



WHO e-Prequalification System (ePQS)

Learning materials
WHO Immunization Devices (IMD-PQS)
2025



Prequalification Applicants
Prequalification-Holders



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

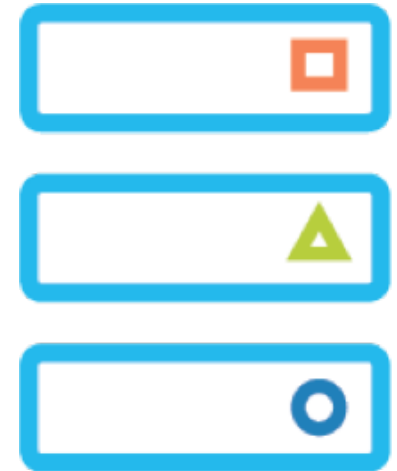
Key access links (for reference)

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



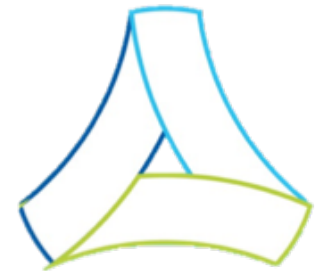
Learning materials are intended as comprehensive resources to support users gain necessary competence and autonomy in using the features and functions of ePQS. **These learning materials concern Immunization Devices (IMD-PQS) users. The deck:**

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



SECTION A - SET-UP

- Introduction
- Pilot
- Registration
- Terminology



SECTION B – DISCOVERY

- Navigating ePQS features & functions



SECTION C – PROCEDURES

- Step-by-step instructions of the application procedures



SECTION D – SUPPORT

- Additional and forthcoming technical support

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SECTION A – SET-UP



1

ePQS Portal Introduction

1. ePQS Introduction – What is ePQS?



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

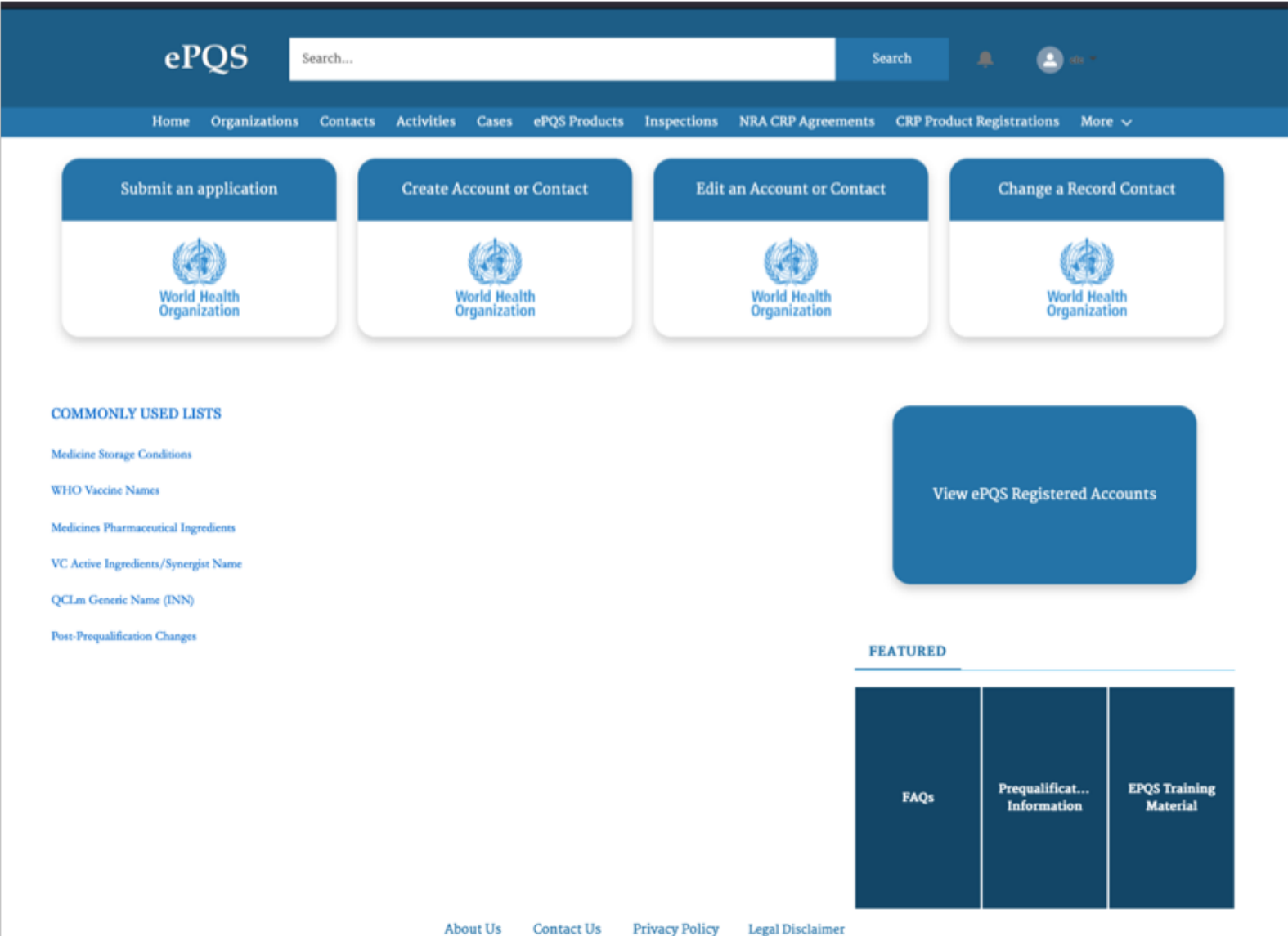
- submit & manage [prequalification applications & post-PQ variations](#)
- follow the [site inspections](#) process
- [view records](#) relevant to them
- submit required changes to account, contact & product information
- upload and download [documents](#) securely
- view and monitor [notifications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

