



WHO e-Prequalification System (ePQS)

Learning materials
WHO Immunization Devices (IMD-PQS)
2025



Prequalification Applicants
Prequalification-Holders



**World Health
Organization**

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

UPDATED: 16/12/2025

Key access links (for reference)

WHO ePQS Portal landing page:

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

ePQS login link:

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



NEW: FAQs & Troubleshooting



WHO IMD ePQS Frequently Asked Questions FAQs & Troubleshooting

<https://extranet.who.int/prequal/key-resources/documents/who-imd-epqs-frequently-asked-questions-faqs-troubleshooting>

WHO Immunization Devices prequalification launched the new WHO e-prequalification (ePQS) platform, a Salesforce application, in late summer 2025. By December, nearly 50 applications have been submitted and begun their journey to prequalification through the system.

The IMD team has collated the experience of these first six months to create a frequently asked questions (FAQs) and troubleshooting guide. It is a summary of the common questions, issues and challenges that new applicants and prequalification-holders have faced to date using ePQS, and practical guidance on how to resolve them.

Purposes of these learning materials



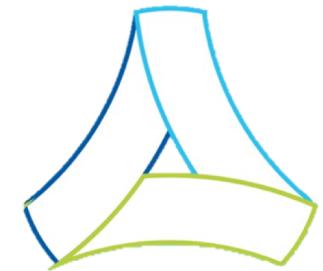
Learning materials are intended as comprehensive resources to support users gain necessary competence and autonomy in using the features and functions of ePQS. **These learning materials concern Immunization Devices (IMD-PQS) users. The deck:**

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

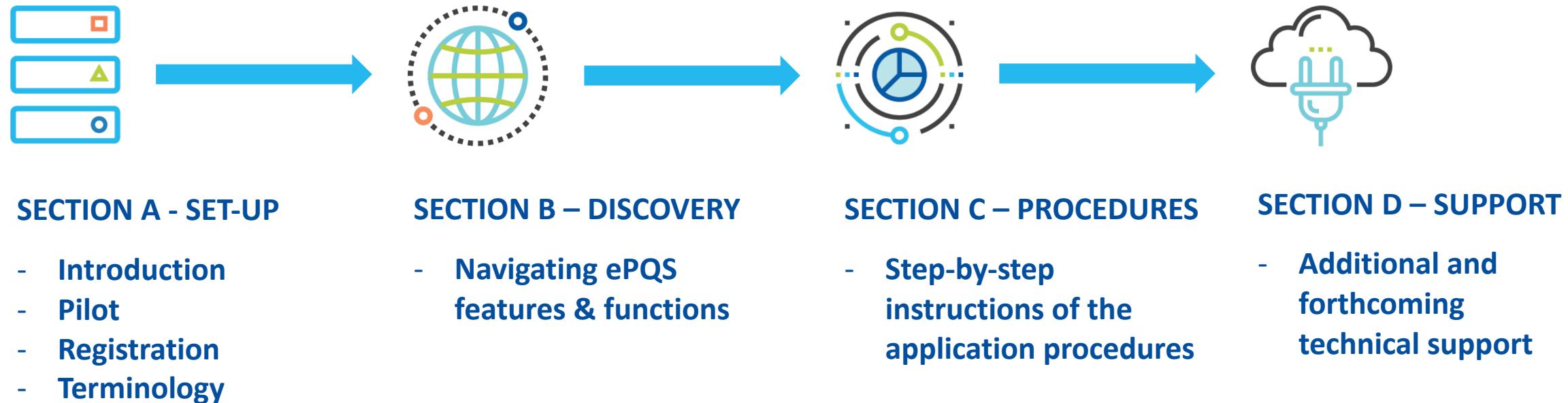


Q&A / coaching sessions with the IMD-PQS ePQS support team may be scheduled subsequent to this self-training.

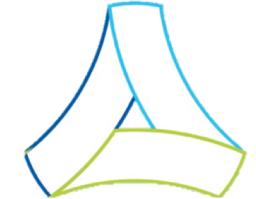
ePQS Portal



Overview of these learning materials



Contents



ePQS Portal

SECTION A – SET-UP

1. ePQS portal introduction	8
2. Registration & access	17
3. Concepts & terminology	20

SECTION B - DISCOVERY

4. Navigating ePQS functions & features	29
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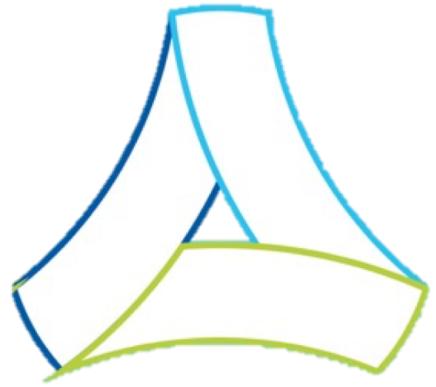
SECTION C – APPLICATION PROCEDURES

5. Step-by-step guide	52
a. Verification of product data sheets	54
b. Accessing registered accounts	61

c. Correct record visibility	65
i. Record visibility - All	
ii. Record visibility - Products	
d. Personal use folder	70
e. Application submission procedure	73
f. Post-PQ variation submission	70
g. Up/downloading of documents	127
h. Assigned activities	132
i. Bell & email notifications	134

SECTION D – TECHNICAL SUPPORT

7. Links to further technical support	137
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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:

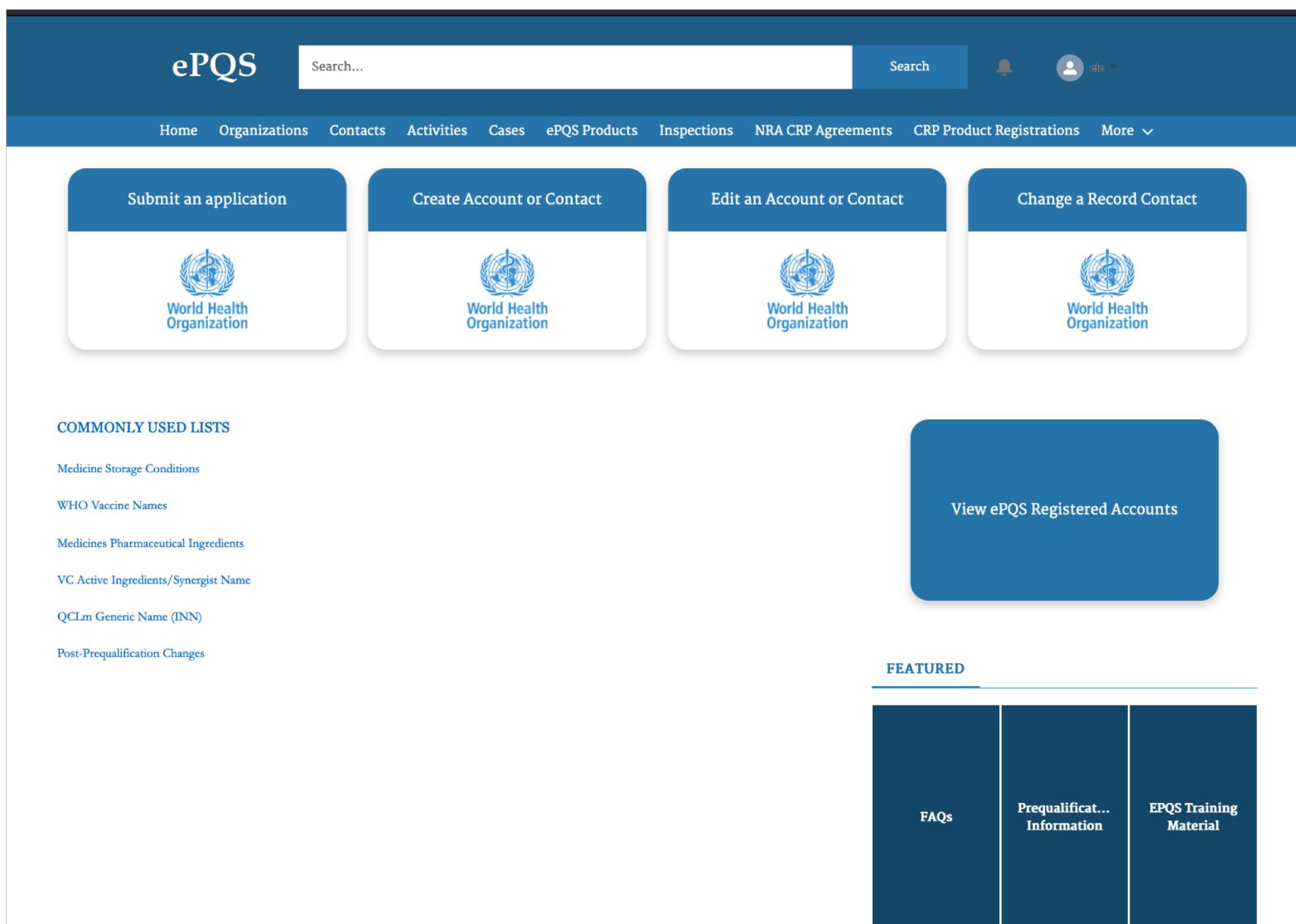
- submit & manage prequalification applications & post-PQ variations
- follow the site inspections process
- view records relevant to them
- submit required changes to account, contact & product information
- upload and download documents securely
- view and monitor notifications for pending activities

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



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

1. ePQS Introduction – Home page appearance



The screenshot shows the ePQS Home page with a dark blue header and a light blue footer. The header features the ePQS logo, a search bar, and a user profile icon. The main menu includes Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and a More dropdown. Below the menu are four large buttons: 'Submit an application' (with WHO logo), 'Create Account or Contact' (with WHO logo), 'Edit an Account or Contact' (with WHO logo), and 'Change a Record Contact' (with WHO logo). A 'COMMONLY USED LISTS' section on the left lists: 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 on the right says 'View ePQS Registered Accounts'. A 'FEATURED' section at the bottom right includes 'FAQs', 'Prequalification... Information', and 'ePQS Training Material'. The footer contains links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer, along with a date: January 2025.

ePQS

Search...

Search

Profile

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

FEATURED

FAQs

Prequalification... Information

ePQS Training Material

About Us

Contact Us

Privacy Policy

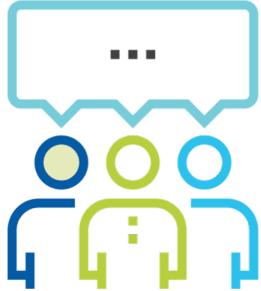
Legal Disclaimer

January 2025

SECTION A – SET-UP

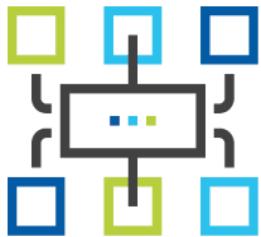
1. ePQS Introduction

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.

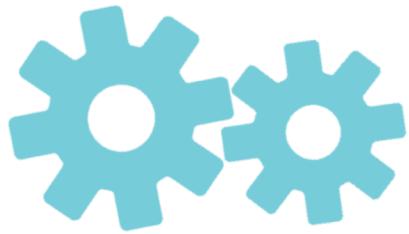


Applications and post-PQ processes

- 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

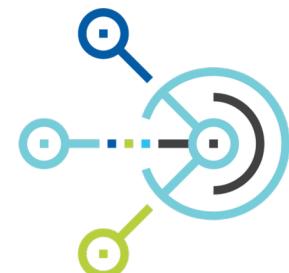
The “application wizard”

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 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.

