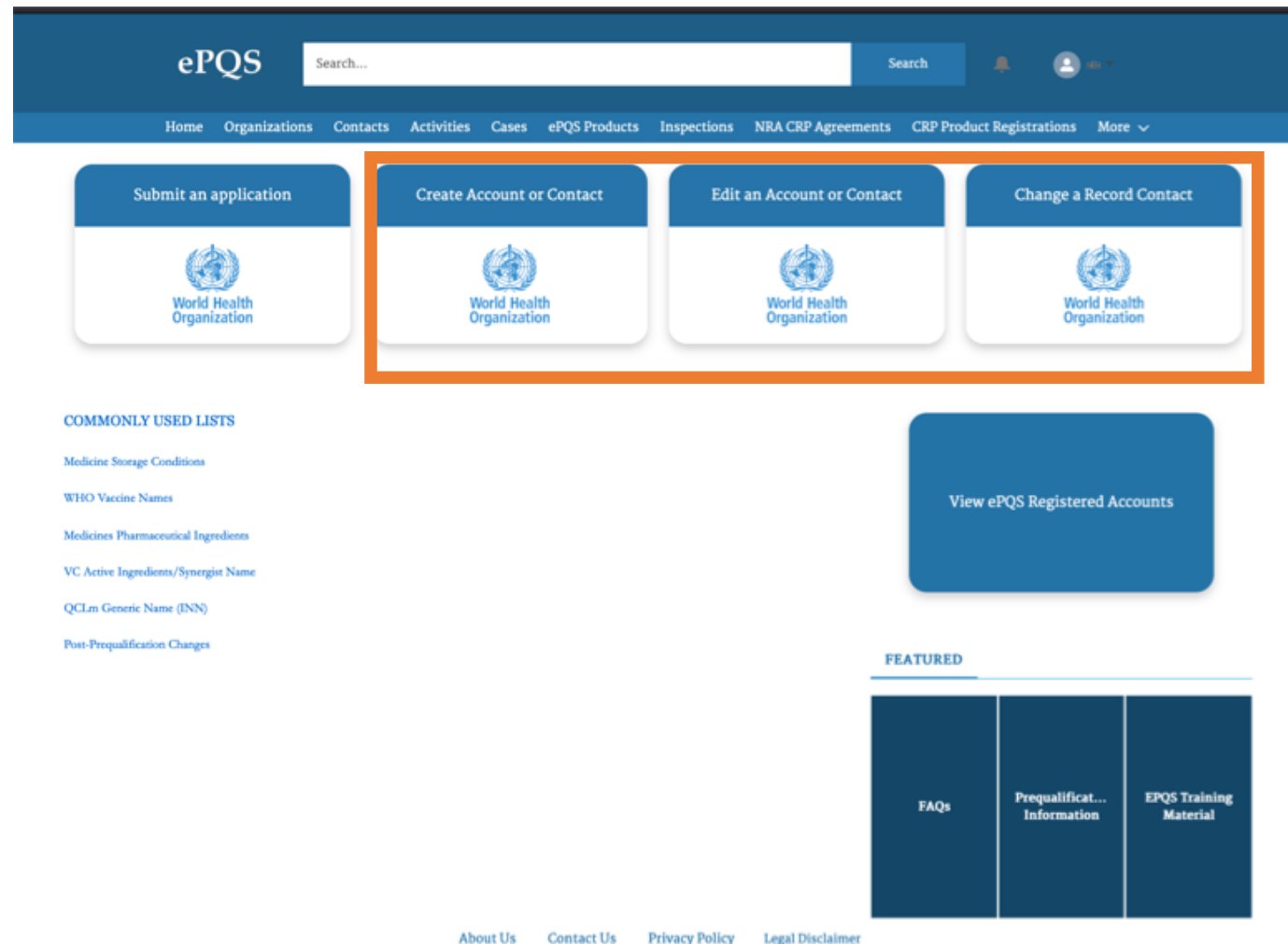
There are no items in this folder.

0 Selected

x

# 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

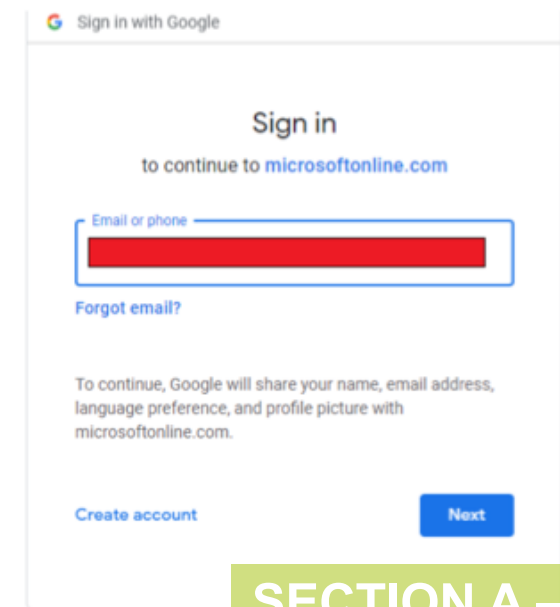
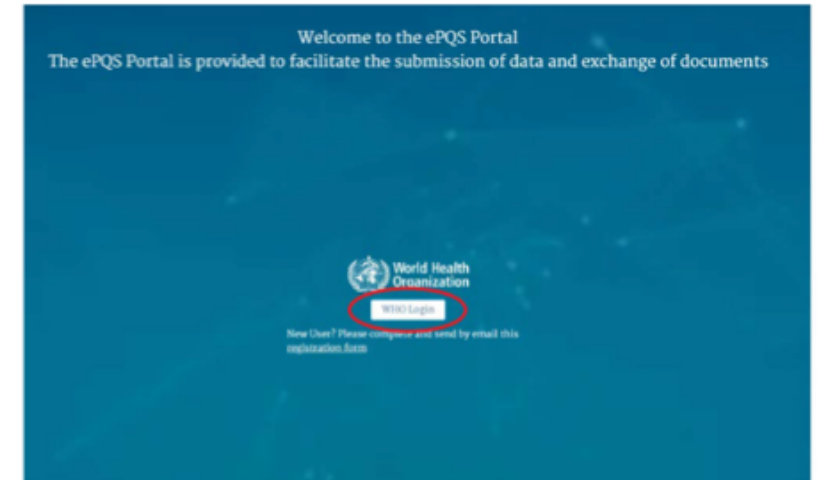
1. Account contacts have already been created for all IMD-PQS Prequalification Holders
2. Prequalification Holders must **verify their account and contact** details prior to registration. The IMD-PQS Secretariat will reach out individually to users with the required forms for this stage.
3. Contacts need to “register” to gain access to the the system.  
Registration is via the:  
**“External Form – New ePQS User”** linked here.
5. You must **complete the “External Form – New ePQS User”** and return it to [vaccprequalification@who.int](mailto:vaccprequalification@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:

1. Accessing the link:  
<https://who.my.site.com/ePQS/s/login/>
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.





# 3

## Concepts & terminology

# 3. Concepts & terminology

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**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*.



# 3. Concepts & terminology – other key terms

## “Records” and “Cases”

<b>Activity</b>	Any system activity taken in relation to an ePQS <i>case</i> .
<b>Case record type</b>	For each case, the record type will be either “Vx <i>IMD Application</i> ”, or “Vx <i>IMD Post-PQ change</i> ” or “Vx <i>IMD Reassessment</i> ”. These terms are defined below.
<b>ePQS Case ID</b>	Once opened, each case will be assigned an ID in the format “PQ-IMD-YEAR-XXXX”.



# 3. Concepts & terminology – other key terms

## Terms related to applications

<b>Application</b>	New application for product prequalification, post-PQ change (variation) or Reassessment. Submitted via the Application Wizard.
<b>Applicant organization</b>	The legal entity submitting a prequalification application or post-prequalification change.
<b>Application number</b>	Unique code assigned to each new application in ePQS, in the format “PQ-IMD-202X-XXXX”. Identical to the “ePQS Case ID”.
<b>Application wizard</b>	ePQS process assistant: a user interface that leads users through each ePQS process via a sequence of prompted, guided steps.



# 3. Concepts & terminology – other key terms

## IMD-PQS-specific application processes on ePQS

<b>Vx IMD Application</b>	IMD-PQS ePQS Application type meaning: “New application for product prequalification”.
<b>Vx IMD Post-PQ change</b>	IMD-PQS ePQS Application type meaning: “Post-prequalification variation, a change to product or manufacturing process”.
<b>Vx IMD Reassessment</b>	IMD-PQS ePQS Application type meaning: “IMD Annual Review of prequalified products”.