[Product annual reassessment](#) (the IMD-PQS [Annual Review](#)) will be included in the ePQS system in future (2027/8).



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

1. ePQS Introduction – Home page appearance



1. ePQS Introduction

Communication with IMD-PQS



First contact with IMD-PQS – “offline”

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



Applications and post-PQ processes

- Communication between applicants / Prequalification Holders and the IMD-PQS Secretariat will take place via:
 - the ePQS application wizard,
 - Standard email OR 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.



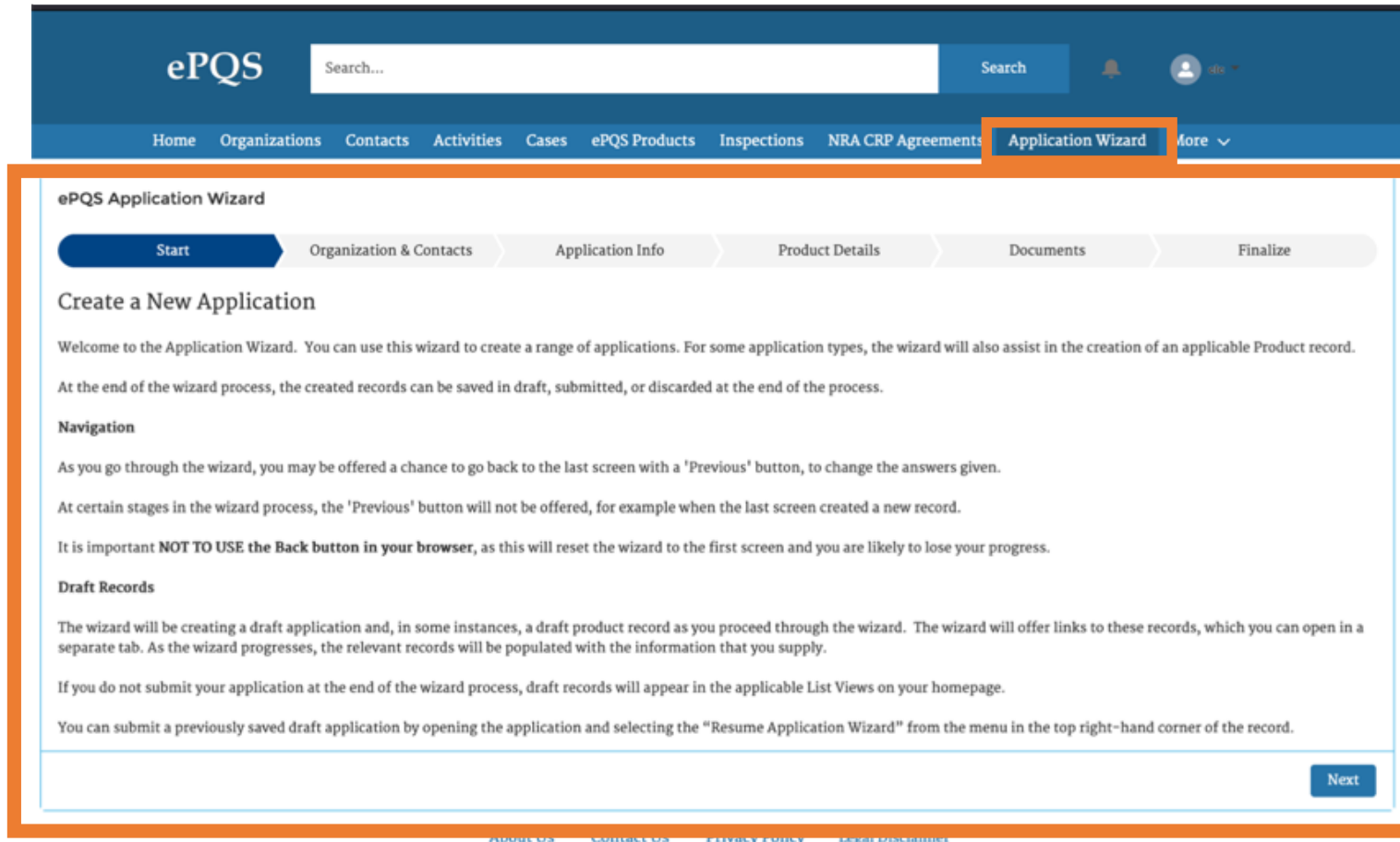
Cloud file-sharing facility (“Box”)