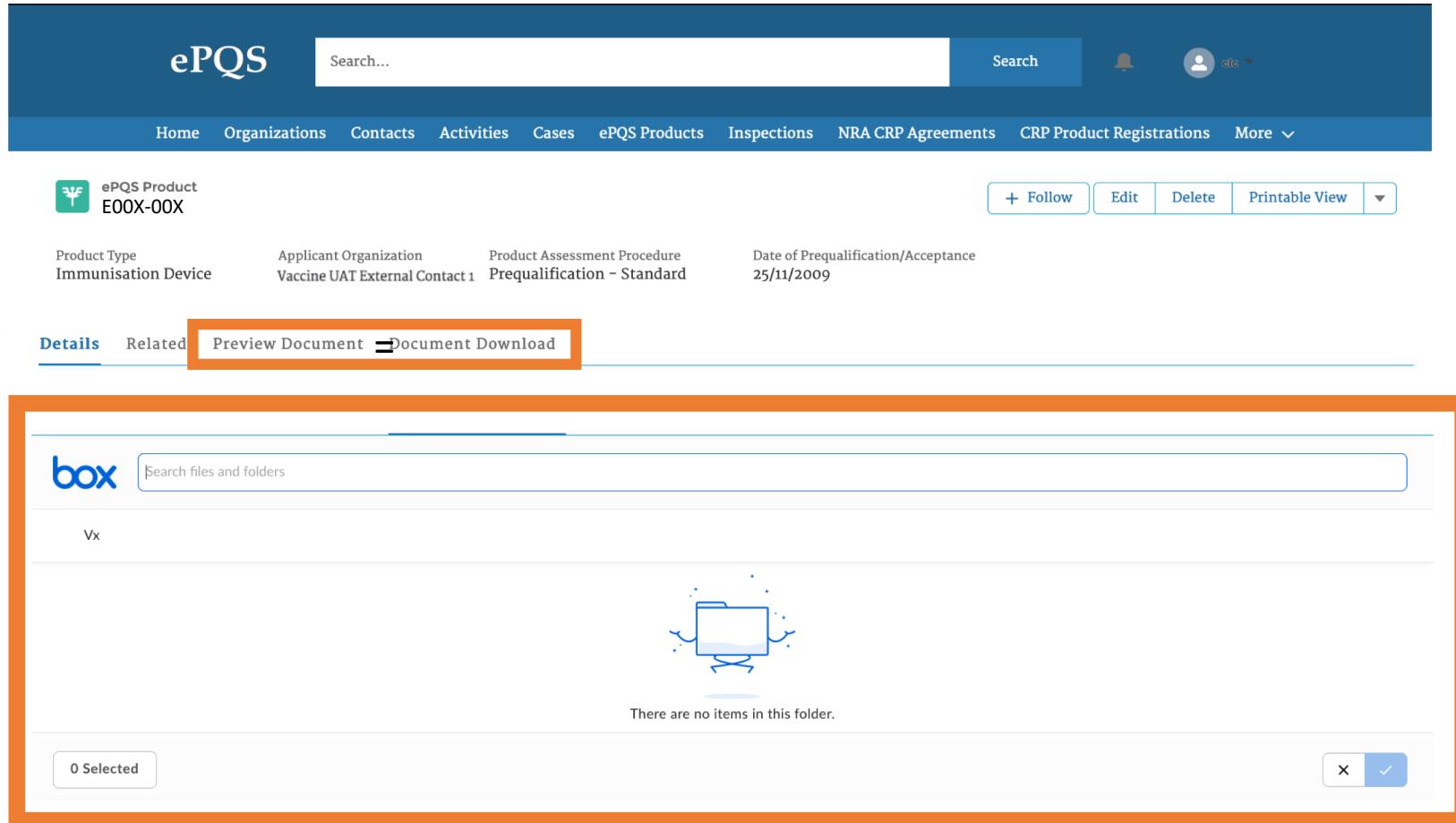
You can submit a previously saved draft application by opening the application and selecting the "Resume Application Wizard" from the menu in the top right-hand corner of the record.

Next

About Us Contact Us Privacy Policy Legal Disclaimer

1. ePQS Introduction

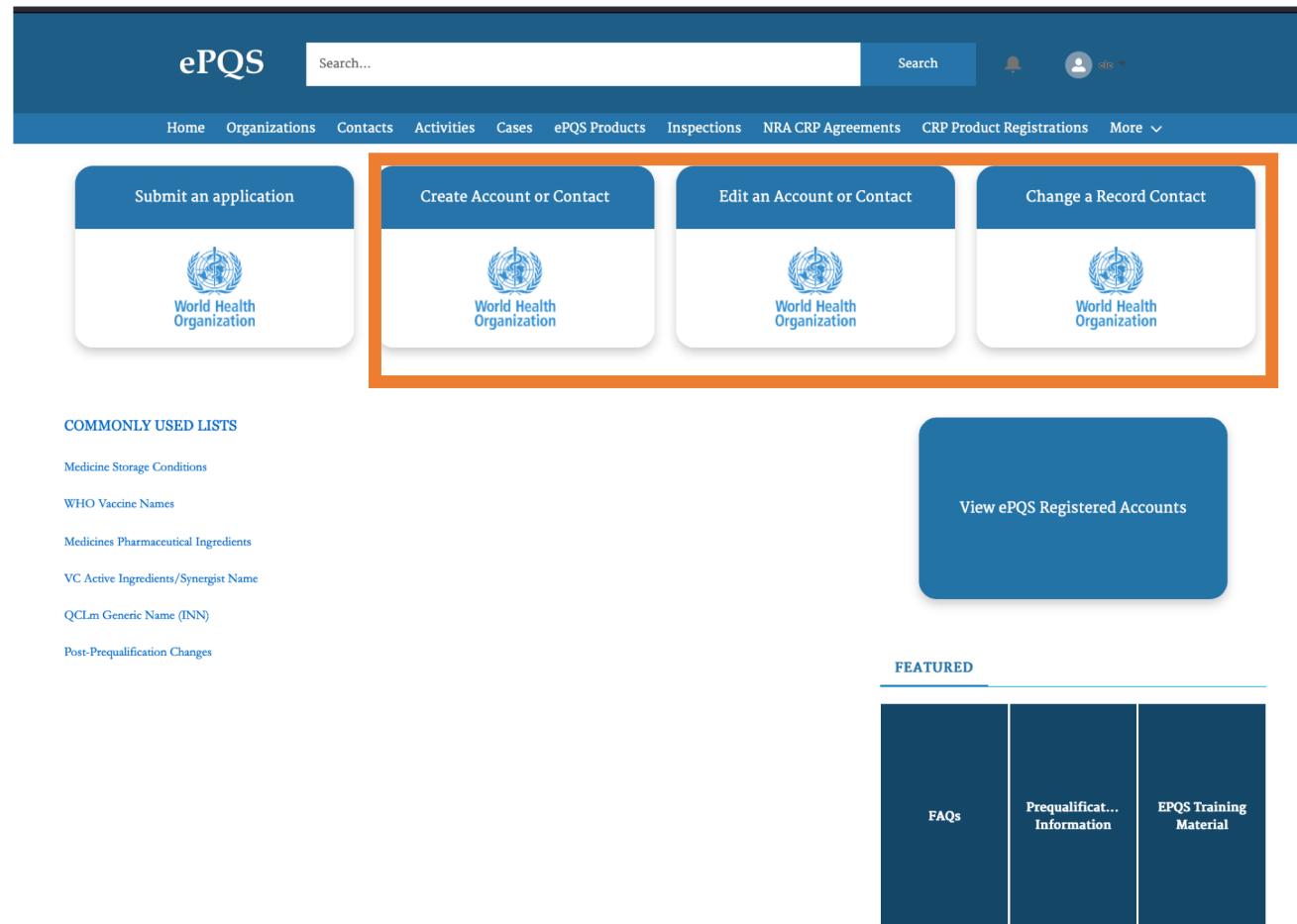
Quick view - Document up/download



The screenshot shows the ePQS software interface. At the top, there is a navigation bar with links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, a product detail page is displayed for an ePQS Product (E00X-00X). The product details include: 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 details, there are tabs for Details, Related, Preview Document, and Document Download. The Document Download tab is highlighted with a red box. A large orange box surrounds the 'Document Download' section, which contains a 'box' logo and a search bar. Below the search bar, there is a message stating 'There are no items in this folder.' At the bottom of the 'Document Download' section, there is a button for '0 Selected' and a close button.

1. ePQS Introduction

Quick view - Data change request forms



The screenshot shows the ePQS web 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, CRP Product Registrations, and More. The main content area features four buttons in a row: 'Submit an application' (with a WHO logo), 'Create Account or Contact' (with a WHO logo), 'Edit an Account or Contact' (with a WHO logo), and 'Change a Record Contact' (with a WHO logo). The 'Create Account or Contact' button is highlighted with an orange border. Below these buttons is a section titled 'COMMONLY USED LISTS' containing links: Medicine Storage Conditions, WHO Vaccine Names, Medicines Pharmaceutical Ingredients, VC Active Ingredients/Synergist Name, QCLm Generic Name (INN), and Post-Precqualification Changes. To the right of this list is a blue box labeled 'View ePQS Registered Accounts'. At the bottom of the page is a 'FEATURED' section with three dark blue boxes: 'FAQs', 'Prequalificat... Information', and 'EPQS Training Material'. At the very bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

1. ePQS Introduction - ALL Features & functions overview

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

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



2



Registration & Access



3. Registration



1. Account contacts have already been created for all IMD-PQS Prequalification Holders
2. Prequalification Holders must **verify their account and contact** details prior to registration. The IMD-PQS Secretariat will reach out individually to users with the required forms for this stage.
3. Contacts need to “register” to gain access to the the system.

Registration is via the:

“External Form – New ePQS User” linked here:

https://who.my.salesforce.com/sfc/p/#3X000005AZtm/a/NN000001rmcH/.Kqqi2wVzq1TliizyfrvIoi_0D5v_7CmXUozH01_Ke0

Each new user / registration request must complete:

- [Section 1 \(Declaration\)](#),
- [Section 3 \(New User\) and](#)
- [Section 4 \(New Account\)](#)

5. **Return the form to imd_amd@who.int (imd_amd@who.int), with the IMD-PQS Secretariat in copy.**

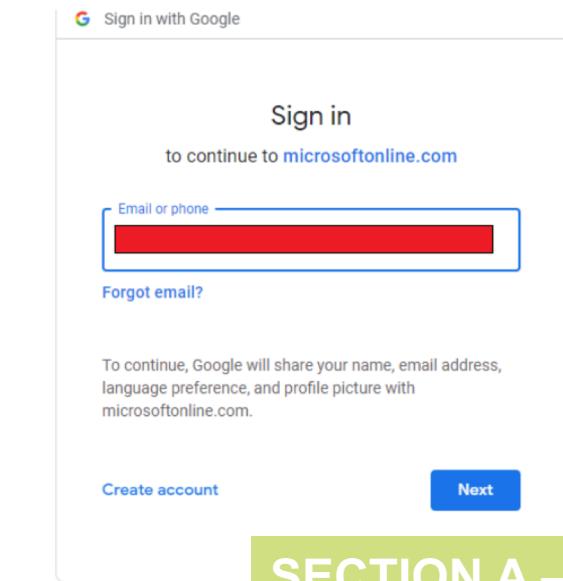
2. Access

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.

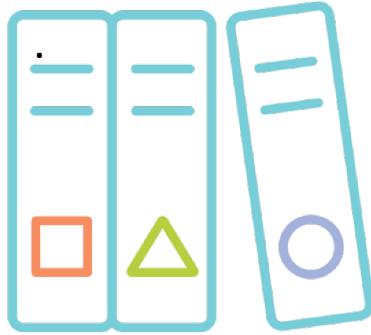


3

Concepts & terminology



3. Concepts & terminology



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”

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

Case record type For each case, the record type will be either “*Vx IMD Application*”, or “*Vx IMD Post-PQ change*” or “*Vx IMD Reassessment*”. These terms are defined below.

ePQS Case ID Once opened, each case will be assigned an ID in the format “PQ-IMD-YEAR-XXXX”.



3. Concepts & terminology – other key terms

Terms related to applications

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



3. Concepts & terminology – other key terms

IMD-PQS-specific application processes on ePQS

Vx IMD Application

IMD-PQS ePQS Application type meaning: “New application for product prequalification”.

Vx IMD Post-PQ change

IMD-PQS ePQS Application type meaning: “Post-prequalification variation, a change to product or manufacturing process”.

Vx IMD Reassessment

IMD-PQS ePQS Application type meaning: “IMD Annual Review of prequalified products”.



3. Concepts & terminology – other key terms

Terms related to products

IMD Product	Section of the application/case/product record that contains the basic information about a product submitted for review. For example, the product name, description, type and applicant organization.
IMD Product Variant	Sub-section of the unique product application/case/product record that contains the record of all of the detailed product technical specifications.
(WHO) Product ID number	Once a prequalification application is completed and submitted in the application wizard, the product will be assigned an ID number in the format: “P-XXXXX”.
External ID	Subsequent to a successful application for prequalification, WHO IMD-PQS will assign an External ID in the traditional format of the “PQS Product number”: “E0XX-XXX”.
Product Site	Location and facility at which a product is manufactured.