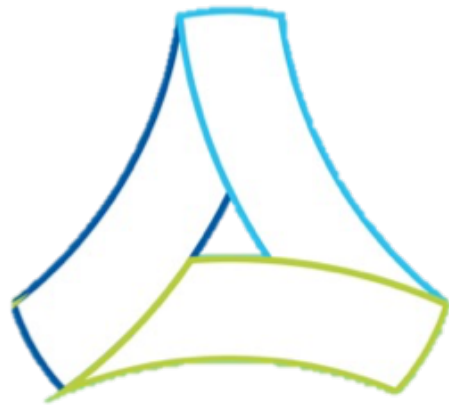


# 3. Concepts & terminology – other key terms

## Terms related to products

<b>IMD Product</b>	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.
<b>IMD Product Variant</b>	Sub-section of the unique product application/case/product record that contains the record of all of the detailed product technical specifications.
<b>(WHO) Product ID number</b>	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”.
<b>External ID</b>	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”.
<b>Product Site</b>	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.**

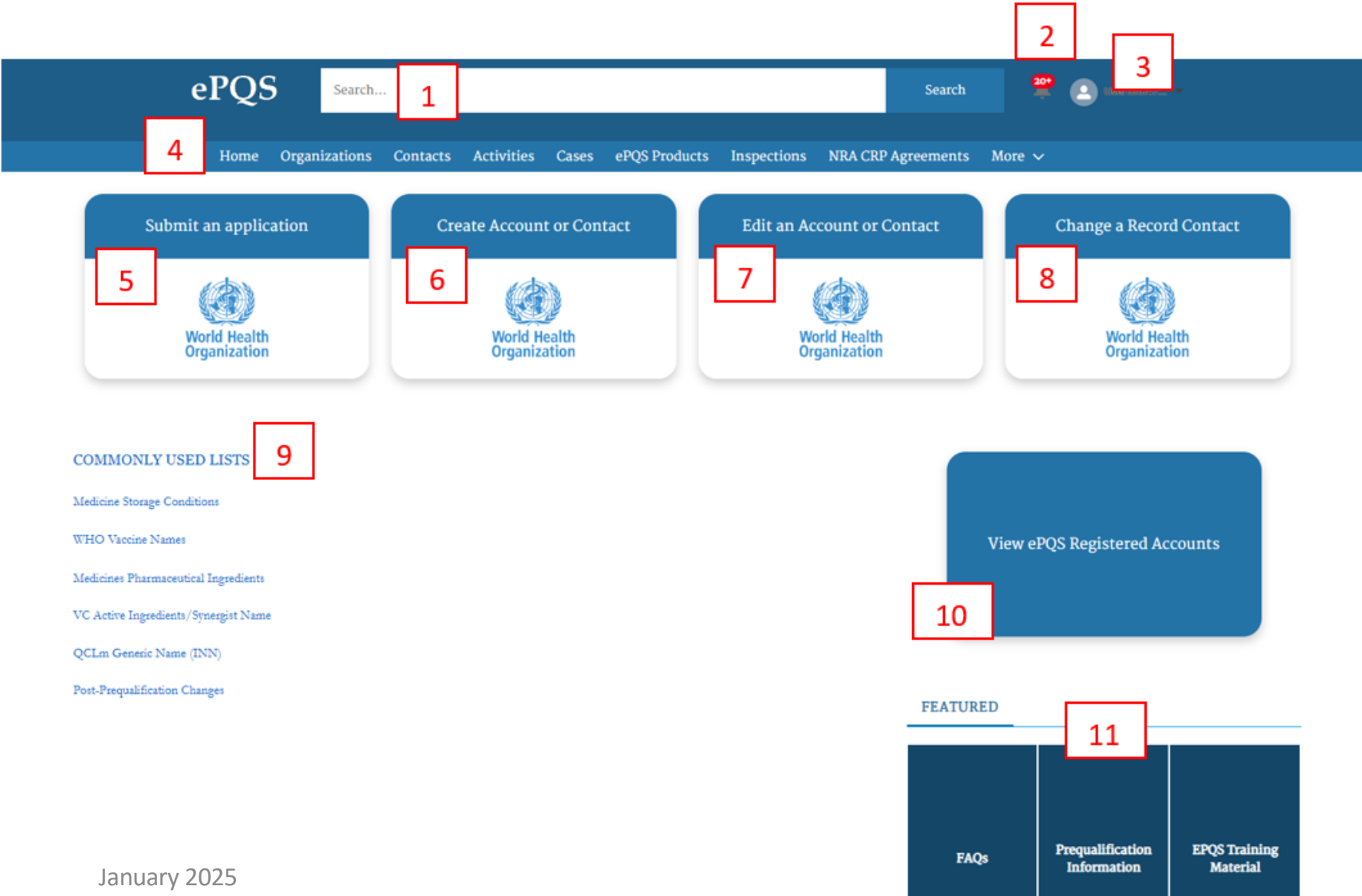
**It is intended as a learning aid and ongoing reference guide.**



# 4

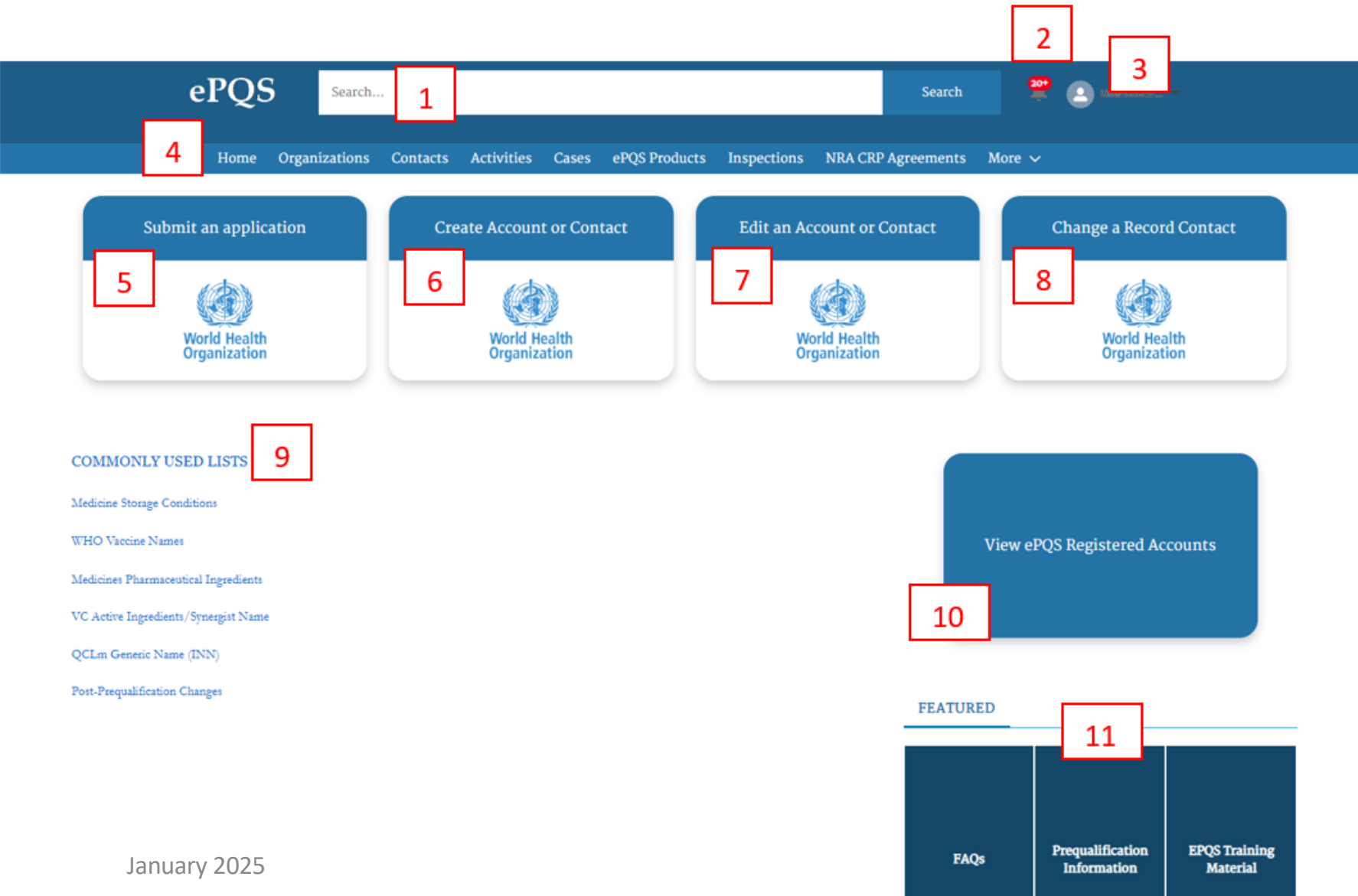
## **Navigating ePQS – General guide**

# 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.

ePQS

Search...

Search

clic

HomeOrganizationsContactsActivitiesCasesePQS ProductsInspectionsNRA CRP AgreementsCRP Product Registration

Home

My Profile

My Account

Logout

Name

Title

Email

Address

About Me

January 2025

Manager

Company Name

Active

☒

Contact

Phone

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



“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.

ePQS

Search...

Search

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

Account

+ Follow New Note DocuSign Arms Tobacco Disclosure Update Published Information

Account Record Type Address (2) Email

Home My Profile My Account Logout

Details Related Preview Documents Document Download Document Submission

Account Information

Organization UID Account Owner

Legal Name Primary Contact

Account Name Phone

Parent Account Email

Account Record Type

Description

Address Information

WHO Country Information

General Details

Related Links

PQT Information

Account Usage - Collaborators

System Information

# 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.

The screenshot shows the ePQS user interface. At the top is a dark blue header with the 'ePQS' logo, a search bar, and navigation links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. A user profile dropdown is visible on the right, with 'My Account' highlighted. Below the header is a section for 'Account' with buttons for '+ Follow', 'New Note', 'DocuSign Arms Tobacco Disclosure', and 'Update Published Information'. The main content area is titled 'Details' and has a 'Related' tab selected. It lists several record categories: 'Notes (0)', 'Related Contacts (2)' (with a table showing Contact Name, Direct, Active, and Start Date), 'Case (Applications) (6+)' (with a table showing Case Number, ePQS Case ID, Status, and Last Modified Date/Time), 'Products (Applicant Organization) (6+)' (with a 'New' button and a table showing WHO Product ID, Product Name, Vaccine Abbreviated Name, and Product Status), 'Product Sites (6+)' (with a table showing Product Site ID, Product Site Status, Site Activity, and Activity Type(s)), 'Inspections (0)', 'CRP Product Registrations (0)', 'CRP Product Registrations (NRA Organisation) (0)', 'NRA CRP Participations (NRA Organization) (0)', 'Files (0)' (with an 'Add Files' button and an 'Upload Files' button), and 'Account History (0)'. At the bottom of the page are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

## 4. ePQS navigation – Documents



**“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.

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a user profile dropdown menu. The user profile menu is open, showing options like 'Home', 'My Profile', 'My Account' (highlighted with an orange border), and 'Logout'. Below the header, there is a navigation bar with links to various sections: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. The main content area is titled 'Account' and includes a table with columns for 'Account Record Type', 'Address (2)', and 'Email'. Below this, there are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Disclosure'. The 'Preview Documents' section is highlighted with an orange border. It contains a 'box' logo and a search bar. Below the search bar, there is a table with columns for 'Name', 'Modified', and 'Size'. Two folders are listed: 'External correspondence' and 'Submitted Documents', both showing '0 Byte' size.