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



1. ePQS Introduction

Quick view - Document up/download

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a 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 shows a product entry for 'ePQS Product E00X-00X'. Below this, there are tabs for 'Details', 'Related', 'Preview Document', and 'Document Download'. The 'Document Download' tab is highlighted with an orange box. An orange arrow points from the 'Document Download' tab to a larger, orange-bordered inset window. This inset window shows a 'box' file manager interface with a search bar and a message: 'There are no items in this folder.' The inset window also has a '0 Selected' button and a close/confirm button.

ePQS

Search...

Search

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

ePQS Product E00X-00X

+ Follow Edit Delete Printable View

Product Type: Immunisation Device
Applicant Organization: Vaccine UAT External Contact 1
Product Assessment Procedure: Prequalification - Standard
Date of Prequalification/Acceptance: 25/11/2009

Details Related **Preview Document** **Document Download**

box Search files and folders

Vx

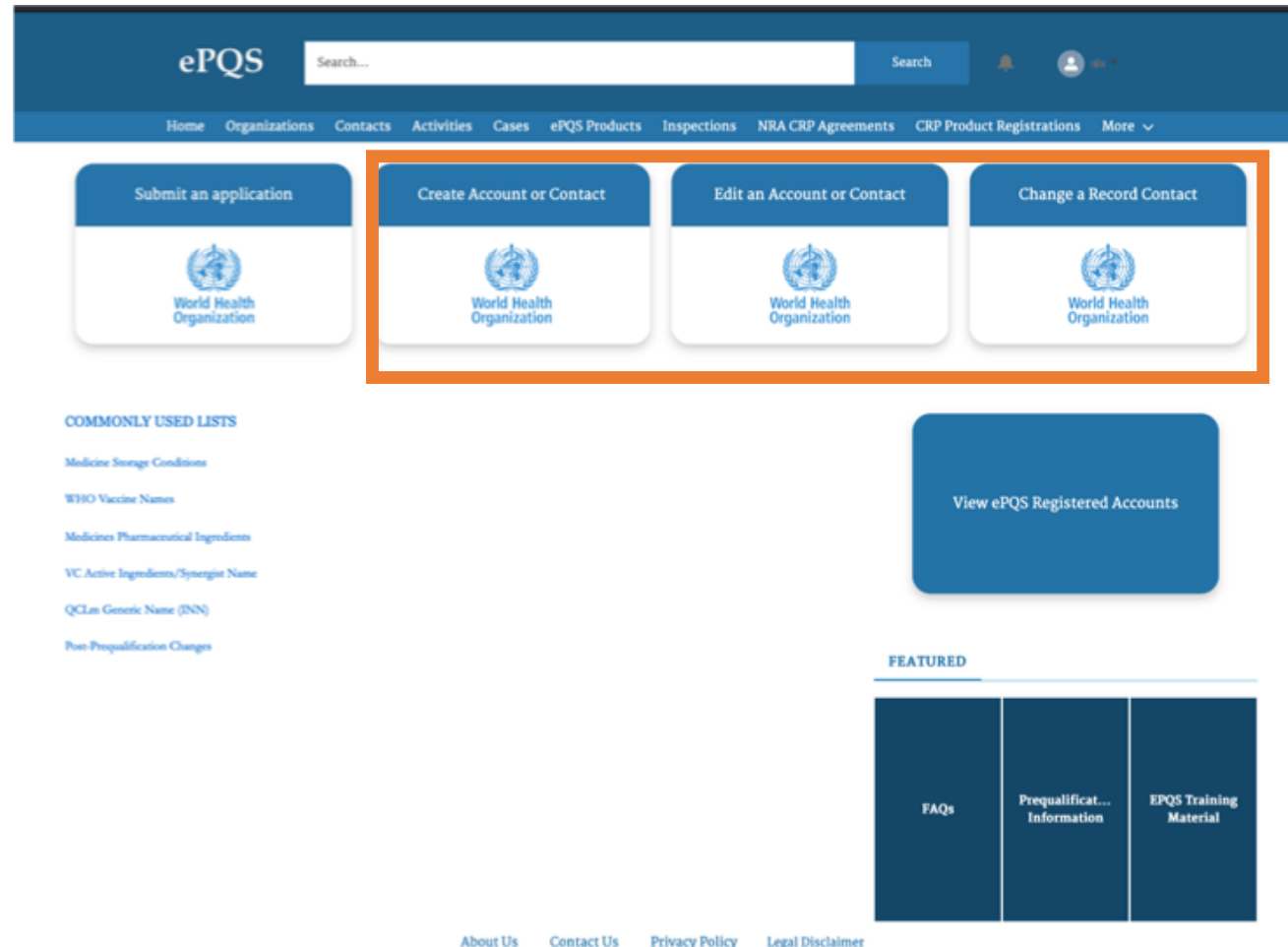
There are no items in this folder.

0 Selected

X ✓

1. ePQS Introduction

Quick view - Data change request forms



1. ePQS Introduction - ALL Features & functions overview

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

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



2

Registration & Access

3. Registration

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

Registration is via the:

“External Form – New ePQS User” linked here:

https://who.my.salesforce.com/sfc/p/#3X000005AZtm/a/NN000001rmcH/.Kqqi2wVzq1Tliizyfrvloi_0D5v_7CmXUozH01_Ke0

Each new user / registration request must complete:

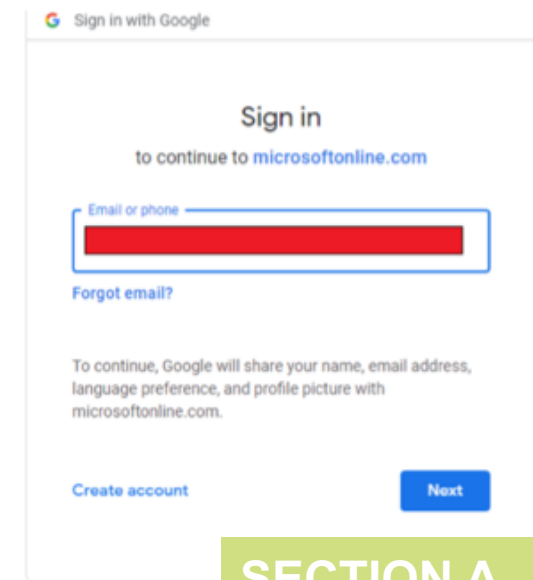
- Section 1 (Declaration),
- Section 3 (New User) and
- Section 4 (New Account)

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.