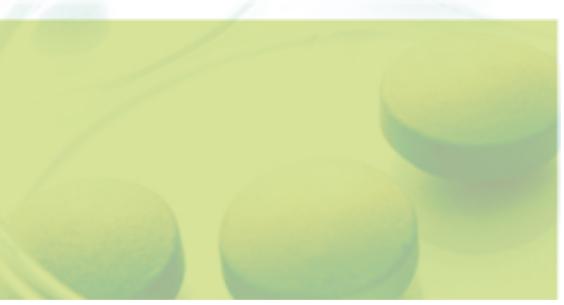
SECTION B – DISCOVERY

ePQS navigation & features - Discovery



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

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



4

Navigating ePQS **– General guide**

4. ePQS navigation – Homepage map

The screenshot shows the ePQS homepage with various menu items and search functions. Red boxes numbered 1 through 11 highlight specific features:

- 1) Global search facility: A search bar with a placeholder "Search..." and a "Search" button.
- 2) Notification "Bell" Icon: A notification icon with a red box containing the number 2.
- 3) Personal Settings and Profile: A user profile icon with a red box containing the number 3.
- 4) Home: The main navigation menu item.
- 5) Submit an application: A button for submitting applications, associated with the WHO logo and a red box containing the number 5.
- 6) Create Account or Contact: A button for creating accounts or contacts, associated with the WHO logo and a red box containing the number 6.
- 7) Edit an Account or Contact: A button for editing accounts or contacts, associated with the WHO logo and a red box containing the number 7.
- 8) Change a Record Contact: A button for changing record contacts, associated with the WHO logo and a red box containing the number 8.
- 9) COMMONLY USED LISTS: A section for commonly used lists, including Medicine Storage Conditions, WHO Vaccine Names, Medicines Pharmaceutical Ingredients, VC Active Ingredients/Synergist Name, QCLm Generic Name (INN), and Post-Preliminary Changes. A red box containing the number 9 is placed over the first item in this list.
- 10) View ePQS Registered Accounts: A button to view registered accounts, with a red box containing the number 10.
- 11) FEATURED: A section for featured content, including FAQs, Prequalification Information, and EPQS Training Material. A red box containing the number 11 is placed over the "FAQs" item.

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

The screenshot shows the ePQS homepage with various sections and buttons highlighted by red boxes and numbers:

- 1**: Search bar with placeholder "Search...".
- 2**: Notification bell icon with a "20+" badge.
- 3**: User profile icon.
- 4**: "Home" button in the main navigation bar.
- 5**: "Submit an application" button with WHO logo.
- 6**: "Create Account or Contact" button with WHO logo.
- 7**: "Edit an Account or Contact" button with WHO logo.
- 8**: "Change a Record Contact" button with WHO logo.
- 9**: "COMMONLY USED LISTS" section with links: Medicine Storage Conditions, WHO Vaccine Names, Medicines Pharmaceutical Ingredients, VC Active Ingredients/Synergist Name, QCLm Generic Name (INN), and Post-Prequalification Changes.
- 10**: "View ePQS Registered Accounts" button.
- 11**: "FEATURED" section with three links: FAQs, Prequalification Information, and ePQS Training Material.

At the bottom left, the text "January 2025" is visible.

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.

SECTION B – DISCOVERY

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.

The screenshot shows the ePQS platform interface. At the top, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Products, and a search bar. On the right side, there is a user profile icon with a dropdown menu. The dropdown menu includes links: Home, My Profile (which is highlighted with an orange box), My Account, and Logout. Below the navigation bar, there are three main buttons: 'Submit an application', 'Create Account or Contact', and 'Edit an Account or Contact', each accompanied by the World Health Organization logo.

4. ePQS navigation – My profile



“My profile” appearance.

Top navigation bar:

- ePQS
- Search...
- Search
- Notification bell
- User icon: clc

Header menu:

- Home
- Organizations
- Contacts
- Activities
- Cases
- ePQS Products
- Inspections
- NRA CRP Agreements
- CRP Product Registration

Submenu for the user icon:

- Home
- My Profile (highlighted with an orange box)
- My Account
- Logout

Form fields (left side):

- Name
- Title
- Email
- Address
- About Me
January 2025

Form fields (right side):

- Manager
- Company Name
- Active (checkbox checked)
- Contact
- Phone
- Mobile

Page footer:

SECTION B – DISCOVERY

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.

The screenshot shows the ePQS interface with a dark blue header. The header includes the ePQS logo, a search bar with a search button, and a user profile icon with a dropdown menu. The dropdown menu is open, showing options: Home, My Profile, My Account (which is highlighted with an orange box), and Logout. Below the header are several buttons for 'Submit an application', 'Create Account or Contact', and 'Edit an Account or Contact', each accompanied by the World Health Organization logo. The overall layout is clean and professional, designed for easy navigation.

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.

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.

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.

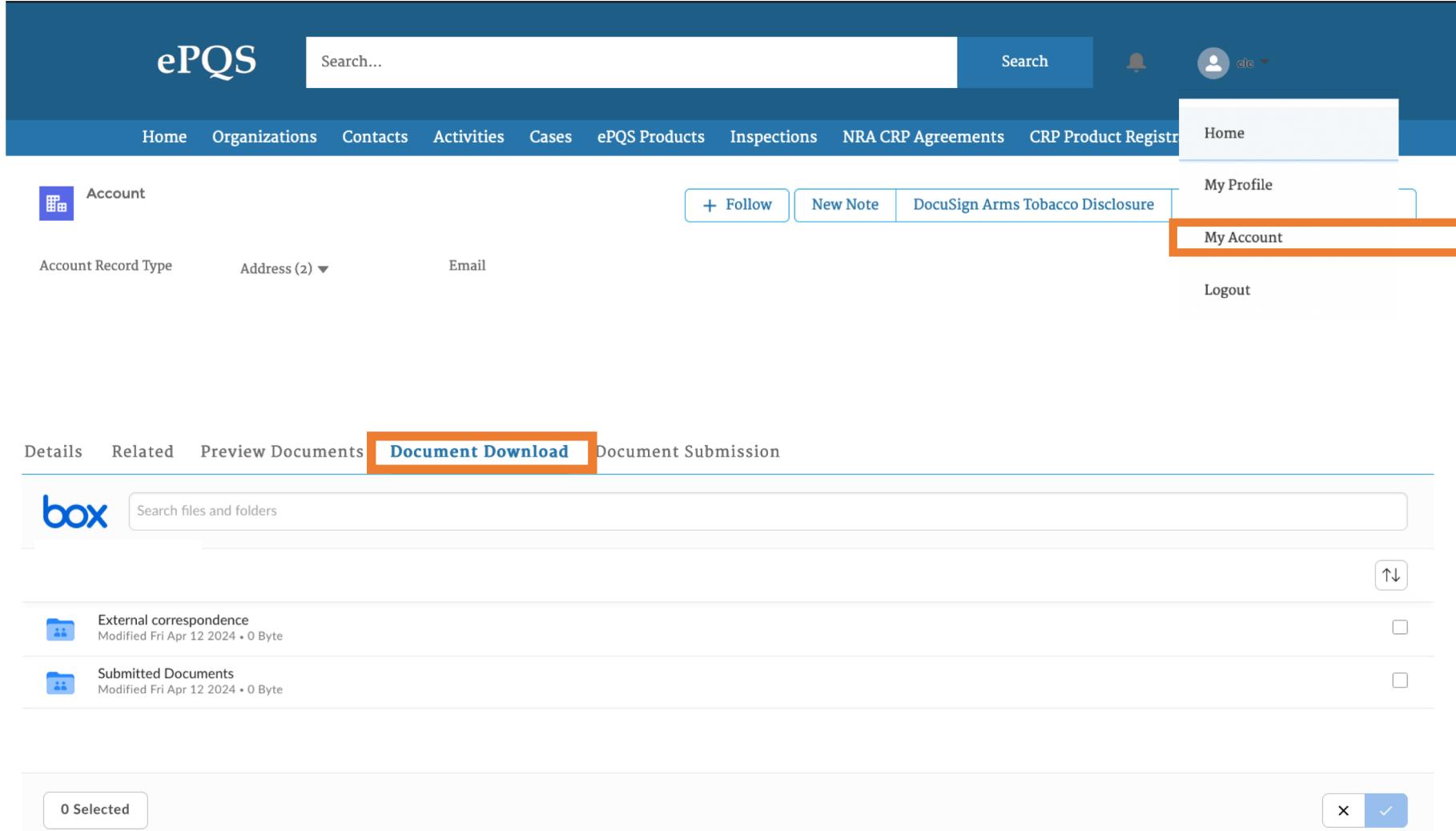
The screenshot shows the ePQS software interface. At the top, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registrations. A search bar is also present. On the right side, there is a user profile icon and a 'Logout' link. Below the navigation bar, the main content area is titled 'Account' and shows 'Account Record Type' (Address (2)), 'Address (2) ▾', and 'Email'. There are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Disclosure'. A 'My Account' link is highlighted with an orange box. At the bottom, there is a 'box' file manager interface showing a list of documents. The 'Preview Documents' tab is selected. The table shows the following data:

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 image shows a screenshot of the ePQS software interface. At the top, there is a dark blue header bar with the ePQS logo on the left, a search bar with a placeholder 'Search...', a 'Search' button, and a user profile icon with the name 'ele' on the right. Below the header is a navigation menu with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registr. The 'Home' link is highlighted with a blue underline. To the right of the menu is a 'Home' button, 'My Profile' link, and a 'Logout' link. A red box highlights the 'My Account' link in the profile menu. Below the menu, the main content area has a title 'Account' with a blue folder icon. It shows fields for 'Account Record Type', 'Address (2) ▾', and 'Email'. To the right are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Disclosure'. At the bottom of the page, there is a navigation bar with tabs: Details, Related, Preview Documents, Document Download (which is highlighted with a red box), and Document Submission. Below the tabs is a 'box' logo and a search bar. A list of documents is shown, including 'External correspondence' and 'Submitted Documents', each with a file icon, a modification date ('Modified Fri Apr 12 2024'), and a file size ('0 Byte'). At the bottom left is a '0 Selected' button, and at the bottom right are 'x' and '✓' buttons.

4. ePQS navigation – Documents



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

The screenshot shows the ePQS software interface. At the top, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. A search bar is also present. On the right side of the header, there is a user profile icon and a dropdown menu with options: Home, My Profile, and My Account (which is highlighted with an orange box). Below the header, there is a section for 'Account' with fields for Account Record Type, Address (2), and Email. There are also buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Disclosure'. On the far right, there is a 'Logout' link. At the bottom of the page, there is a navigation bar with links: Details, Related, Preview Documents, Document Download, and Document Submission (which is highlighted with an orange box). Below this, there is a section titled 'Upload to Account Submission' with the text: 'Welcome to Document Submission Wizard. Please click on Next to proceed for Account#Vestfrost Solutions'. At the bottom right of this section, there is a 'Next' button. At the very bottom of the page, there are links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

4. ePQS navigation – Documents



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

4. ePQS navigation – Wizard



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

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

The screenshot shows the ePQS application wizard interface. At the top, there is a navigation bar with links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. A search bar is also present. On the right side of the header, there are notifications and user profile icons. Below the header, there are four main buttons: "Submit an application" (highlighted with an orange border), "Create Account or Contact", "Edit an Account or Contact", and "Change a Record Contact", each accompanied by the World Health Organization logo. At the bottom left, there is a list of "COMMONLY USED LISTS" including Medicine Storage Conditions, WHO Vaccine Names, Medicines Pharmaceutical Ingredients, VC Active Ingredients/Synergist Name, QCLm Generic Name (INN), and Post-Prequalification Changes. On the bottom right, there is a blue button labeled "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 shows the ePQS homepage with a dark blue header. The header includes the ePQS logo, a search bar with placeholder text 'Search...', a 'Search' button, and a user profile icon with a dropdown menu. Below the header is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area features four large buttons with rounded corners, each containing a World Health Organization logo and text: 'Submit an application', 'Create Account or Contact', 'Edit an Account or Contact', and 'Change a Record Contact'. The 'Create Account or Contact' button is highlighted with an orange border. Below these buttons 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. To the right, a blue button labeled 'View ePQS Registered Accounts' is visible.