Name	Modified	Size
External correspondence	Fri Apr 12 2024	0 Byte
Submitted Documents	Fri Apr 12 2024	0 Byte

## 4. ePQS navigation – Documents



**“Download documents”** allows users to download and save locally all the documents related to their account.

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a user profile icon. Below the header is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registrations. A dropdown menu is open for the user profile, showing options: Home, My Profile, My Account (highlighted with an orange border), and Logout. Below the navigation bar, there is a section for 'Account' with a table of account records. The table has columns for Account Record Type, Address (2), and Email. Below the table, there are tabs for Details, Related, Preview Documents, Document Download (highlighted with an orange border), and Document Submission. The Document Download tab is active, showing a 'box' logo and a search bar. Below the search bar, there is a list of folders: 'External correspondence' and 'Submitted Documents', both modified on Fri Apr 12 2024 and 0 Byte. At the bottom, there is a selection bar showing '0 Selected' and a confirmation button.

## 4. ePQS navigation – Documents



“Document submission” enables users to upload documents to their account.

ePQS

Search...

Search

edf

[Home](#)[Organizations](#)[Contacts](#)[Activities](#)[Cases](#)[ePQS Products](#)[Inspections](#)[NRA CRP Agreements](#)[CRP Product Registration](#)

Account

+ Follow

New Note

DocuSign Arms Tobacco Disclosure

U

Account Record Type

Address (2) ▼

Email

Home

My Profile

My Account

Logout

Details

Related

Preview Documents

Document Download

Document Submission

Upload to Account Submission

Welcome to Document Submission Wizard. Please click on **Next** to proceed for Account#Vestfrost Solutions

Next

About Us

Contact Us

Privacy Policy

Legal Disclaimer


## 4. ePQS navigation – Documents



**“Document submission”** interface allow users to upload documents by drag-and-drop or browsing their device.

Details   Related   Preview Documents   Document Download   **Document Submission**

Upload to Account Submission



Drag and drop files and folders  
[Browse your device](#) or [Select Folders](#)

## 4. ePQS navigation – Wizard



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

ePQS

Search...

Search

Notifications

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

Submit an application

Create Account or Contact

Edit an Account or Contact

Change a Record Contact

World Health Organization

World Health Organization

World Health Organization

World Health Organization

COMMONLY USED LISTS

Medicine Storage Conditions

WHO Vaccine Names

Medicines Pharmaceutical Ingredients

VC Active Ingredients/Synergist Name

QCLm Generic Name (INN)

Post-Prequalification Changes

View ePQS Registered Accounts

## 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.

The screenshot displays the ePQS homepage. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a 'Search' button. To the right of the search bar are icons for notifications and a user profile. Below the header is a navigation bar with the following tabs: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and a 'More' dropdown menu. The main content area features four large blue buttons, each with the World Health Organization logo and text: 'Submit an application', 'Create Account or Contact', 'Edit an Account or Contact', and 'Change a Record Contact'. These four buttons are highlighted by an orange rectangular border. Below this row, on the left, is a section titled 'COMMONLY USED LISTS' with links to 'Medicine Storage Conditions', 'WHO Vaccine Names', 'Medicines Pharmaceutical Ingredients', 'VC Active Ingredients/Synergist Name', 'QCLm Generic Name (INN)', and 'Post-Prequalification Changes'. On the right side of the main content area, there is a large blue button labeled 'View ePQS Registered Accounts'.

## 4. ePQS navigation – Notes



Under the users **“account”** interface, users may also create **“notes”**.

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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a user profile icon. Below the header is a navigation menu with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registrations. On the right side, a dropdown menu is open, showing options: Home, My Profile, My Account (highlighted with an orange box), and Logout. In the main content area, there is a 'New Note' button (highlighted with an orange box) and a '+ Follow' button. An orange callout arrow points from the 'New Note' button to a 'New Note' window. This window has a title bar 'New Note' and a content area with a text input field and a 'Share' button (highlighted with an orange box) at the bottom right.

## 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”

The screenshot shows the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a user profile icon. Below the header is a navigation bar with tabs: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The 'Organizations' tab is highlighted with an orange box. Below the navigation bar, there is a section titled 'Accounts' with a sub-header 'ePQS Accounts (Portal)'. A dropdown menu is open, showing a list of views: 'All Vx accounts', 'ePQS Accounts (Portal)' (selected with a blue checkmark), 'Recently Viewed (Pinned list)', and 'Recently Viewed Accounts'. To the right of the dropdown menu, there is a search bar labeled 'Search this list...' and a table with a column header 'Country (Physical)'.

## 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”

The screenshot shows the ePQS web application interface. At the top is a dark blue header with the ePQS logo, a search bar, and a user profile icon. Below the header is a navigation menu with tabs: Home, Organization, **Contacts** (highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation menu, the 'Contacts' section is active, showing a dropdown menu with three options: 'All ePQS Contacts (Portal)' (selected), 'Recently Viewed (Pinned list)', and 'Recently Viewed Contacts'. To the right of the dropdown is a search bar labeled 'Search this list...' and three icons (settings, refresh, filter). Below the dropdown is a table with two columns: 'Account Name' and 'Account: Legal Name'. The table contains two rows, both with the value 'Vestfrost Solutions'.

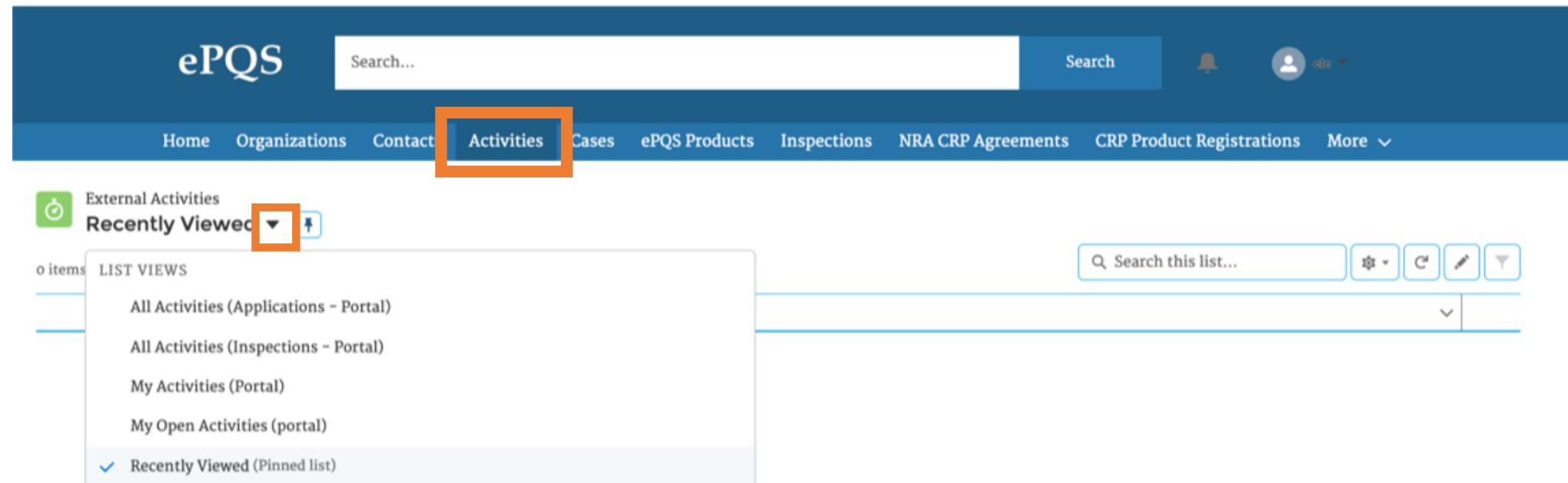
	Account Name	Account: Legal Name
1	Vestfrost Solutions	Vestfrost Solutions
2	Vestfrost Solutions	Vestfrost Solutions

## 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”.

The screenshot shows the ePQS web application interface. At the top is a dark blue header with the 'ePQS' logo, a search bar, and user account icons. Below this is a navigation bar with tabs: Home, Organizations, Contacts, Activities, **Cases** (highlighted with an orange box), PQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, the 'Cases' section is active, showing a dropdown menu for 'All Cases (Portal)' (also highlighted with an orange box). The dropdown menu lists four options: 'All Cases (Portal)' (selected with a blue checkmark), 'All Closed Cases (Portal)', 'All Open Cases (Portal)', and 'Recently Viewed (Pinned list)'. To the right of the dropdown, there is a 'Printable View' button and a search bar for the list. Below the dropdown, a table of cases is visible with columns: Application S..., WHO Pro..., Date Appl..., Date Appl..., and Date of Pr... The table contains four rows of data, each with a 'Standard' application and a date of '01/01/1900'.

	Application S...	WHO Pro...	Date Appl...	Date Appl...	Date of Pr...
1	Standard		01/01/1900	01/01/1900	
2	Standard		01/01/1900	01/01/1900	
3	Standard		01/01/1900	01/01/1900	
4	Standard		01/01/1900	01/01/1900	

## 4. ePQS navigation – Products



Likewise, a list of all “**products**” related to a user’s account is available via the main tab.

The screenshot shows the ePQS web application interface. The navigation bar at the top includes the ePQS logo, a search bar, and a user profile icon. The 'ePQS Products' tab is highlighted in the navigation bar. Below the navigation bar, the 'ePQS Products' section is visible, showing a dropdown menu for 'All Products (Portal)'. The dropdown menu lists four options: 'All Active Products (Portal)', 'All Closed Products (Portal)', 'All Products (Portal)' (which is selected and marked with a checkmark), and 'Recently Viewed (Pinned list)'. The main content area displays a table of products. The table has columns for 'Product Subtype', 'Date of Preq...', 'Date of ...', and 'Date of Pro...'. The table shows three rows of data, each with a product subtype 's' and a date.

Product Subtype	Date of Preq...	Date of ...	Date of Pro...
s	25/11/2009		
s	18/03/2010		
s	14/07/2010		

## 4. ePQS navigation – Inspections



And a list of all **“Inspections”** related to a user’s product sites is available via the main tab.

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header bar with the 'ePQS' logo on the left, a search bar in the center, and a 'Search' button on the right. Below the header is a horizontal navigation bar with several tabs: 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'CRP Product Registrations', and 'More'. The 'Inspections' tab is highlighted with an orange box. Below the navigation bar, the 'Inspections' section is active, showing a dropdown menu for 'All Inspections (Portal)' which is also highlighted with an orange box. The dropdown menu lists 'LIST VIEWS' with two options: 'All Inspections (Portal)' (selected with a blue checkmark) and 'Recently Viewed (Pinned list)'. To the right of the dropdown menu, there is a search bar labeled 'Search this list...' and three icons: a settings gear, a refresh arrow, and a filter funnel. Below the dropdown menu, a table header is visible with columns: 'Site Contact', 'Manner of Inspection', and 'Inspection Type', each with a dropdown arrow.

## 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





# 5a

## Verification of product data sheets

## 5a. Verification of product records



### TASK

Once registration and access is **obtained**, 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:  
[pqsinfo@who.int](mailto:pqsinfo@who.int) & [huckerbyg@who.int](mailto:huckerbyg@who.int)

# 5a. Verification of product data records



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

The screenshot displays the ePQS web application interface. The top navigation bar includes a search bar and various menu items. The left sidebar shows the 'ePQS Products' section with a dropdown menu. The main content area displays a table of product data records.

WHO Product ID	Applicant Organization	Product Status	Date of Application ...	Date of Prequalificat...	Date of Product Can...
E001-		Prequalified	01/01/1900	17/08/2010	
E001-		Prequalified	01/01/1900	20/04/2011	
E001-		Prequalified	01/01/1900	25/10/2011	

# 5a. Verification of product data records



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

Important: users need to progress further to the “**Product Variant page**” to see product’s technical specifications.

Users should click on the “**Related**” sub-tab.

ePQS Product E001-001	
Product Type	Immunisation Device
Applicant Organization	
Product Assessment Procedure	Prequalification - Standard
Date of Application Submission	01/01/1900
Date of Prequalification/Acceptance	17/08/2010

Details | **Related** | Document | Activity | Chatter | Audit Trail

Comments

Information

WHO Product ID	E001-
Product Name	
Product Description	
Product Type	Immunisation Device
Product Subtype	E001: Cold rooms, freezer rooms, and related equipment
Responsible team	Vaccines Team
Product Assessment Procedure	Prequalification - Standard
Applicant Organization	
Applicant Organization (Legal)	
Primary Contact	
Secondary Contact	
Alternative Secondary Contact	
Site Address	

# 5a. Verification of product data records



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

Select the record displayed under “**IMD Product Variant**”



ePQS Product E001-005

Product Type: Immunisation Device | Applicant Organization: | Product Assessment Procedure: Prequalification - Standard | Date of Application Submission: 01/01/1900 | Date of Prequalification/Acceptance: 05/06/2019

Details **Related** Document Activity Chatter Audit Trail

**Product Sites (1)**  
1 item - Updated a few seconds ago

<input type="checkbox"/>	Product Site ID	Product Site Status	Site	Site Activity	Activity Type(s)
1		Accepted		IMD Manufacture	Refrigerators and freezers

[View All](#)

**IMD Product Variants (WHO Product ID) (1)**  
1 item - Updated a few seconds ago

<input type="checkbox"/>	IMD Variant Ref.
1	

**Applications (1)**  
1 item - Updated a few seconds ago

<input type="checkbox"/>	Case Number	ePQS Case ID	Status	Application Type	Application Subty...	Date Application A...	Date of Prequalificat...
1			Prequalified	Prequalification	Standard	01/01/1900	05/06/2019

[View All](#)

**Commitments/Established Conditions (0)** [New](#)

**Fees (0)** [New](#)

**Files (0)** [Add Files](#)

# 5a. Verification of product data records



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](mailto:pqsinfo@who.int) & [huckerbyg@who.int](mailto:huckerbyg@who.int)

- To report issues please use the templates on the following slide.

The screenshot displays the 'IMD Product Variant' page for 'E001'. The page is divided into several sections, each with a dropdown arrow. The 'Product identification' section includes fields for 'IMD Variant Ref', 'IMD Product ID', 'Product Name', 'Device sub-category', and 'Manufacturer'. The 'Product specifications - Main' section includes fields for 'Temperature Class', 'Temperature Class (Other)', 'Maximum time (h)', 'Maximum time (d)', 'Maximum time (y)', 'Pre-qualified region', 'Auto-approval', 'Pre-qualified region', and 'Auto-approval'. The 'Enclosure construction options' section includes fields for 'Cold room class available (except, n/a)', 'Cold room class available (except, n/a)', 'Pressure room class available (n/a)', 'Pressure room class available (n/a)', 'Door size options available', 'Door frame handling available', 'Panel insulation material', 'Panel joining system', 'Panel thickness options', 'Strapping system', 'Strapping material', 'Strapped wall construction', 'Stitching available', 'Pressure release valve (PR valve)', 'Floor panel heater mat (PR mat)', 'Modulating panel/foam', 'Floor panel finish', and 'Type of Training Agent'. The 'Product specifications - Equipment options' section includes fields for 'Refrigerant', 'Refrigerant unit mounting options', 'Refrigerant unit type', 'Lighting system', 'Data sharing', 'Cold climate protection (C)', 'Explosion alarm guard (C)', 'IMO 1001/1000 certified', 'IMO 1001/1000 certified (Other)', 'Explosion Safety Compliance (to BS 5337)', 'Intrinsically safe protection', 'Voltage Frequency/Phase options?', 'Voltage Regulator Available?', 'Surge Protection Available?', and 'Explosion system'. The 'Product specifications - Temperature monitoring & alarm options' section includes fields for 'Temperature recording system', 'Alarm system', and 'IMO 1001 certified'. The 'Warranty, installation and maintenance' section includes fields for 'Warranty period (months)', 'Maintenance service', and 'Installation service'. The 'Quality standard' section includes fields for 'Quality standard', 'Quality standard (Other)', and 'Specification Reference'. The 'Verification' section includes fields for 'Verification laboratory' and 'Verification Report Reference'. The 'Records' section includes fields for 'Remarks for Publishing', 'Created By', 'Last Modified By', and 'Published Record Details'. The 'Published Record Details' section includes fields for 'Published Stringent?' and 'Published Stringent Record'.



# 5a. Verification of product data records



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



# 5b

**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”**.

ePQS Search... Search

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

Submit an application  
World Health Organization

Create Account or Contact  
World Health Organization

Edit an Account or Contact  
World Health Organization

Change a Record Contact  
World Health Organization

COMMONLY USED LISTS

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

View ePQS Registered Accounts

## 5b. Accessing registered accounts



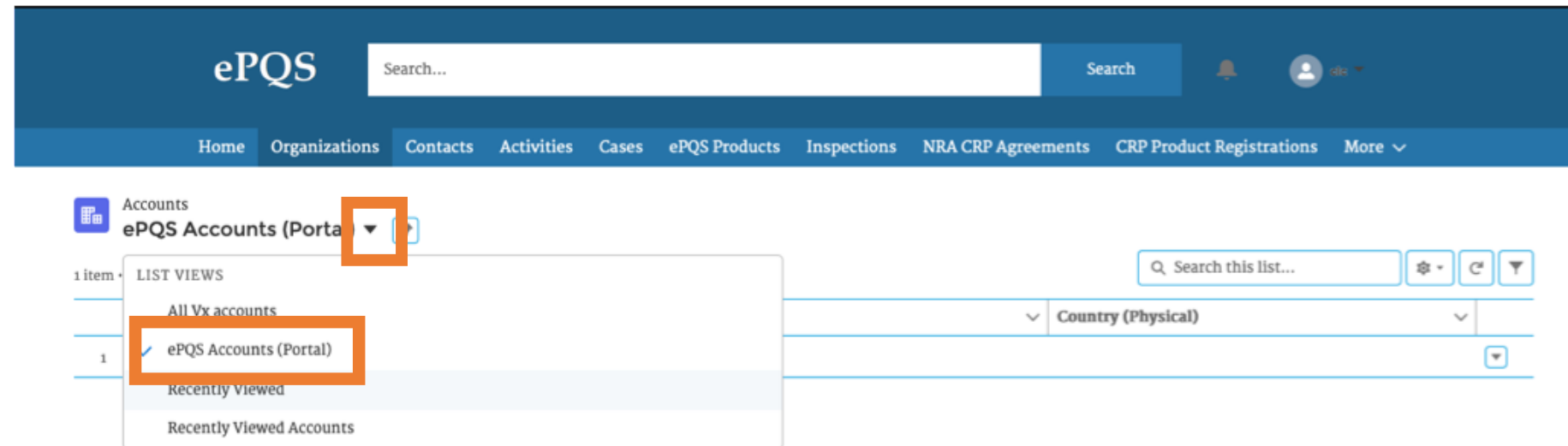
Users may select different **list views**.