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 shows the ePQS application interface. At the top, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and a search bar. On the right side of the header, there is a user profile icon and a dropdown menu. Below the header, the main content area has a title 'Account' with a blue icon. In the center, there is a button labeled '+ Follow' and a blue button labeled 'New Note' which is highlighted with an orange box and a callout arrow pointing to it. To the right of the 'New Note' button, there are links for 'DocuSign Arms Tobacco Disclosure' and 'My Account' (which is also highlighted with an orange box). At the bottom of the main content area, there is a 'Logout' link. A large orange callout arrow points from the 'New Note' button down to a detailed view of the note creation interface. This interface shows a title 'Untitled Note', a rich text editor toolbar, a text input field with placeholder 'Enter a note...', and a bottom row with buttons for 'Share', 'Add to Records', and 'Done'.

4. ePQS navigation – Organisations



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

Accounts

ePQS Accounts (Portal)

1 item

LIST VIEWS

- All Vx accounts
- ePQS Accounts (Portal)
- Recently Viewed (Pinned list)
- Recently Viewed Accounts

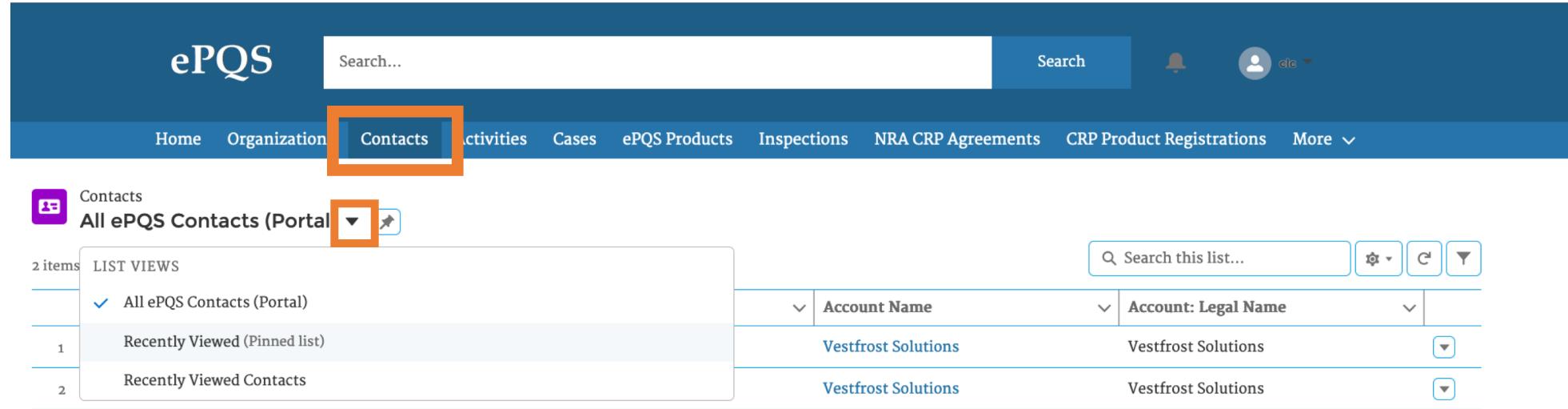
Search this list...

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

4. ePQS navigation – Contacts



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



The screenshot shows the ePQS software interface. The top navigation bar has a search bar and a 'Search' button. Below the bar are several tabs: Home, Organization, **Contacts** (which is highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. A dropdown menu is open under the 'Contacts' tab, titled 'All ePQS Contacts (Portal)'. It contains three items: 'All ePQS Contacts (Portal)', 'Recently Viewed (Pinned list)', and 'Recently Viewed Contacts'. The main content area displays a table with two rows. The first row has 'Account Name' and 'Vestfrost Solutions'. The second row has 'Account: Legal Name' and 'Vestfrost Solutions'. There are search and filter buttons on the right side of the table.

Account Name	Account: Legal Name
Vestfrost Solutions	Vestfrost Solutions
Vestfrost Solutions	Vestfrost Solutions

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

4. ePQS navigation – Activities



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

The screenshot shows the ePQS navigation bar with the following structure:

- Top bar: ePQS, Search bar, Search button, Notifications, User profile.
- Navigation tabs: Home, Organizations, Contact, **Activities** (highlighted with an orange box), Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, More.
- Left sidebar:
 - External Activities
 - Recently Viewed (selected, highlighted with an orange box)
 - 0 items
 - LIST VIEWS
 - All Activities (Applications – Portal)
 - All Activities (Inspections – Portal)
 - My Activities (Portal)
 - My Open Activities (portal)
 - Recently Viewed (Pinned list) (selected, highlighted with a blue box)
- Right sidebar:
 - Search this list...
 - Filter icons: search, sort, refresh, edit, filter.

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”.

31 item

Cases

All Cases (Portal) ▾ ↗

1

2

3

4

LIST VIEWS

- ✓ All Cases (Portal)
- All Closed Cases (Portal)
- All Open Cases (Portal)
- Recently Viewed (Pinned list)
- Recently Viewed Cases

seconds ago

Search this list...

Application S...	WHO Pro...	Date Appli...	Date Appli...	Date of Pr...
Standard		01/01/1900	01/01/1900	
Standard		01/01/1900	01/01/1900	
Standard		01/01/1900	01/01/1900	
Standard		01/01/1900	01/01/1900	

Printable View

4. ePQS navigation – Products



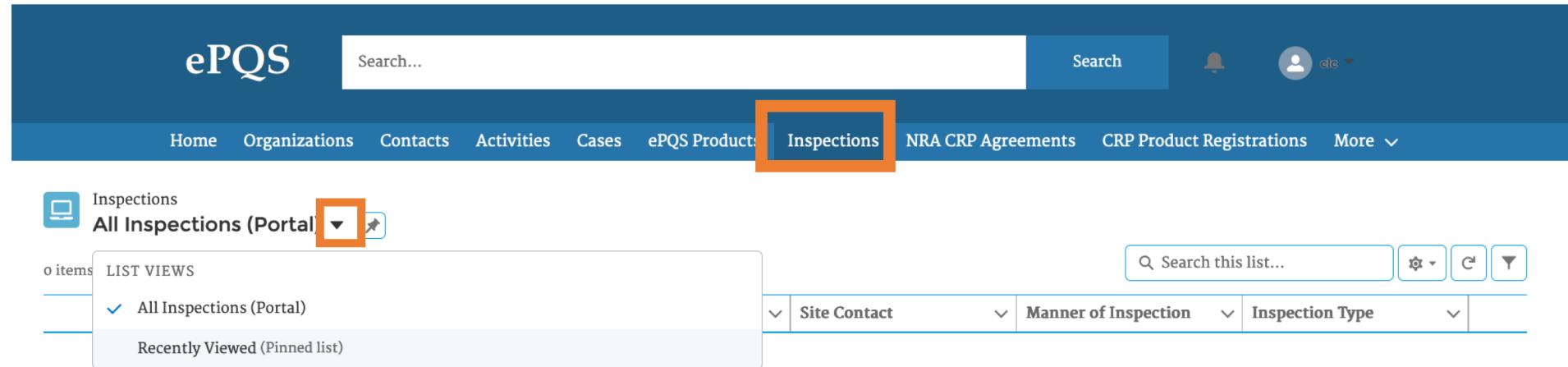
Likewise, a list of all “products” related to a user’s account is available via the main tab.

The screenshot shows the ePQS software interface. At the top, there is a navigation bar with tabs: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The 'ePQS Products' tab is highlighted with an orange box. Below the navigation bar, there is a search bar and a user profile icon. On the left, there is a sidebar with a 'ePQS Products' section and a dropdown menu for 'All Products (Portal)'. The dropdown menu shows 'All Active Products (Portal)', 'All Closed Products (Portal)', 'All Products (Portal)' (which is selected and highlighted with a blue box), and 'Recently Viewed (Pinned list)'. On the right, there is a table with columns: Product Subtype, Date of Preq..., Date of ..., and Date of Pro... . The table contains three rows with data: 1. Product Subtype: S, Date of Preq...: 25/11/2009, Date of ...: 25/11/2009, Date of Pro...: 25/11/2009. 2. Product Subtype: S, Date of Preq...: 18/03/2010, Date of ...: 18/03/2010, Date of Pro...: 18/03/2010. 3. Product Subtype: S, Date of Preq...: 14/07/2010, Date of ...: 14/07/2010, Date of Pro...: 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.

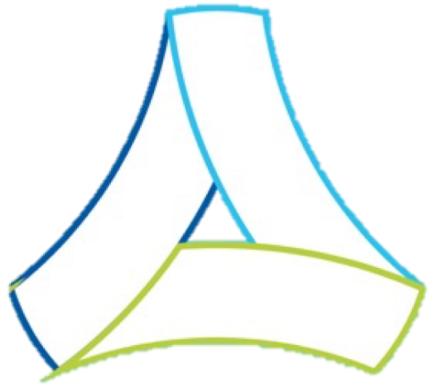
A screenshot of the ePQS application interface. The top navigation bar is dark blue with the ePQS logo on the left and a search bar with a 'Search' button on the right. Below the search bar are several tabs: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The 'Inspections' tab is highlighted with a blue box and a white border. The main content area has a white background. On the left, there is a sidebar with a blue header that says 'Inspections' and 'All Inspections (Portal)'. Below this, there is a list titled 'LIST VIEWS' with two items: 'All Inspections (Portal)' (which is checked) and 'Recently Viewed (Pinned list)'. To the right of the sidebar, there is a search bar with the placeholder 'Search this list...', and below it are three small icons. At the bottom of the content area, there are three dropdown menus: 'Site Contact', 'Manner of Inspection', and 'Inspection Type'.

4. ePQS navigation – Bell



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

The screenshot shows the ePQS application interface. At the top, there is a navigation bar with links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA, and Help. A search bar is located above the navigation bar. On the right side of the header, there is a user profile icon and a bell icon. A callout box with an orange border highlights the bell icon and the 'Notifications' section. The 'Notifications' section is titled 'Notifications' and contains the message 'You don't have any notifications right now.' Below the notifications, there are four cards, each featuring the World Health Organization logo and the text 'World Health Organization'.



SECTION C

– APPLICATION PROCEDURES



5

Step-by-step guide

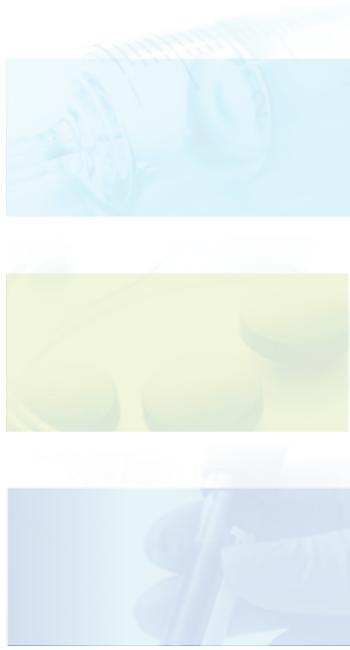
5. Step-by-step guide



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

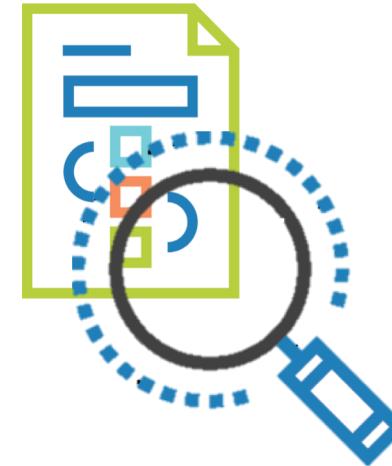
Verification of product data sheets

5a. Verification of product records



TASK

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



Communicate any omissions or errors to: pqsinfo@who.int & huckerbyg@who.int using the relevant change request form linked on slide 60 of this deck.

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 shows the ePQS software interface. A red box labeled '1' highlights the 'ePQS Products' tab in the top navigation bar. A red box labeled '2' highlights the 'IMDs (All)' dropdown in the main content area. A red box labeled '3' highlights the WHO Product ID 'E001-' in the list of products. The interface includes a search bar, a toolbar with various icons, and a detailed product list table.

WHO Product ID	Applicant Organization	Product Status	Date of Application	Date of Prequalification	Date of Product Can...
1 E001-		Prequalified	01/01/1900	17/08/2010	
2 E001-		Prequalified	01/01/1900	20/04/2011	
3 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.