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:

[pqsinfo@who.int](mailto:pqsinfo@who.int) & [huckerbyg@who.int](mailto:huckerbyg@who.int)

The screenshot displays the ePQS (e-Personal Quality System) web application. The top navigation bar includes the ePQS logo, a search bar, and a user profile dropdown menu with options: Home, My Profile, My Account, and Logout. Below the navigation bar, the main content area shows the profile of 'vestrost solutions'. It includes a 'Follow' button, a 'New Note' button, and a 'DocuSign Arms Tobacco Dis' button. The profile details are organized into sections: Account Record Type (Non-State Actor), Address (2), and Email. Below these, there are tabs for 'Details', 'Related', 'Preview Documents', 'Document Download', and 'Document Submission'. The 'Details' tab is active, showing a list of expandable sections: Account Information, Address Information, WHO Country Information, General Details, Related Links, PQT Information, Account Usage - Collaborators, and System Information. At the bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.



# 5c

**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”**.

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a user profile icon. The user profile icon is highlighted with an orange box and a red circle with the number 1. A dropdown menu is open from this icon, showing options: Home, My Profile, My Account (highlighted with an orange box and a red circle with the number 1), and Logout. Below the header, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Products. The main content area shows an 'Account' section with a 'Non-State Actor' record type. Below this, there are tabs: Details, Related (highlighted with an orange box and a red circle with the number 2), Preview Documents, Document Download, and Document Submission. The 'Related' tab is active, showing a list of related information items: Account Information, Address Information, WHO Country Information, General Details, Related Links, PQT Information, Account Usage - Collaborators, and System Information.

# 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

The screenshot shows the ePQS 'Related' sub-tab interface. The top navigation bar includes 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'CRP Product Registrations', and 'More'. The 'Related' sub-tab is selected, and an orange arrow points to the list of record types. The list includes:

- Notes (0)
- Related Contacts (2)
- Product Sites (6+)
- Case (Applications) (6+)
- Products (Applicant Organization) (6+)
- Inspections (0)
- CRP Product Registrations (0)
- CRP Product Registrations (NRA Organisation) (0)
- NRA CRP Participations (NRA Organization) (0)
- Files (0)
- Account History (0)



# 5cii. Correct record visibility - Products

## Products

Expand or click directly on the Products sub-tab.

ePQS

Search...

Search

Home

Organizations

Contacts

Activities

Cases

ePQS Products

Inspections

NRA CRP Agreements

CRP Product Registrations

More

Account

+ Follow

New Note

DocuSign Arms Tobacco Disclosure

Update Published Information

Account Record Type

Address (1)

Email

Non-State Actor

Details

Related

Preview Documents

Document Download

Document Submission

Notes (0)

Related Contacts (2)

Contact Name	Direct	Active	Start Date
--------------	--------	--------	------------

Product Sites (6+)

Product Site ID	Product Site Status	Site Activity	Activity Type(s)
-----------------	---------------------	---------------	------------------

Case (Applications) (6+)

Case Number	ePQS Case ID	Status	Last Modified Date/Time
-------------	--------------	--------	-------------------------

Products (Applicant Organization) (6+)

New

WHO Product ID	Product Name	Vaccine Abbreviated Name	Product Status
----------------	--------------	--------------------------	----------------

Inspections (0)

CRP Product Registrations (0)

CRP Product Registrations (NRA Organisation) (0)

NRA CRP Participations (NRA Organization) (0)

Files (0)

Add Files

Upload Files

Or drop files

Account History (0)

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Contact Us

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SECTION C – PILOT

# 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.

**ePQS** Search... Search

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

Accounts > Vestfrost Solutions  
**Products (Applicant Organization)**  
29 items • Updated a few seconds ago

New

Product listing details ...

Product listing details ...

Product listing details ...

Product listing details ...

Product listing details ...

Product listing details ...

Product listing details ...

Product listing details ...

Product listing details ...

Product listing details ...

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# 5d

## 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.

The screenshot shows the ePQS web application interface. The top navigation bar is dark blue with the ePQS logo, a search bar, and a user profile icon. Below the navigation bar, the 'Contacts' tab is highlighted with an orange box. The main content area shows 'All ePQS Contacts (Portal)' with a search bar and a table of contacts. The table has two items, with the first item 'YOUR NAME' highlighted by an orange box. The table headers are '1' and '2'.

1	2
YOUR NAME	

## 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 not private. Internal users (IMD-PQS) can view all external user Personal Folders.

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a user profile icon. Below the header is a navigation bar with tabs: Home, Organization, **Contacts** (highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows a contact record for 'Contact'. Below the contact information, there are tabs: Details, Related, **Preview Documents** (highlighted with an orange box), Download Documents, Preview Mx Documents, and Download Mx Documents. The 'Preview Documents' tab is active, showing a 'box' logo and a search bar. Below the search bar, there is a folder named 'YOUR Personal Folder' (highlighted with an orange box). To the right of the folder name is a '+ ' icon (highlighted with an orange box). Below the folder name, there is a message: 'There are no items in this folder.' At the bottom of the page, there are links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer.



# 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:

ePQS Application Wizard

Start

Organization & Contacts

Application Info

Product Details

Documents

Finalize

### Create a New Application

Welcome to the Application Wizard. You can use this wizard to create a range of applications. For some application types, the wizard will also assist in the creation of an applicable Product record.

At the end of the wizard process, the created records can be saved in draft, submitted, or discarded at the end of the process.

#### Navigation

As you go through the wizard, you may be offered a chance to go back to the last screen with a 'Previous' button, to change the answers given.

At certain stages in the wizard process, the 'Previous' button will not be offered, for example when the last screen created a new record.

It is important **NOT TO USE the Back button in your browser**, as this will reset the wizard to the first screen and you are likely to lose your progress.

#### Draft Records

The wizard will be creating a draft application and, in some instances, a draft product record as you proceed through the wizard. The wizard will offer links to these records, which you can open in a separate tab. As the wizard progresses, the relevant records will be populated with the information that you supply.

If you do not submit your application at the end of the wizard process, draft records will appear in the applicable List Views on your homepage.

You can submit a previously saved draft application by opening the application and selecting the “Resume Application Wizard” from the menu in the top right-hand corner of the record.

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## 5e. Application submission procedure

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 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

# 5e. Application submission procedure



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

# 5e. Application submission procedure



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 list of application types available.

\* Application Type

☒ Prequalification

☐ Post-PQ Change

☐ Reassessment

Previous

Next

## 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
- Organization: Vaccine UAT External Test Account 1
- Primary Contact: Vaccine UAT External Contact 1

Previous

Next

## 5e. Application submission procedure



The Wizard will provide the your **case number**.  
Make a physical note of this reference number:

ePQS Application Wizard

Organization & ContactsApplication InfoProduct DetailsDocumentsFinalize

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

# 5e. Application submission procedure



Next, select the “**Product Subtype**” (the IMD-PQS Product Category):

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Additional Application Info

\* Product Subtype

- ✓ E001: 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

## 5e. Application submission procedure



The Wizard will provide the **application number** (which is the same as the case number shown previously):

ePQS Application Wizard

Organization & Contacts

✓

Product Details

Documents

Finalize

### Create a Product

**New Product**  
Since this is a Prequalification type application, a new product will be created of type:

- Immunization Device (IMD): E001: Cold rooms, freezer rooms, and related equipment

It will be linked to your application [PQ-IMD-2023-0040](#).

Previous

Next



## 5e. Application submission procedure

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

✓

Product Details

Documents

Finalize

Create a Product

Further Vx IMD Details

*(Please fill out all required fields)*

\*Product Name

Product Description

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, m3)

Range of cold room sizes available large (largest, m3)

Freezer room sizes (smallest, m3)

Freezer room sizes (largest, m3)

\* Pre-qualified regions

--None--

\* ISO 9001/13485 certified

--None--

\* ISO 14001 certified

--None--

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

## 5e. Application submission procedure



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

✓

Product Details

Documents

Finalize

Create IMD Product Variants

Success  
IMD Product Variant Ref. **IMDV-00033** created.

Next



## 5e. Application submission procedure

Next, it is possible to provide information about the “**product site**” (the site of product manufacture). Select “Product Site” if the product is being manufactured on a site that is **different from the site already registered in ePQS** (accessible under *Account* → *Related* → *Product sites*)

Otherwise, select “I don’t want to add any more product related information at this time”:

The screenshot displays the 'ePQS Application Wizard' interface. At the top, a progress bar shows five steps: 'Organization & Contacts' (completed, dark blue), two green steps with checkmarks, 'Product-Related Info' (current step, light blue), 'Documents' (grey), and 'Finalize' (grey). Below the progress bar, the section is titled 'Add Product Related Information'. A red asterisk indicates a required selection: '\* Choose Product Related Information to Add to Application'. Two radio button options are listed: 'Product Site' and 'I don't want to add any more product related information at this time'. The second option is selected with a blue dot. At the bottom right, there are 'Previous' and 'Next' buttons.