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”



The screenshot shows the ePQS Product record page. At the top, there is a header with the product type 'Immunisation Device', the applicant organization, the product assessment procedure 'Prequalification - Standard', the date of application submission '01/01/1900', and the date of prequalification/acceptance '05/06/2019'. Below the header, there are tabs for 'Details', 'Related', 'Document', 'Activity', 'Chatter', and 'Audit Trail'. The 'Related' tab is selected and highlighted with a red box. The 'Related' section displays a list of record types: 'Product Sites (1)', 'IMD Product Variants (WHO Product ID) (1)', 'Applications (1)', 'Commitments/Established Conditions (0)', 'Fees (0)', and 'Files (0)'. The 'IMD Product Variants' section is also highlighted with a red box. The 'Product Sites' section shows one item with status 'Accepted'. The 'IMD Product Variants' section shows one item with 'IMD Variant Ref.'. The 'Applications' section shows one item with status 'Prequalified'. The 'Commitments/Established Conditions', 'Fees', and 'Files' sections show zero items.

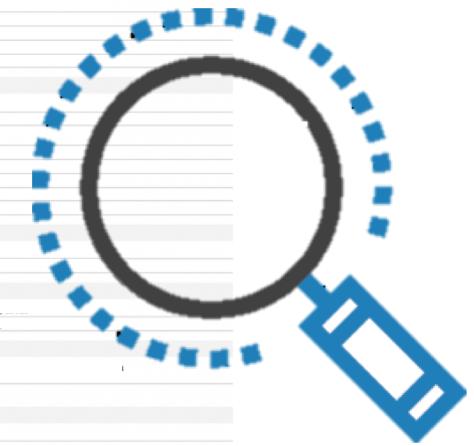
5a. Verification of product data records



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 &
huckerbyg@who.int
- **To report issues please use the templates on the following slide.**



IMD Product Variant
IMDV-00065

Related Details Activity Audit Trail

Comments

Product identification

IMD Variant Ref: WHD Product ID: Record Type: Device sub-category: Valid Until: Supplier: Manufacturers Reference: Country or Manufacture:

Product specifications - Main

Temperature Zones: Holdover time CR: Holdover time FR: Pre-qualified regions: Auto default:

Enclosure construction options

Cold room sizes available (largest, m³): Cold room sizes available (smallest, m³): Freezer room sizes available (L, m³): Freezer room sizes available (S, m³): Door size options available: Door frame heating available: Panel insulation material: Panel joining system: Panel thickness options: Sheling system: Sheling material: Shored wall construction: Strip curtain available: Pressure release valve (PRV) only: Floor stand heater mat (PRV only): Wall/Ceiling Panel Finish: Floor panel finish: Type of Foaming Agent:

Product specifications - Equipment options

Refrigerant: Refrigeration unit mounting options: Refrigeration unit types: Lighting system: Duty sharing: Cold climate protection CR: Evaporator plenum guard CR: ISO 9001/14001 certified: ISO 9001/14001 certified (Other): Electric Safety Compliant To IEC 60335-1: High/vlow voltage protection: Voltage/Frequency/Phasing options?: Voltage Regulator Available?: Surge Protection Available?: Cut-out system:

Product specifications - Temperature monitoring & alarm options

Temperature recording system: Alarm system: ISO 14001 certified:

Warranty, installation and maintenance

Warranty period (months): 12 Maintenance service: Installation service:

Quality standard

Quality Standard: Quality Standard (Other): Specification Reference:

Verification

Verification Laboratory: Verification Report Reference:

Records

Remarks for Publishing: Created By: IMD Data Migration, 16/11/2023, 06:40 Last Modified By: IMD Data Migration - 16/11/2023, 06:40

Published Record Details

Published Snapshot 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”**.

The screenshot shows the ePQS application interface. At the top, there is a navigation bar with the ePQS logo, a search bar, and a user profile. Below the navigation bar, there is a horizontal menu with options: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The 'Organizations' button is highlighted with an orange box. Below the menu, there are four large buttons: 'Submit an application' (with a WHO logo), 'Create Account or Contact' (with a WHO logo), 'Edit an Account or Contact' (with a WHO logo), and 'Change a Record Contact' (with a WHO logo). At the bottom left, there is a section titled 'COMMONLY USED LISTS' with links to: Medicine Storage Conditions, WHO Vaccine Names, Medicines Pharmaceutical Ingredients, VC Active Ingredients/Synergist Name, and QCLm Generic Name (INN). At the bottom right, there is a large button titled 'View ePQS Registered Accounts' with an orange border.

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

The screenshot shows the ePQS software interface. In the top navigation bar, the 'Accounts' tab is selected, showing a dropdown menu. The menu is titled 'ePQS Accounts (Portal)' and contains two options: 'All Vx accounts' and 'ePQS Accounts (Portal)'. The 'ePQS Accounts (Portal)' option is highlighted with an orange box. Below the menu, there are sections for 'Recently Viewed' and 'Recently Viewed Accounts'. The top right of the interface includes a search bar, a 'Search' button, and a user profile icon.

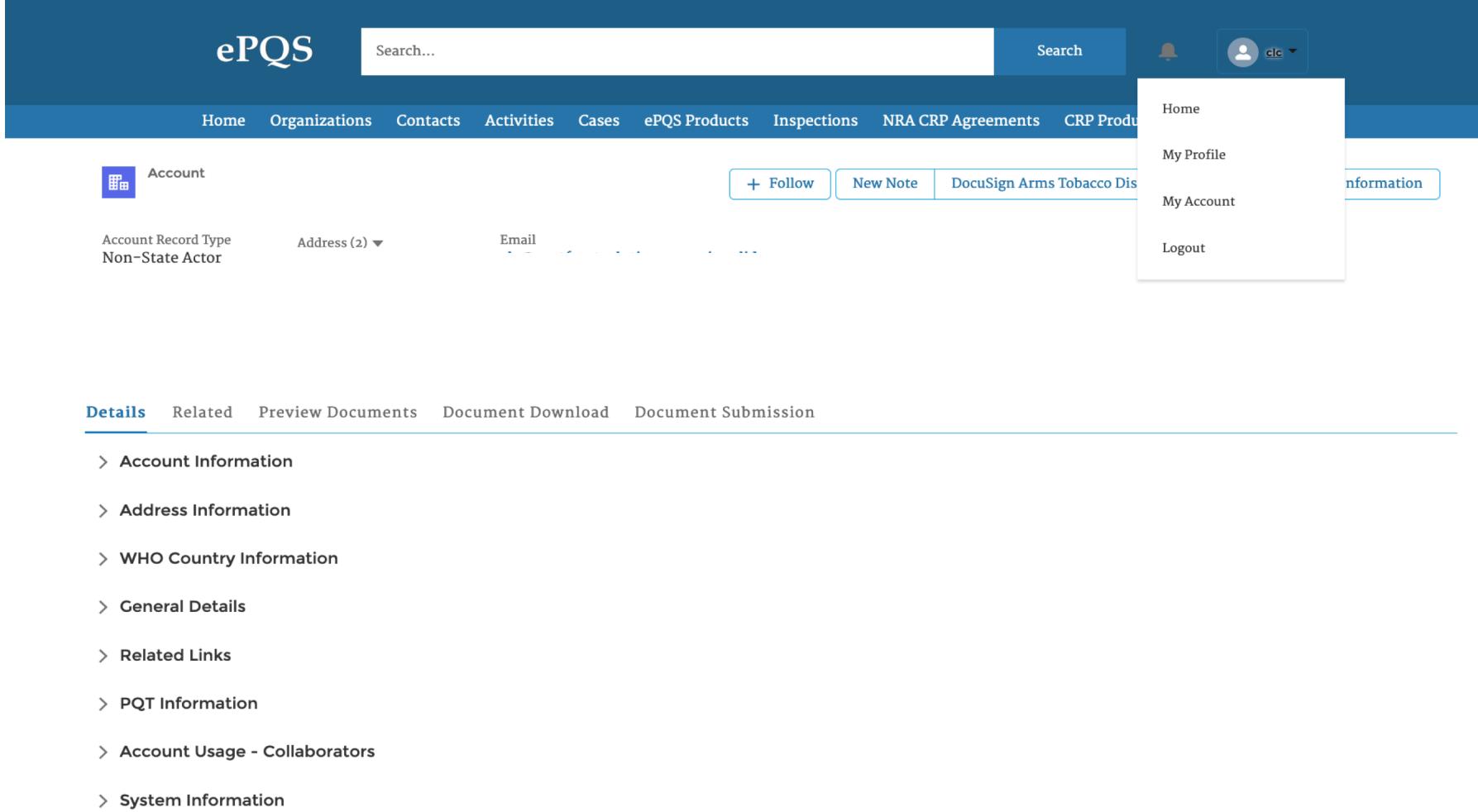
*** As an IMD-PQS prequalified manufacturer or reseller, the only account to which a user is associated is their own company.

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:
pqsinformation@who.int & huckerbyg@who.int



The screenshot shows the ePQS application interface. At the top, there is a navigation bar with links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Products. A search bar is also present. On the right side, there is a user profile icon and a dropdown menu with options: Home, My Profile, My Account, and Logout. The main content area displays account details for a 'Non-State Actor'. It includes fields for Account Record Type (Non-State Actor), Address (2), and Email. Below this, there is a 'Details' tab and a list of expandable sections: Account Information, Address Information, WHO Country Information, General Details, Related Links, PQT Information, Account Usage - Collaborators, and System Information. The 'Details' tab is currently selected.



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 shows the ePQS application interface. At the top, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Products. To the right of the navigation bar is a search bar with a 'Search' button. Further right is a user profile icon, which is highlighted with a red box and a red circle containing the number '1'. A dropdown menu is open from this icon, listing 'Home', 'My Profile', 'My Account' (which is also highlighted with a red box and a red circle containing the number '1'), and 'Logout'. Below the navigation bar, the main content area has a title 'Account' with a small icon. It shows 'Account Record Type: Non-State Actor', 'Address (2) ▾', and an 'Email' field. To the right of this are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco'. At the bottom of the main content area is a navigation bar with tabs: 'Details' (which is highlighted with a red box and a red circle containing the number '2'), 'Related', 'Preview Documents', 'Document Download', and 'Document Submission'. The 'Related' tab is currently selected. Below this navigation bar is a list of links: '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:

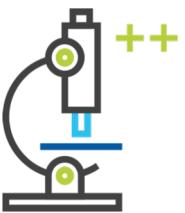
- Notes
- Related contacts
- Product sites
- Case
- Products
- Files
- Account history

The screenshot shows the ePQS software interface with the 'Related' sub-tab selected. The sub-tab displays a list of related records. The records are categorized as follows:

- 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 Organization) (0)
- NRA CRP Participations (NRA Organization) (0)
- Files (0)
- Account History (0)

At the bottom of the 'Files (0)' section, there is a 'Upload Files' button and a placeholder text 'Or drop files'.

5cii. Correct record visibility - Products



Products

Expand or click directly on the Products sub-tab.

Screenshot of the ePQS software interface showing the 'Products' sub-tab selected. The interface includes a top navigation bar with links like Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation is a search bar and a toolbar with buttons for Follow, New Note, DocuSign Arms Tobacco Disclosure, and Update Published Information. The main content area displays various related entities: 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), and Files (0). The 'Products (Applicant Organization)' section is highlighted with an orange box. At the bottom of the page, there is a footer with links to About Us, Contact Us, Privacy Policy, and Legal Disclaimer, and a 'SECTION C – APPLICATION PROCEDURES' heading.

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.

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

WHO Prod...	Product Name	Vaccine ...	Product Status	Product Type	Product Subtype
1	Product listing details ...				
2	Product listing details ...				
3	Product listing details ...				
4	Product listing details ...				
5	Product listing details ...				
6	Product listing details ...				
7	Product listing details ...				
8	Product listing details ...				
9	Product listing details ...				
10	Product listing details ...				

About Us Contact Us Privacy Policy Legal Disclaimer



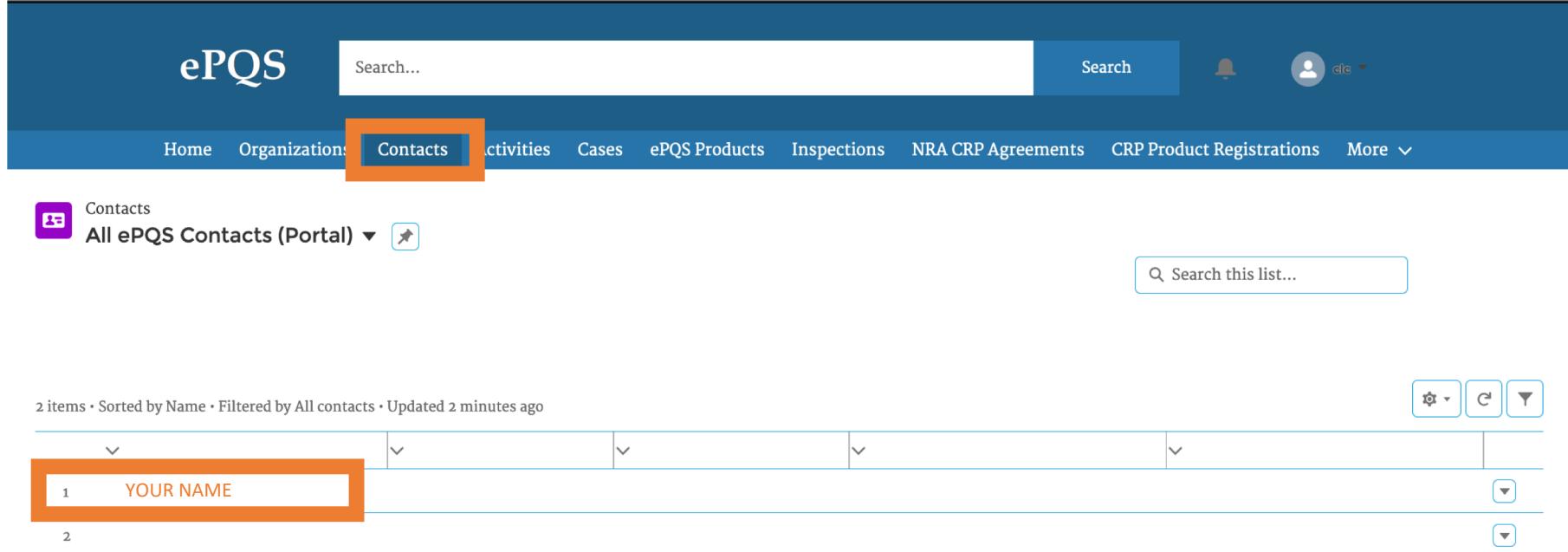
5d

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.



The screenshot shows the ePQS application interface. The top navigation bar includes links for Home, Organizations, Contacts (which is highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. A search bar and a user profile icon are also present. The main content area is titled 'Contacts' and shows a list titled 'All ePQS Contacts (Portal)'. The list contains one item: '1 YOUR NAME'. A search bar labeled 'Search this list...' is located to the right of the contact list. The bottom of the page shows pagination with '2' and a dropdown arrow.

2 items • Sorted by Name • Filtered by All contacts • Updated 2 minutes ago

1	YOUR NAME
2	

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

5d. Personal use folder



Once inside their own contact record, users should click the **“Preview Documents”** tab. Users will see a folder: **(YourName)** **“PersonalFolder”**. Upload documents by clicking on the “+” icon.

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

The screenshot shows the ePQS software interface. At the top, there is a navigation bar with links: Home, Organization, **Contacts** (which is highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, there is a search bar with the placeholder "Search..." and a "Search" button. To the right of the search bar are a bell icon and a user profile icon with the name "clic".

The main content area is titled "Contact" and shows fields for Job Title, Account Name, Phone (2) ▾, Email, and Contact Owner. Below these fields, there are tabs: Details, Related, **Preview Documents** (which is 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 with the placeholder "Search files and folders".

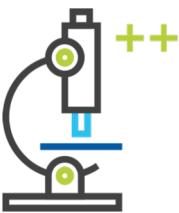
Under the "Preview Documents" tab, there is a section titled "YOUR Personal Folder" with an orange " +" icon. Below this section, there is a small icon of a folder with a plus sign and the text "There are no items in this folder." At the bottom of the page, there are links: About Us, Contact Us, Privacy 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.

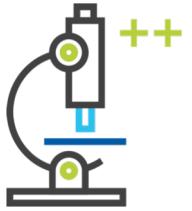
If you do not submit your application at the end of the wizard process, draft records will appear in the applicable List Views on your homepage.

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.

Next

January 2025

SECTION C – APPLICATION PROCEDURES



5e. Application submission procedure

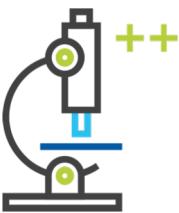
VERY IMPORTANT INFORMATION:

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

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



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 & Contacts Application Info Product Details Documents Finalize

Continue Application

A draft application has been created.

For reference the new application has the case number **PQ-IMD-2023-0040**. You can view the draft application details by following the link.

Next

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

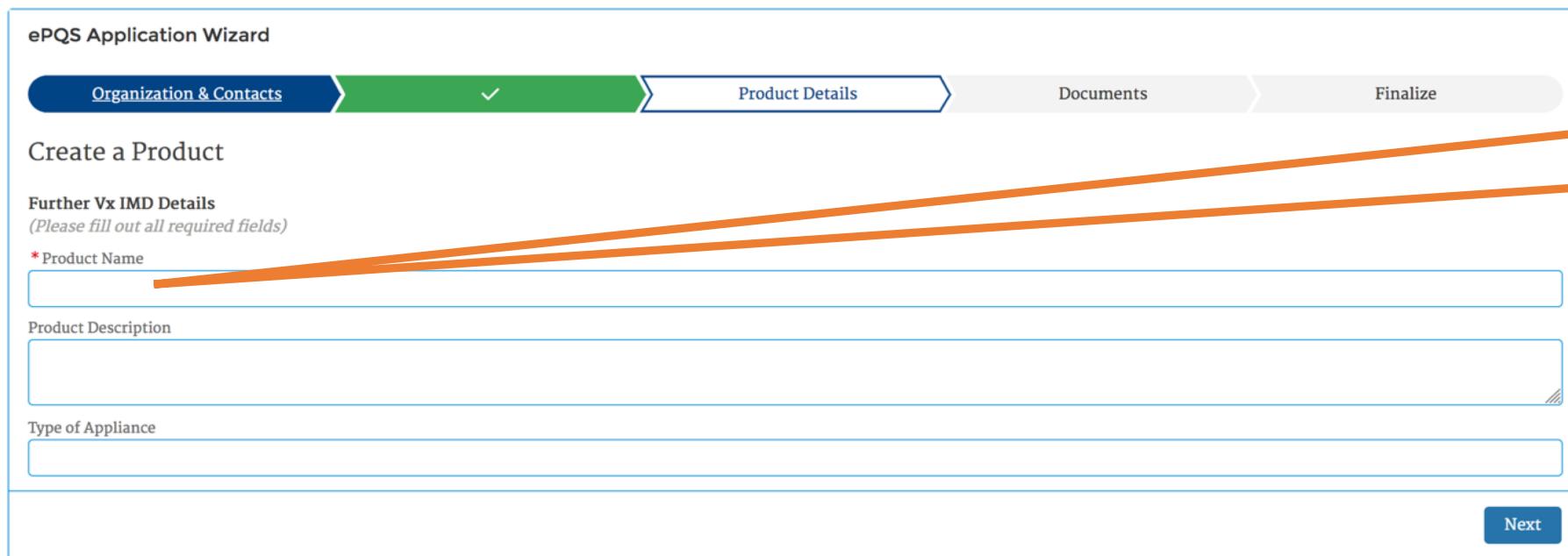
Further Vx IMD Details
(Please fill out all required fields)

* Product Name

Product Description

Type of Appliance

Next



Refer to the following document to identify the list of options for "Product descriptions". (Picklist or free text)



[ePQS "Product description" data labels for WHO Immunization Devices](#)

5e. Application submission procedure



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

For the data field “Device sub-category”, use the **same label** that you selected for the “Product Description” field.

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.
Please fill the appropriate ‘Other’ fields – if ‘Other’ option is selected as one of the values in the picklist/multipicklist, to prevent errors while submitting the application.)

Product Identification

IMD Variant Reference
WHO Product ID
Record Type : IMD Product Variant

* Device Sub-Category
--None--

* Supplier
Search Accounts...

Manufacturers Reference

* Country of Manufacture
--None--

Refer to the following document to identify the list of options for “Product descriptions” (Picklist or free text)



[ePQS “Product description” data labels for WHO Immunization Devices](#)

[\(<https://extranet.who.int/prequal/key-resources/documents/epqs-product-description-data-labels-who-immunization-devices>\)](https://extranet.who.int/prequal/key-resources/documents/epqs-product-description-data-labels-who-immunization-devices)

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--

January 2025

****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



IMPORTANT INFORMATION REGARDING VERIFICATION LABORATORIES:

At the present time the ePQS data field for Verification Laboratory selection does not function.

Kindly submit this information to the IMD-PQS team by email, copying huckerbyg@who.int.

ePQS Application Wizard

Organization & Contacts Product Details Documents Finalize

Create IMD Product Variants

Variant Information Details Screen 2
(Please fill out all required fields. For picklist fields, --None-- should be selected if the answer is not available.)

- > Product specifications - Temperature monitoring & alarm options
- > Comments
- > Warranty, installation and maintainence
- ▽ Quality Standard

Quality Standard

- ISO 9001: 2000
- ISO 9004: 2000
- ISO 17025:2017
- ISO 13485: 2016
- Other

Specification Reference

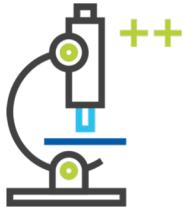
Verification

Verification Laboratory

Search ePQS Products...

Verification Report Reference

Previous Next



5e. Application submission procedure

IMPORTANT REMINDER:

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

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

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

- If the product site option provided is NOT the required site (e.g. you have multiple manufacturing sites) please contact Huckerbyg@who.int and provide the manufacturing site address. The addresses will then be correctly assigned in ePQS.
- If you are the a product reseller, please contact Huckerbyg@who.int and provide the OEM manufacturing name and site address. A new account record will be created and linked to your account.



ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Related Information

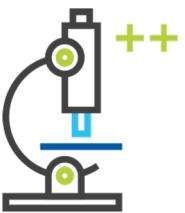
* Choose Product Related Information to Add to Application

Product Site

I don't want to add any more product related information at this time

Previous Next

5e. Application submission procedure



“Product site” guidance:

ePQS Application Wizard

Organization & Contacts > ✓ > ✓ Product-Related Info > Documents > Finalize

Add Product Sites

Choose Site

Indicate which site will be linked to your product, [P-14064](#):

* Site search – enter at least 2 characters of the site you wish to add

Previous Next

<-- Add the first two characters of your company name

ePQS Application Wizard

Organization & Contacts > ✓ > ✓ Product-Related Info > Documents > Finalize

Add Product Sites

Choose Site

Click 'Previous' if the site you require is not on the list. Please ensure you are choosing the manufacturing site address.

* Site Name

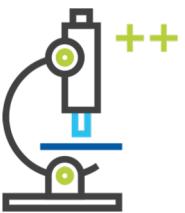
ooAwaitingNewOrganistion -



Previous Next

<-- Expand the list to view the matches found, and select your company.

5e. Application submission procedure



“Product site” guidance (cont.):

ePQS Application Wizard

Organization & Contacts > ✓ > ✓ Product-Related Info > Documents > Finalize

Add Product Sites

Select Site Activity

Indicate the site activity and activity types relevant.