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 Next

# 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:



ePQS Application Wizard


Organization & Contacts ✓ ✓ ✓ Documents Finalize

### Upload Documents

Please attach all supporting documentation for your application below. Either drag-and-drop or select one or more files from your desktop, and then click Upload to attach them to this application.

You can review the folders for submission in the next page. There you can also rename, tag or remove documents. You can return to this screen to upload additional documents as part of this submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review documents once again before final submission.

When finished, click Next.



Drag and drop files and folders  
Browse your device or [Select Folders](#)

Cancel

Upload

January 2025

## 5e. Application submission procedure



### 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 Section 3.4.3 of the [\*IMD-PQS Prequalification Holder Guidelines\*](#) for a generic list of the documentation that must be provided for a complete application for each product category.

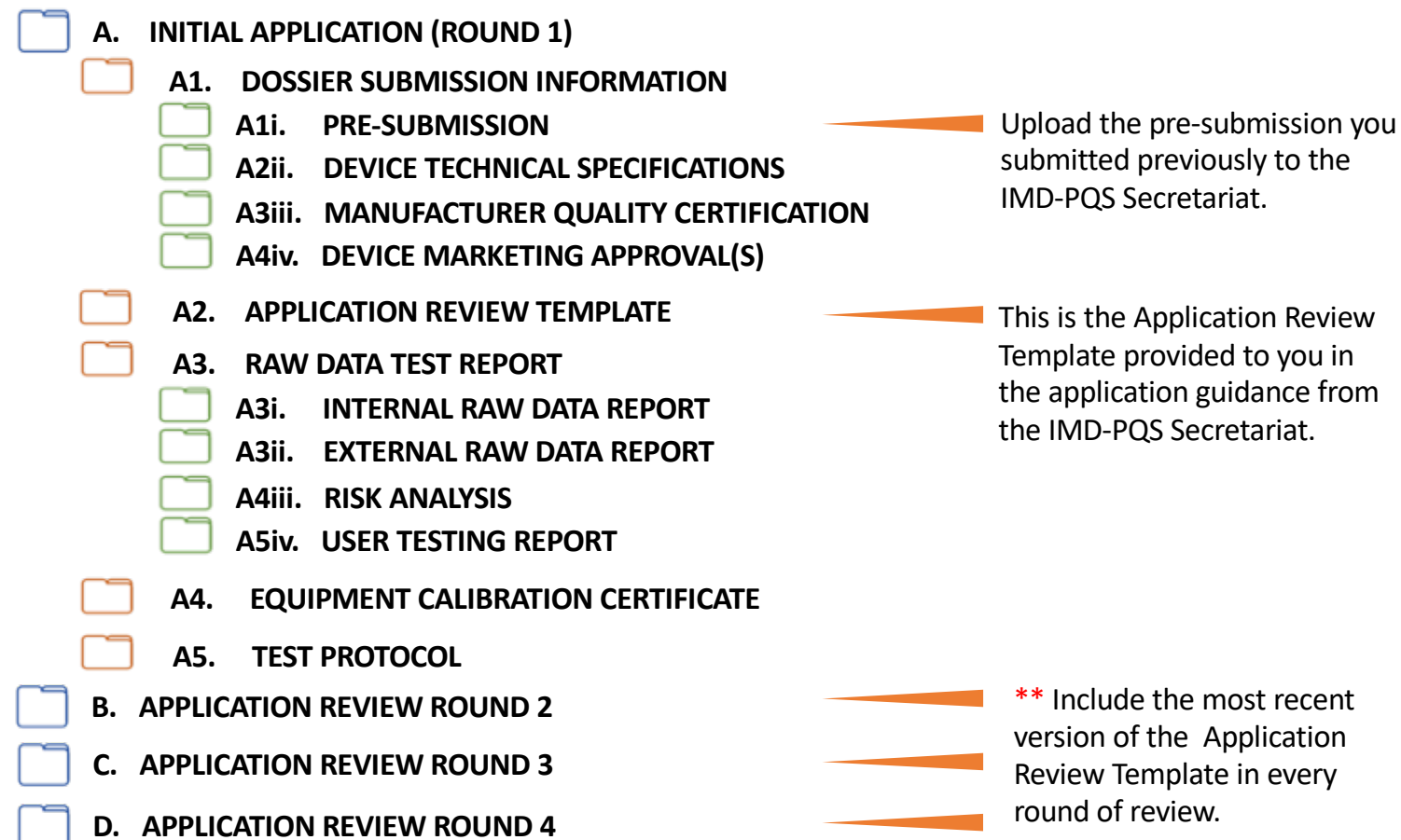
The Prequalification Guidelines can be downloaded from: <https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-applicants-prequalification-holders>



# 6e. Application submission procedure

## MANDATORY folder structure

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



- This folder structure is **mandatory**.
- However, applicants are only required to create and upload the **specific folders and subfolders that are relevant** and required for their application.
- Refer to the detailed list of application requirements provided to you by the WHO IMD-PQS Secretariat.
- **Application review templates** are available at:  
<https://extranet.who.int/prequal/immunization-devices/application-dossier-requirements>



# 6e. Application submission procedure

## MANDATORY folder structure

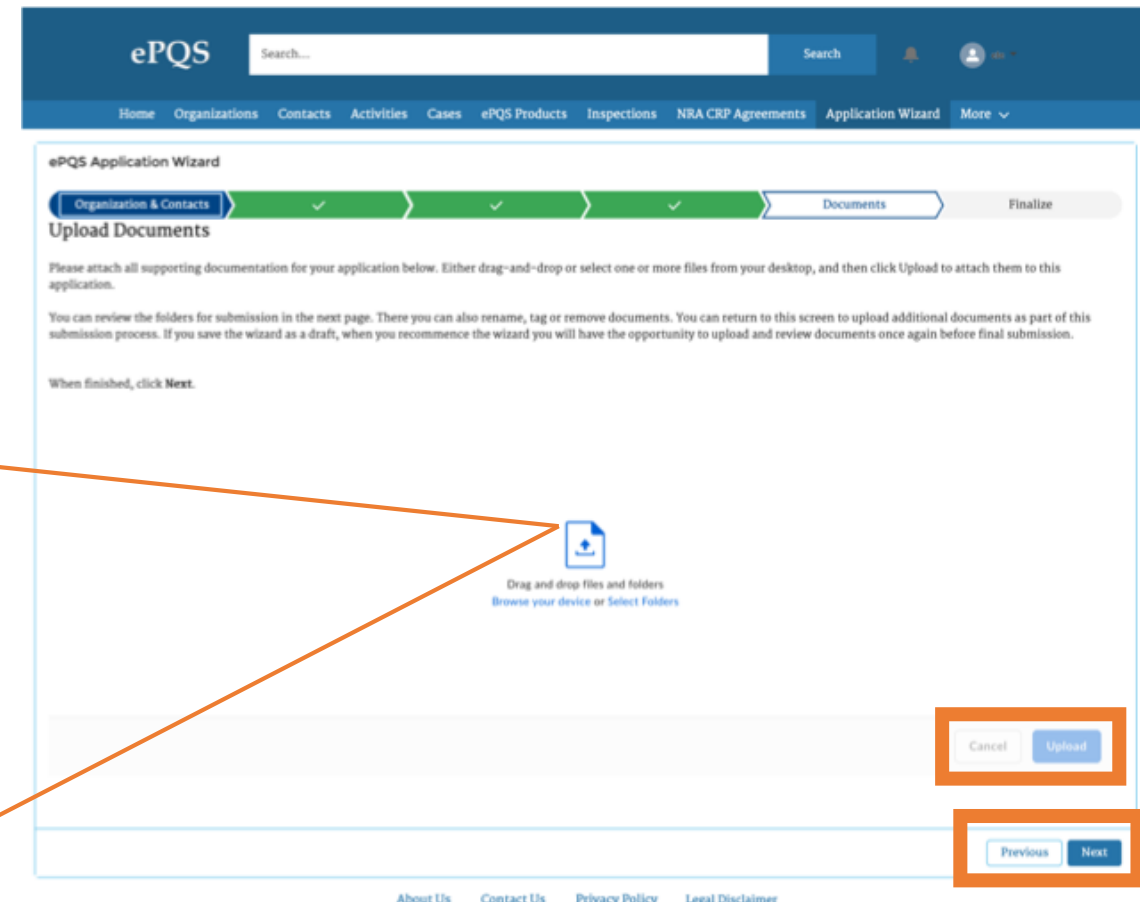
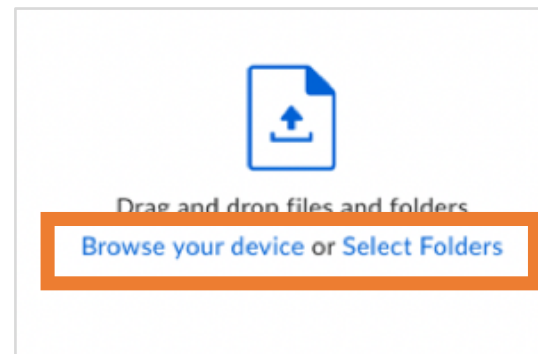
- 1 Users should **create the folder structure locally** on their computer.

OR **download the folder structure\*** in .zip format:

[https://drive.google.com/drive/folders/1BpGTOUmRs7K8hFHiXL1USSr\\_I6uGq7e5](https://drive.google.com/drive/folders/1BpGTOUmRs7K8hFHiXL1USSr_I6uGq7e5)



- 2 Then, users should **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).