* Site Activity

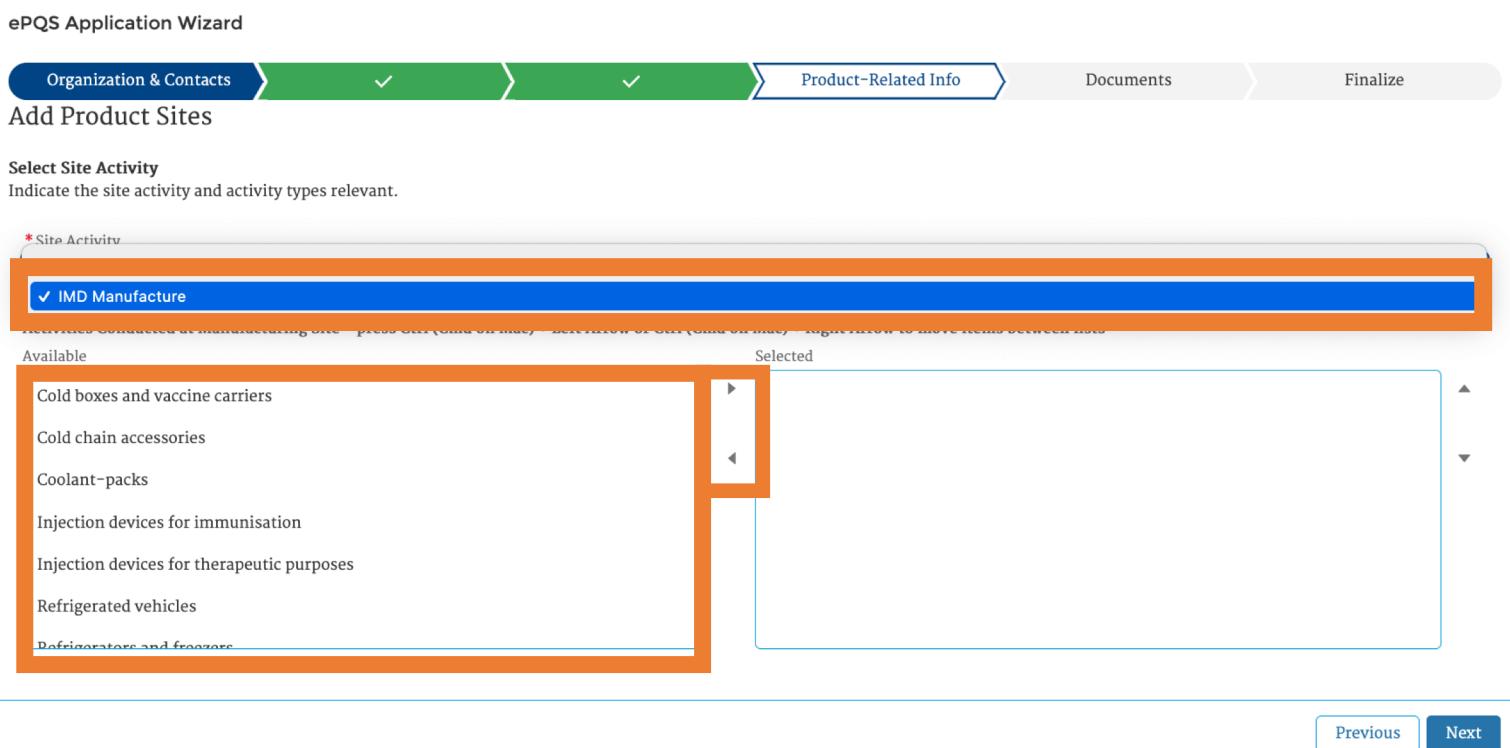
IMD Manufacture

Available

Cold boxes and vaccine carriers
Cold chain accessories
Coolant-packs
Injection devices for immunisation
Injection devices for therapeutic purposes
Refrigerated vehicles
Refrigerators and freezers

Selected

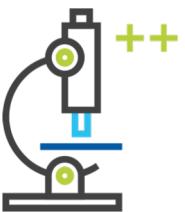
Previous Next



<-- Select “site activity”: “IMD manufacturer”

<-- Then select the correct product category and move the value to the right hand box.

5e. Application submission procedure



“Product site” guidance (cont.):

ePQS Application Wizard

Organization & Contacts > ✓ > ✓ Product-Related Info > Documents > Finalize

Add Product Sites

Check
Is this the site you were expecting to be linked to this product?

- Site Name: ooAwaitingNewOrganistion
- Site Street:
- Site City:
- Site Zip/Postcode:
- Site Country:

Previous Next

<-- Lastly, the Wizard will prompt you to review the product site information and selections you have made.

5e. Application submission procedure



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

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

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



5e. Application submission procedure



List of mandatory documents.

The IMD-PQS Secretariat has provided 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>

5e. Application submission procedure

MANDATORY folder structure



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

A. INITIAL APPLICATION ROUND 1

-  A1. DOSSIER SUBMISSION INFORMATION
 -  A1i. PRE-SUBMISSION APPLICATION
 -  A2ii. DEVICE TECHNICAL SPECIFICATION
 -  A3iii. LABORATORY/MANUFACTURER QUALITY CERTIFICATION(S)
 -  A4iv. DEVICE MARKETING APPROVAL(S)
-  A2. COMPLETED APPLICATION REVIEW TEMPLATE
-  A3. SUBMISSION DATA
 -  A3i. TEST REPORTS
 -  A3ii. INSPECTION REPORTS
 -  A4iii. USER-TESTING REPORTS
 -  A5iv. RISK ANALYSIS
-  A4. EQUIPMENT CALIBRATION CERTIFICATES
-  A5. TEST PROTOCOLS

B. APPLICATION REVIEW ROUND 2

C. APPLICATION REVIEW ROUND 3

Upload the pre-submission you submitted previously to the IMD-PQS Secretariat (if relevant).

This is the Application Review Template provided to you in the application guidance from the IMD-PQS Secretariat.

****** *Include the up-to-date, most recent version of the Application Review Template in every round of review.*

- **This folder structure is mandatory.**
- **However, applicants are only required to create & upload the folders & subfolders that are relevant & required for their application.**
- **Refer to the detailed list of application requirements provided to you by the WHO IMD-PQS Secretariat.**

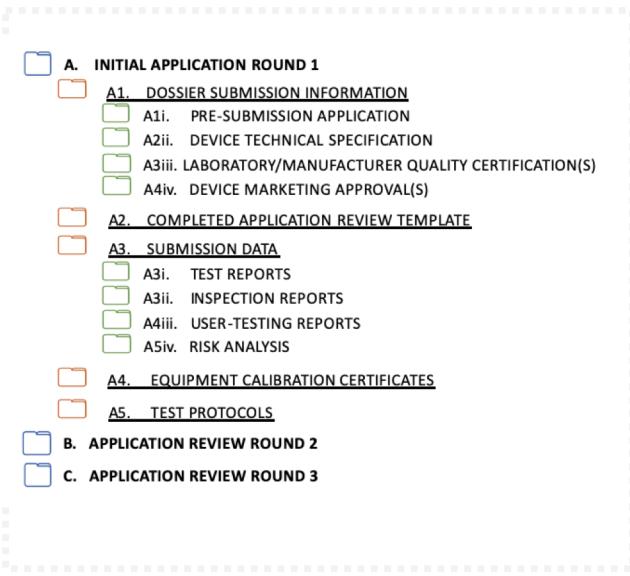
- **CLICK HERE TO DOWNLOAD THIS FOLDER STRUCTURE IN PRE-FORMATTED .ZIP FORMAT:**
<https://extranet.who.int/prequal/key-resources/documents/imd-pqs-epqs-mandatory-folder-structure>

5e. Application submission procedure

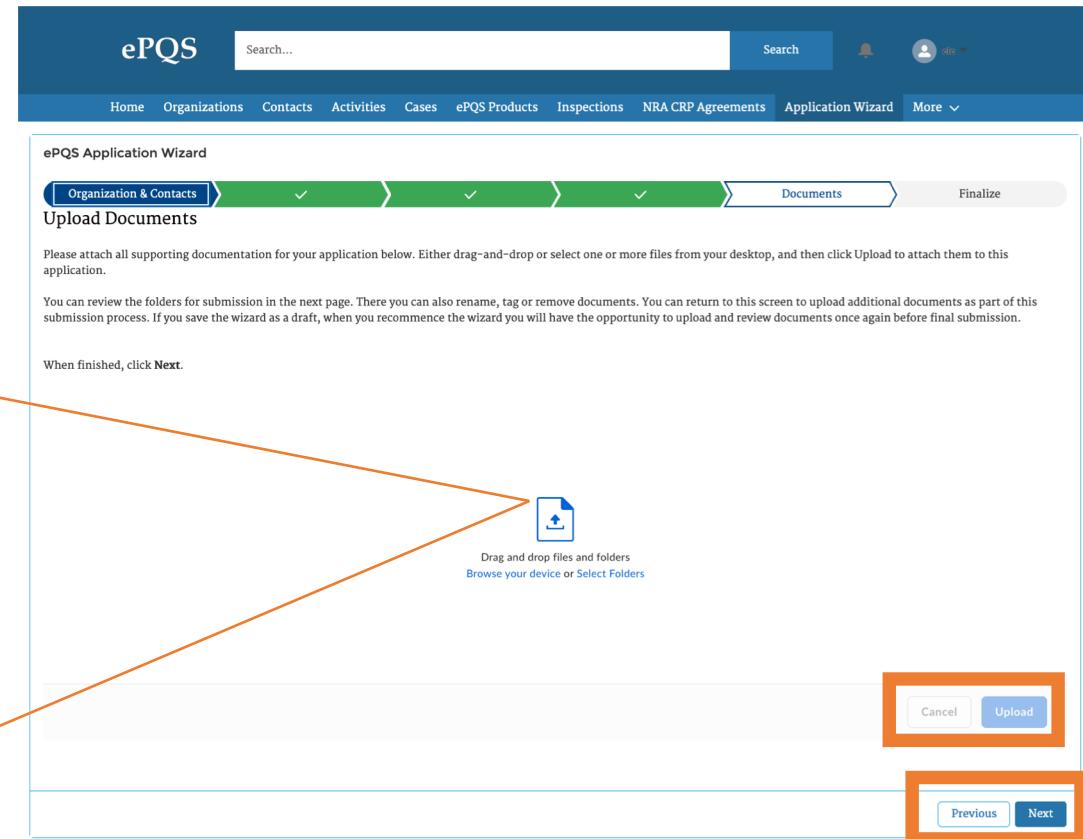
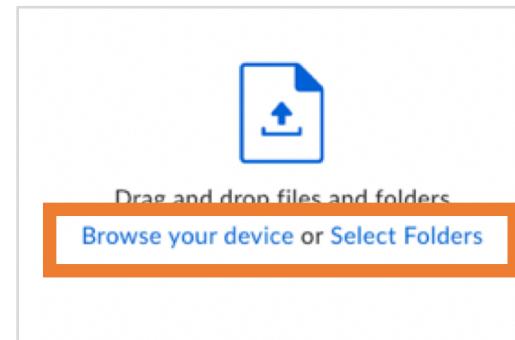
MANDATORY folder structure



1 Create the folder structure locally on your computer.



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





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

A. Initial application (Round 1)

NAME	UPDATED	SIZE
A1. Dossier submission information	Aug 15, 2025 by WHO_JWT	18 Files
A2. Completed Application Review Template	Aug 15, 2025 by WHO_JWT	1 File
A3. Submission data	Aug 15, 2025 by WHO_JWT	8 Files
A4. Equipment calibration certificates	Aug 15, 2025 by WHO_JWT	0 Files
A5. Test protocols	Aug 15, 2025 by WHO_JWT	1 File

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

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](#)

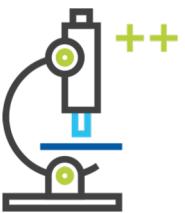
Submit, Save or Discard
Please choose whether you are ready to submit this application, if you need more time then save the existing draft, or discard if made in error.

*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](#)

5e. Application submission procedure



Receiving application feedback from the IMD team

During the course of the application assessment you may receive up to 3 requests for further information. The IMD team's feedback on your application will always, and only, appear in the "External Correspondence" documents folder related to the specific submission/application:

Case Record Type: Vx IMD Application

Case Number: [redacted]

Status: Under Assessment

Applicant Organization: [redacted]

Date of Prequalification/Acceptance: [redacted]

Case Owner: ePQS Vx IMD Queue

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

box Search files and folders

PQ-IMD-2025-0118

Correspondence (External)
Modified Wed Oct 29 2025 • 0 Byte

0 Selected



5e. Application submission procedure

Receiving application feedback from the IMD team (cont.)

You will always also receive an “Activity notification” by email, from the ePQS system, when the feedback is uploaded. This notification is labelled “Request for Information”:

External Activities

All Activities (Applications - Portal)

1 item • Sorted by Activity Name • Filtered by All external activities - Related To (Inspection) • Updated a few seconds ago

Activity Name ↑ Subject Owner Las... Related To (C... Status Start Date Due Date End Date

Activity Name ↑	Subject	Owner Las...	Related To (C...	Status	Start Date	Due Date	End Date
1 EA-	Request for Information			In-Progress			

Continues on next slide →

5e. Application submission procedure



Receiving application feedback from the IMD team (cont.)

Example Activity Notification:

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

External Activity EA-

Edit Change Owner

Details Related

Comments

Information

Case Information

System Information

Owner

Time Assignment

Manufacturer

Status

In-Progress

Activity Outcome

Activity Phase

In Progress

Response Date

Component Type

Dossier Assessment

Last Modified By

Gemma HUCKERBY, 20/11/2025, 21:01

Record Type

ePQS Workflow Task

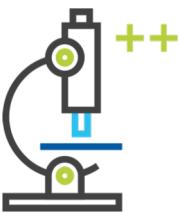
Comments	Related To (Case)	Related To (Inspection)	Owner	Time Assignment	Manufacturer	Status	In-Progress	Activity Outcome	Activity Phase	Response Date	Component Type	Dossier Assessment	Last Modified By	Record Type
Comments	Related To (Case)	Related To (Inspection)	Owner	Time Assignment	Manufacturer	Status	In-Progress	Activity Outcome	Activity Phase	Response Date	Component Type	Dossier Assessment	Gemma HUCKERBY, 20/11/2025, 21:01	ePQS Workflow Task



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

Optional 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

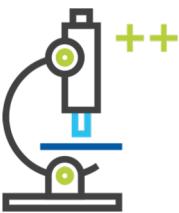
Select the product area to narrow down the list of application types.

* 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

[Previous](#) [Next](#)

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

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.

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Choose Application Subtype

Please enter the following additional information:

* Application Subtype

Type A(Administration)
Type B (Technical)

Previous Next

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.

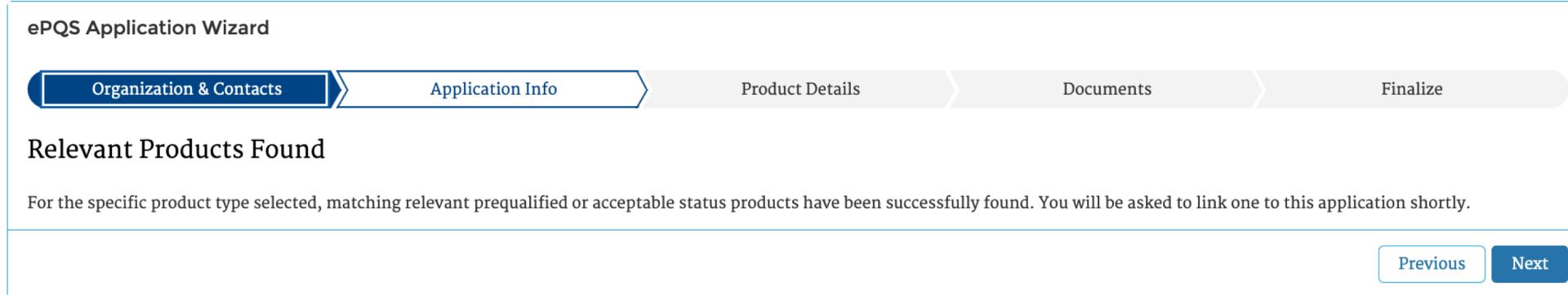
ePQS Application Wizard

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.

Previous Next



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

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: [redacted]

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

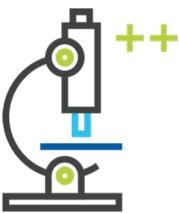
Continue Application

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.

Next

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...**”

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



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

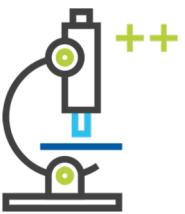
Eoo

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](#)

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

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

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](#)

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

5f. Post-PQ variation submission procedure



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

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

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

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](#)

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

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”.

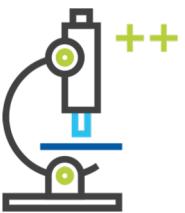
ePQS Application Wizard

* Select Document Type

eCTD
 Non-eCTD

[Previous](#) [Next](#)

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.**

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.

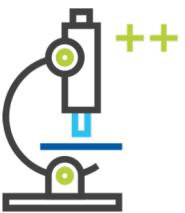
When finished, click **Next**.

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

Cancel Upload

Previous Next

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

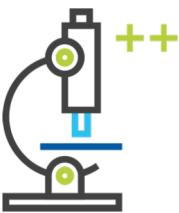
2024-08-23-16:29

There are no items in this folder.

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

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.

Case PQC-IMD-2024-0007

Case Record Type Vx IMD Post-PQ Change Case Number 00026713

Status Under Screening

Applicant Organization Date of Prequalification/Acceptance Case Owner 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



5g

Up/downloading of documents

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



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

The screenshot shows the ePQS software interface. The top navigation bar includes 'ePQS', a search bar, and a user profile. The 'Cases' tab is highlighted with an orange box. The left sidebar shows a list of cases under 'Cases' and 'All Cases (Portal)'. The main content area displays a table of cases with the following data:

	Application S...	WHO Pro...	Date Appli...	Date Appli...	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	

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

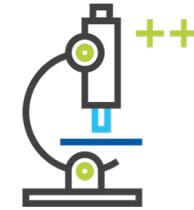


Only an “External correspondence” folder is available for cases.

The “Preview”, “Download” and “Submission” functions are available.

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

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



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

The screenshot shows the ePQS software interface. At the top, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. A search bar is also present. On the right side of the header, there is a user profile icon, a bell icon, and a dropdown menu with options: Home, My Profile, and Logout. Below the header, the main content area has a title 'Account' with a small icon. It displays 'Account Record Type: Non-State Actor' and an 'Email' field. At the bottom of this section, there are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Disclosure'. Below this, there is a navigation bar with tabs: Details, Related, Preview Documents, Document Download, and Document Submission. The 'Document Submission' tab is highlighted with an orange box. Below the tabs, there is a section titled 'Upload to Account Submission' with the sub-instruction: 'Welcome to Document Submission Wizard. Please click on **Next** to proceed for Account#Vestfrost Solutions'. At the very bottom of the screenshot, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

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



Document submission interface →

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

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

Upload to Account Submission

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

Cancel Upload Next



5h

Viewing assigned activities

5i. Viewing of assigned activities



Clicking on the “Activities” tab will display a list of all pending activities related to your account. Clicking on each list item will take you to the detailed instructions / requirements of each task. **Users should note that they will automatically receive an email (via the contact-registered email address) each time a new activity is assigned.**

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

A screenshot of the ePQS software interface. The top navigation bar is dark blue with the ePQS logo on the left, a search bar in the center, and user profile and notification icons on the right. Below the navigation bar is a secondary menu with links: Home, Organizations, Contacts, Activities (which is highlighted with an orange box), Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area has a white background. On the left, there is a sidebar with a green circular icon containing a white circle and the text "External Activities". Below this is a dropdown menu labeled "All Activities (Applications - Portal)" with a downward arrow and a blue square icon. The main content area displays a table header with columns: Activity Name (with an upward arrow), Subject (with a downward arrow), Owner Last Name (with a downward arrow), Related To (Case) (with a downward arrow), Status (with a downward arrow), Start Date (with a downward arrow), Due Date (with a downward arrow), and End Date (with a downward arrow). Below the header, there is a search bar with the placeholder "Search this list...", and several small blue icons for filtering and sorting. At the bottom of the content area, there is a large orange rectangular box containing three small black dots (...).



5i

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 shows the ePQS application interface. At the top, there is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA, and Help. A search bar is also present. On the right side of the header, there is a user profile icon and a bell icon. A dropdown menu labeled 'Notifications' is open, showing the message: 'You don't have any notifications right now.' The main content area features four large buttons: 'Submit an application' (with WHO logo), 'Create Account or Contact' (with WHO logo), 'Edit an Account or Contact' (with WHO logo), and 'View ePQS Registered Accounts' (with WHO logo). Below these buttons, there 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. At the bottom right, there is a 'FEATURED' section with a blue button labeled 'View ePQS Registered Accounts'.

COMMONLY USED LISTS

[Medicine Storage Conditions](#)

[WHO Vaccine Names](#)

[Medicines Pharmaceutical Ingredients](#)

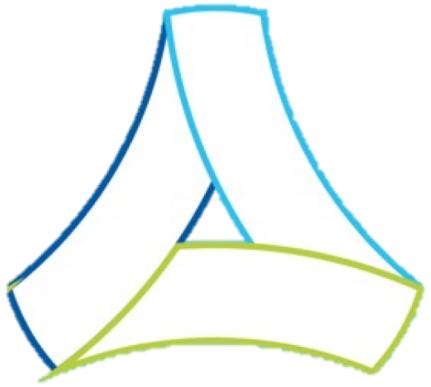
[VC Active Ingredients/Synergist Name](#)

[QCLm Generic Name \(INN\)](#)

[Post-Prequalification Changes](#)

[View ePQS Registered Accounts](#)

FEATURED



SECTION D – TECHNICAL SUPPORT

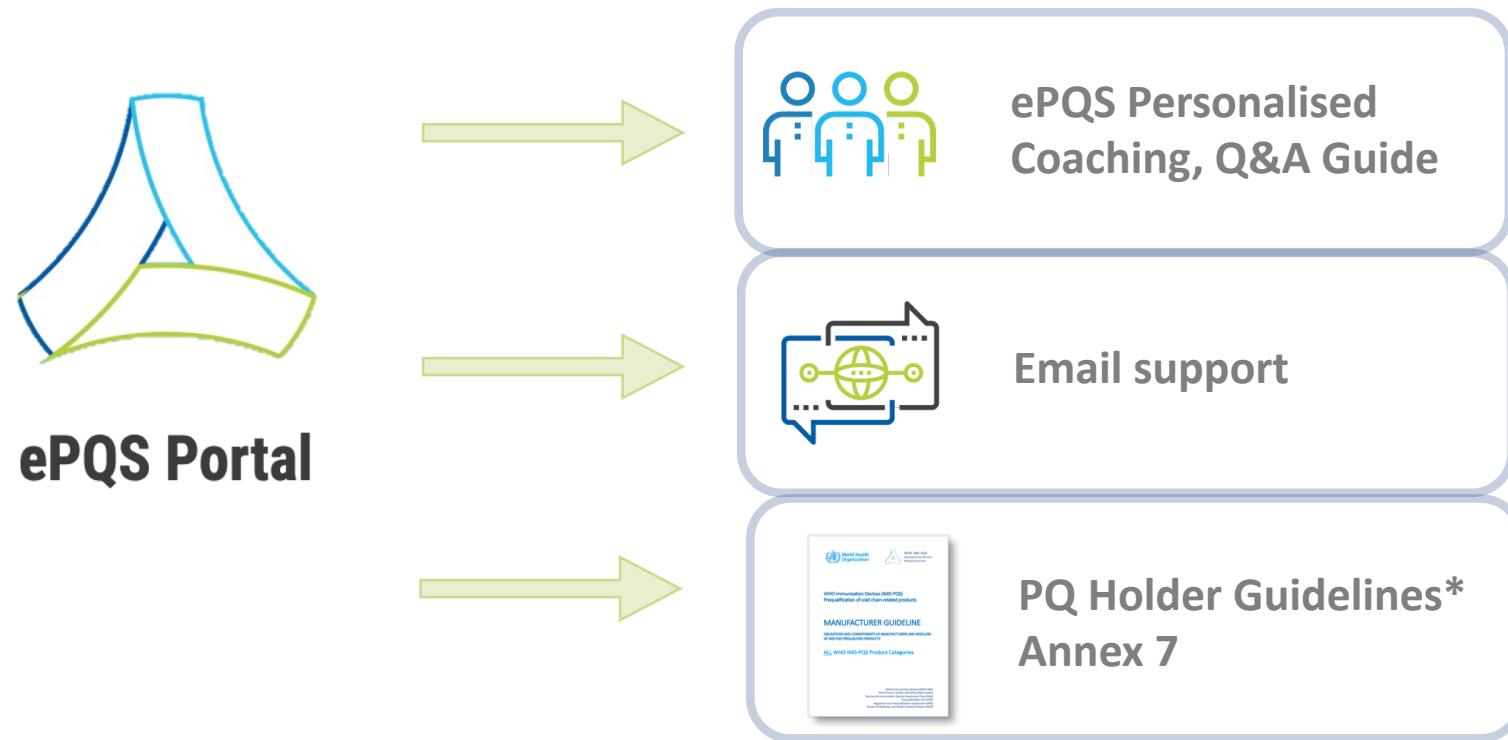


6

Additional technical support

6i. IMD-PQS Technical support

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



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

6ii. General user guidance – specific training

General guidance is available on the ePQS landing page:

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

General Portal Information

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

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

[ePQS - Portal Introduction and Features](#)

[ePQS - Terms and Conditions of use \(4 October 2023\)](#)

[ePQS - User Registration and accessing the ePQS Portal](#)

ePQS Portal



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

Within the portal, users will have the ability to:

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

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

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

Guidance notes related to the features of the portal, processes around applications, document submissions, and many other topics will be progressively posted to this 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](#)

[ePQS - Portal Introduction and Features](#)

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