## 5e. Application submission procedure

### MANDATORY folder structure

- 3 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.

ePQS

Search...

Search

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

ePQS Resume Wizard

Organization & Contacts Documents Finalize

Document Review

Please review the documents and folders you intend to upload. You may navigate through the folder structure, renaming and deleting folders as necessary. If you wish to upload further documents or folders please use the Previous button to return to the Upload document page. Document type meta-data may also be added to individual documents by opening these documents and adding the metadata value via the document menu that appears.

box Search files and folders

2024-09-19-20:54

Name	Modified	Size
1. Dossier submission information	Today by WHO_JWT	8 KB
2. Completed ART	Today by WHO_JWT	0 Byte
3. Raw data test report	Today by WHO_JWT	8 KB
4. Equipment calibration certificate	Today by WHO_JWT	12 KB
5. Test protocol	Today by WHO_JWT	12 KB

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## 5e. Application submission procedure

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)

Previous

Next



## 5e. Application submission procedure

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.

ePQS Application Wizard

Organization & Contacts ✓ ✓ ✓ ✓ Finalize

### Application Submitted

Your application has been successfully submitted. You cannot make any further changes but you can view the information provided on the record directly:

- Case ID: [PQ-IMD-2023-0040](#)
- Application Type: Prequalification
- Product Type: Immunisation Device

**Close This Tab or Navigate Away**  
The application wizard has now finished – you can either close this browser window/tab or navigate to another Salesforce tab. (No need to click 'Next' button.)

Next



# 6f

**Post-PQ  
variation  
submission**

# 5f. Post-PQ variation 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:

ePQS Application Wizard

Start

Organization & Contacts

Application Info

Product Details

Documents

Finalize

Create a New Application

Welcome to the Application Wizard. You can use this wizard to create a range of applications. For some application types, the wizard will also assist in the creation of an applicable Product record.

At the end of the wizard process, the created records can be saved in draft, submitted, or discarded at the end of the process.

Navigation

As you go through the wizard, you may be offered a chance to go back to the last screen with a 'Previous' button, to change the answers given.

At certain stages in the wizard process, the 'Previous' button will not be offered, for example when the last screen created a new record.

It is important **NOT TO USE** the Back button in your browser, as this will reset the wizard to the first screen and you are likely to lose your progress.

Draft Records

The wizard will be creating a draft application and, in some instances, a draft product record as you proceed through the wizard. The wizard will offer links to these records, which you can open in a separate tab. As the wizard progresses, the relevant records will be populated with the information that you supply.

If you do not submit your application at the end of the wizard process, draft records will appear in the applicable List Views on your homepage.

You can submit a previously saved draft application by opening the application and selecting the “Resume Application Wizard” from the menu in the top right-hand corner of the record.

Next

January 2025

# 5f. Post-PQ variation submission procedure



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

# 5f. Post-PQ variation submission procedure



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

# 5f. Post-PQ variation submission procedure



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

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## 5f. Post-PQ variation submission procedure



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 concern product specifications

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

The screenshot displays the 'ePQS Application Wizard' interface. At the top, a progress bar shows five steps: 'Organization & Contacts' (active), 'Application Info', 'Product Details', 'Documents', and 'Finalize'. Below the progress bar, the heading 'Choose Application Subtype' is followed by the instruction 'Please enter the following additional information:'. A text input field is shown with a red asterisk and the label '\* Application Subtype'. The dropdown menu is open, showing two options: 'Type A (Administration)' and 'Type B (Technical)'. At the bottom right of the form, there are 'Previous' and 'Next' buttons.

## 5f. Post-PQ variation submission procedure



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.

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## 5f. Post-PQ variation submission procedure



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

**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 Post-PQ Change. This draft application will be available in your List View of Cases.

- Application Type: Post-PQ Change
- Application Subtype: Type A (Major)
- Product Type: Immunisation Device
- Organization:
- Primary Contact: }

Previous

Next

## 5f. Post-PQ variation submission procedure



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.

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## 5f. Post-PQ variation submission procedure



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...**”

The screenshot shows the 'ePQS Application Wizard' interface. At the top, a progress bar contains five steps: 'Organization & Contacts' (dark blue), two green steps with checkmarks, 'Post-PQ Changes' (light blue), 'Documents' (light grey), and 'Finalize' (light grey). Below the progress bar, the title 'Add Change Information' is displayed. A text prompt states: 'You will need to list the products that are being changed, and also record the change types that apply'. Under the heading 'Either', there are three radio button options: 'Add products that are the subject of post-prequalification changes' (which is selected), 'Add one or more pieces of information about the change, including the type', and 'No more at this time'. A 'Next' button is located in the bottom right corner of the form area.

# 5f. Post-PQ variation submission procedure



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.

ePQS Application Wizard

Organization & Contacts

✓

✓

Post-PQ Changes

Documents

Finalize

Select Products

Choose a product that is the subject of a change

Only those with a status of Prequalified or Acceptable are available.

\*Product(s): To select multiple items, hold down the Ctrl (PC) or Command (Mac) key

Eoo:

Eoo:

Eoo:

Eoo:

Eoo:

Previous

Next

# 5f. Post-PQ variation submission procedure



The next slide confirms the product selection.

ePQS Application Wizard

Organization & Contacts

✓

✓

Post-PQ Changes

Documents

Finalize

Add Products

**Success**  
The following product(s) have been linked with your [PQC-IMD-2024-0007](#) application:  
Eoo;

Next

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## 5f. Post-PQ variation submission procedure



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

✓

✓

Post-PQ 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

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# 5f. Post-PQ variation submission procedure



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.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Post-PQ Changes Documents Finalize

Add Change Info

\* Change Type

- ✓ 1. Administrative - Change in primary contact
- 2. Administrative - Change to contact details (email, telephone)
- 3. Administrative - Change in ownership
- 6. Technical - Change in the manufacturing process
- 5. Technical - Change in product components or materials
- 7. Technical - Change in batch size
- 8. Technical - Change in product specifications
- 9. Technical - Change in primary packaging
- 10. Technical - Change in secondary packaging
- 11. Technical - Change in the packaging size or dimensions
- 12. Technical - Other
- 4. Administrative - Other

## 5f. Post-PQ variation submission procedure



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.

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 relevant documentation on the following screen.

Change Description

Previous

Next

## 5f. Post-PQ variation submission procedure



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

ePQS Application Wizard

Organization & Contacts

✓

✓

Post-PQ 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

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## 5f. Post-PQ variation submission procedure



Next the **“Add change information”** screen displays for a third time.

Note - If it 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 is NOT wished to add additional products, select **“No more at this time”**.

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 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

## 5f. Post-PQ variation submission procedure



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](#)

## 5f. Post-PQ variation submission procedure



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:

<https://extranet.who.int/prequal/ectd-portal>

**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

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## 5f. Post-PQ variation submission procedure



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.**

The screenshot shows the 'ePQS Application Wizard' interface. At the top, a progress bar indicates four steps: 'Organization & Contacts' (completed with a green checkmark), two intermediate steps (also completed with green checkmarks), and 'Documents' (the current step, highlighted in blue). A 'Finalize' button is at the end of the bar. Below the progress bar, the heading 'Upload Documents' is followed by instructions: 'Please attach all supporting documentation for your application below. Either drag-and-drop or select one or more files from your desktop, and then click Upload to attach them to this application.' Further instructions state: 'You can review the folders for submission in the next page. There you can also rename, tag or remove documents. You can return to this screen to upload additional documents as part of this submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review documents once again before final submission.' A note at the bottom left says 'When finished, click Next.' In the center, there is a large blue square with a white document icon and a plus sign, with the text 'Drag and drop files and folders' and 'Browse your device or Select Folders' below it. At the bottom right of the main content area, there are 'Cancel' and 'Upload' buttons. At the very bottom of the wizard, there are 'Previous' and 'Next' buttons.

## 5f. Post-PQ variation submission procedure



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

ePQS Application Wizard


Organization & Contacts ✓ ✓ ✓ Documents Finalize

### Document Review

Please review the documents and folders you intend to upload. You may navigate through the folder structure, renaming and deleting folders as necessary. If you wish to upload further documents or folders please use the Previous button to return to the Upload document page. Document type meta-data may also be added to individual documents by opening these documents and adding the metadata value via the document menu that appears.

**box** Search files and folders

2024-08-23-16:29



There are no items in this folder.

Previous Next

## 5f. Post-PQ variation submission procedure



Users are now at the **review and submit stage**. On this screen, users may opt to use the generated ePQS case number 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**”.

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: [PQC-IMD-2024-0007](#)

**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)

Previous

Next

## 5f. Post-PQ variation submission procedure



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

✓

✓

✓

✓

Finalize

Application Submitted

The application wizard has now finished – click on the **Finish** button to be redirected to the detailed page of your submitted application.

Finish

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# 5f. Post-PQ variation submission procedure



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.

The screenshot displays the ePQS system interface for case PQC-IMD-2024-0007. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The case header shows the Case Record Type as 'Vx IMD Post-PQ Change', Case Number '00026713', and Status 'Under Screening' (highlighted with an orange box). The Case Owner is 'ePQS Vx IMD Queue'. Below the header, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The Details tab is active, showing sections for General Details, Case Progress, and System Information. The General Details section includes fields for WHO Application Number, ePQS Case ID, Product Type, Application Type, Application Subtype, and Product Assessment Procedure. The Case Progress section includes Date Application Submitted (23/08/2024) and Date Application Accepted For Assessment. The System Information section includes Created By, Last Modified By, Case Record Type, and Record Status (Active). The bottom of the page features links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance	Case Owner
Vx IMD Post-PQ Change	00026713	Under Screening			ePQS Vx IMD Queue

**Details** | Related | Activities | Preview Document | Document Download | Document Submission

**General Details**

WHO Application Number	PQC-IMD-2024-0007	Case Owner	ePQS Vx IMD Queue
ePQS Case ID	PQC-IMD-2024-0007	Status	Under Screening
Product Type	Immunisation Device	Applicant Organization	
Application Type	Post-PQ Change	Applicant Organization (Legal)	
Application Subtype	Type A (Major)	Applicant Primary Contact	
Product Assessment Procedure		Applicant Secondary Contact	
		Alternative Applicant Secondary Contact	

**Case Progress**

Date Application Submitted	23/08/2024	Date Of Suspension	
Date Application Accepted For Assessment		Date of Prequalification/Acceptance	
		Cancellation/Withdrawal/Rejection Reason	
		Cancellation/Withdrawal/Rejection Date	

**System Information**

Created By		Last Modified By	
Case Record Type	Vx IMD Post-PQ Change	Record Status	Active

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# 5g

## Uploading of documents

# 5g. Uploading of documents – account / organisation



Under “**My Account**” or “**Document Submission**”, users may upload documents.

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a navigation menu. The navigation menu includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. A user profile dropdown menu is open, showing options for Home, My Profile, My Account (highlighted with an orange border), and Logout. Below the header, the main content area is divided into two sections. The top section, titled 'Account', contains a sidebar with 'Account Record' and 'Non-State Act', and a main area with 'Email' and 'rg 0'. The bottom section, titled 'Document Submission', contains a sidebar with 'Details', 'Related', 'Preview Documents', and 'Document Download', and a main area with 'Upload to Account Submission'. The 'Document Submission' section includes a welcome message: 'Welcome to Document Submission Wizard. Please click on **Next** to proceed for Account#Vestfrost Solutions'. A 'Next' button is located at the bottom right of the 'Document Submission' section. At the bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

# 5g. Uploading of documents – account / organisation



## Document submission interface →

Once documents are uploaded, users can view them in “**Preview**”.

A screenshot of a web application interface for document submission. At the top, there are five tabs: 'Details', 'Related', 'Preview Documents', 'Document Download', and 'Document Submission'. The 'Document Submission' tab is highlighted with an orange border. Below the tabs, the main area is titled 'Upload to Account Submission'. In the center, there is a blue square icon with a white document and an upward arrow. Below this icon, the text reads 'Drag and drop files and folders' and 'Browse your device or Select Folders'. At the bottom right of the main area, there are two buttons: 'Cancel' and 'Upload'. At the bottom right of the entire interface, there is a 'Next' button.

# 5g. Uploading of documents - cases



Documents related to cases (i.e. product applications) are available under the “Cases” tab.

ePQS

Search...

Search

cto

[Home](#) [Organizations](#) [Contacts](#) [Activities](#) [Cases](#) [PQS Products](#) [Inspections](#) [NRA CRP Agreements](#) [CRP Product Registrations](#) [More](#)

Cases

All Cases (Portal)

31 item

LIST VIEWS

✓ All Cases (Portal)

All Closed Cases (Portal)

All Open Cases (Portal)

Recently Viewed (Pinned list)

Recently Viewed Cases

seconds ago

Q Search this list...

Application S...

WHO Pro...

Date Appli...

Date Appl...

Date of Pr...

Standard

01/01/1900

01/01/1900

▼

Standard

01/01/1900

01/01/1900

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## 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.

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

The screenshot displays the ePQS web application interface. At the top, there is a navigation bar with the ePQS logo, a search bar, and a user profile icon. Below the navigation bar, a horizontal menu contains several options: Home, Organizations, Contacts, Activities, **Cases** (highlighted with an orange box), ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows a case titled "Case PQC-IMD-2024-0007" (highlighted with an orange box). To the right of the case title are buttons for "+ Follow", "Edit", "Resume Application Wizard", and "New Component(s)". Below the case title, there is a table with columns: Case Record Type (Vx IMD Post-PQ Change), Case Number, Status (Under Screening), Date of Prequalification/Acceptance, and Case Owner (ePQS Vx IMD Queue). Under the "Status" column, there is a sub-menu with options: Details, Related, Activities, **Preview Document** (highlighted with an orange box), Document Download, and Document Submission. Below the sub-menu, there is a "box" logo and a search bar for files and folders. The main content area shows a table with columns: Name, Modified, and Size. The table contains one row: "Correspondence (External)" (highlighted with an orange box), Modified: Yesterday, and Size: 0 Byte.

Case Record Type	Case Number	Status	Date of Prequalification/Acceptance	Case Owner
Vx IMD Post-PQ Change		Under Screening		ePQS Vx IMD Queue

Name	Modified	Size
Correspondence (External)	Yesterday	0 Byte



# 5h

## Downloading of documents

# 5h. Downloading of documents



Under “My Account” or “Document Download”, at least two folders should appear: “External correspondence” folder and “Submitted documents”.

Once an application has been submitted, open the folders and test-download the contents.

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a user profile icon. Below the header is a navigation bar with links to Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registrations. A dropdown menu is open for the user profile, showing options: Home, My Profile, My Account (highlighted with an orange border), and Logout. Below the navigation bar, there is a section for 'Account' with a table of account records. The table has columns for Account Record Type, Address (2), and Email. Below the table, there are tabs for Details, Related, Preview Documents, Document Download (highlighted with an orange border), and Document Submission. The Document Download tab is active, showing a 'box' logo and a search bar. Below the search bar, there are two folders listed: 'External correspondence' and 'Submitted Documents', both modified on Fri Apr 12 2024 and 0 Byte. At the bottom of the interface, there is a footer with links to About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

# 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.

Users should ensure they can download documents from this location.

The screenshot displays the ePQS web application interface. At the top, there is a navigation bar with the ePQS logo, a search bar, and a user profile icon. Below the navigation bar, a horizontal menu contains several options: Home, Organizations, Contacts, Activities, **Cases** (highlighted with an orange box), ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows a case record for 'Case PQC-IMD-2024-0007' (also highlighted with an orange box). Below the case title, there are buttons for '+ Follow', 'Edit', 'Resume Application Wizard', and 'New Component(s)'. A table below the buttons lists case details: Case Record Type (Vx IMD Post-PQ Change), Case Number, Status (Under Screening), Date of Prequalification/Acceptance, and Case Owner (ePQS Vx IMD Queue). Below the table, there are three tabs: Details, Related, and Activities. The 'Preview Document' tab is selected and highlighted with an orange box. Below the tabs, there is a 'box' logo and a search bar. A table below the search bar shows the file structure for the case, with a folder named 'Correspondence (External)' listed under the 'PQC-IMD-2024-0007' case.

Case Record Type	Case Number	Status	Date of Prequalification/Acceptance	Case Owner
Vx IMD Post-PQ Change		Under Screening		ePQS Vx IMD Queue

Name	Modified	Size
Correspondence (External)	Yesterday	0 Byte



# 5i

**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.

ePQS

Search...

Search

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

External Activities

All Activities (Applications - Portal) ▾

0 items • Sorted by Activity Name • Filtered by All external activities - Related To (Inspection) • Updated 14 minutes ago

Search this list...

Activity Name ↑ ▾	Subject ▾	Owner Last Na... ▾	Related To (Case) ▾	Status ▾	Start Date ▾	Due Date ▾	End Date ▾
...							



# 5j

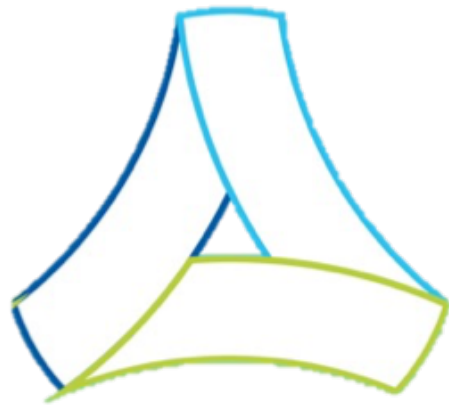
**Bell and email  
notifications &  
associations  
with actions**

# 5j. Assignment of activities to applicants



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

The screenshot displays the ePQS (Electronic Product Quality System) website. The header includes the ePQS logo, a search bar, and a notification bell icon highlighted with an orange box. A dropdown menu for notifications is open, showing the message: "You don't have any notifications right now." Below the header, there are four main action buttons: "Submit an application", "Create Account or Contact", "Edit an Account or Contact", and "Change a record contact". Each button features the World Health Organization logo. The page also includes a "COMMONLY USED LISTS" section with links to "Medicine Storage Conditions", "WHO Vaccine Names", "Medicines Pharmaceutical Ingredients", "VC Active Ingredients/Synergist Name", "QCLm Generic Name (INN)", and "Post-Prequalification Changes". A large blue button labeled "View ePQS Registered Accounts" is positioned on the right. The footer contains links for "About Us", "Contact Us", "Privacy Policy", and "Legal Disclaimer".



## **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.



**ePQS Portal**



**ePQS Personalised Coaching, Q&A Guide**



**Email support**



**ePQS Training video**



**PQ Holder Guidelines\*  
Annex 7**

## 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 webpage.

**Webinars** will be announced soon and regular clinics will be held post-go live to support users, answer questions, and identify issues in order to make continuous improvements.

### General Portal Information

[ePQS - Accounts Contacts Users and Record Visibility](#)

[ePQS - Creating or editing a Contact or Account](#)

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