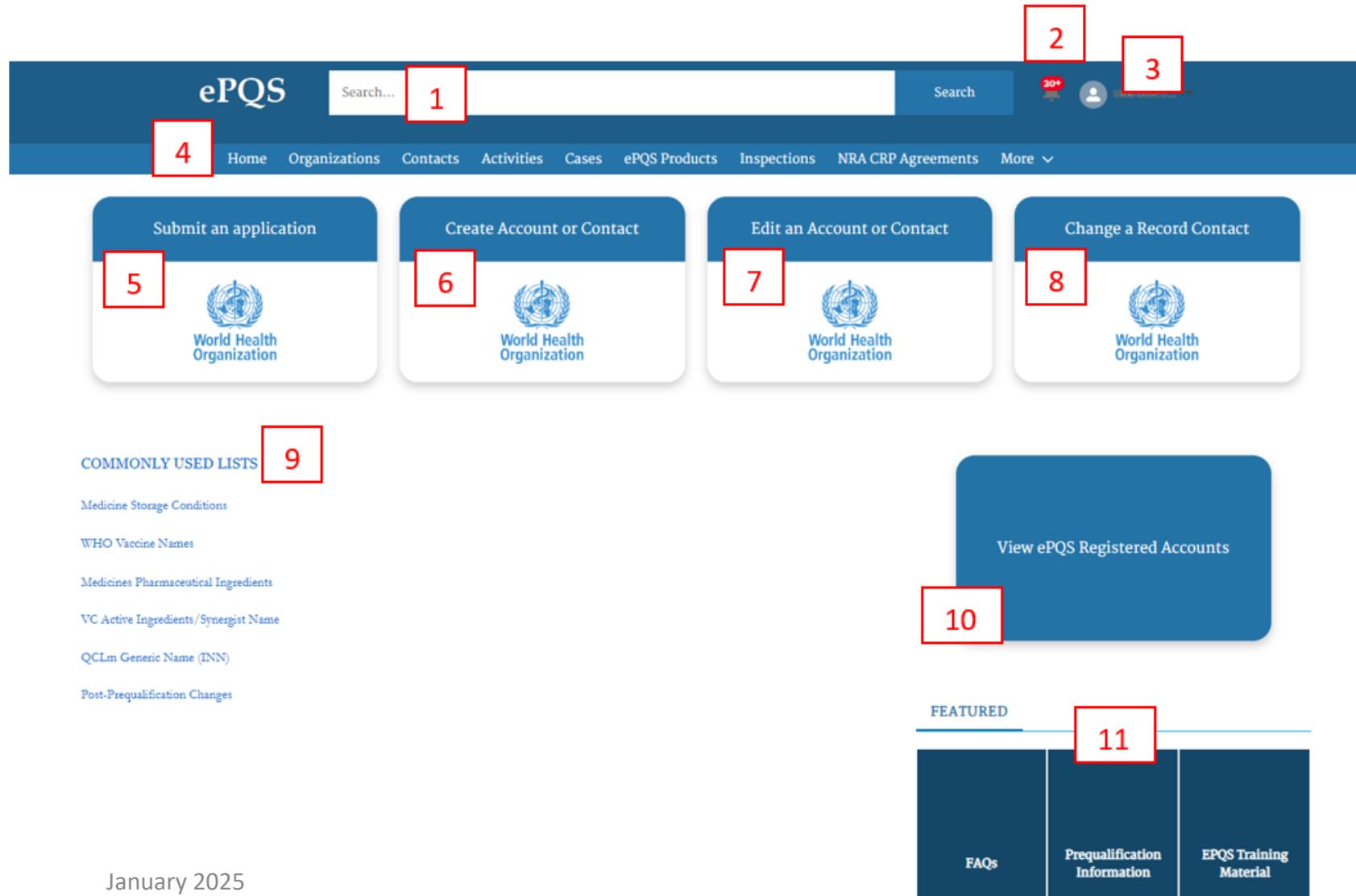
It is intended as a learning aid and ongoing reference guide.



4

Navigating ePQS – General guide

4. ePQS navigation – Homepage map



1) Global search facility

Key word searches will retrieve any record matching the entered criteria, provided the user has access to the record.

2) Notification “Bell” Icon

System generated notifications will be recorded here.

3) Personal Settings and Profile

Using this menu you can access your personal user details and log out of the system.

4) Object Menu Bar

List views of the major record types can be accessed from this menu. The menu items will vary depending on the type of external user.

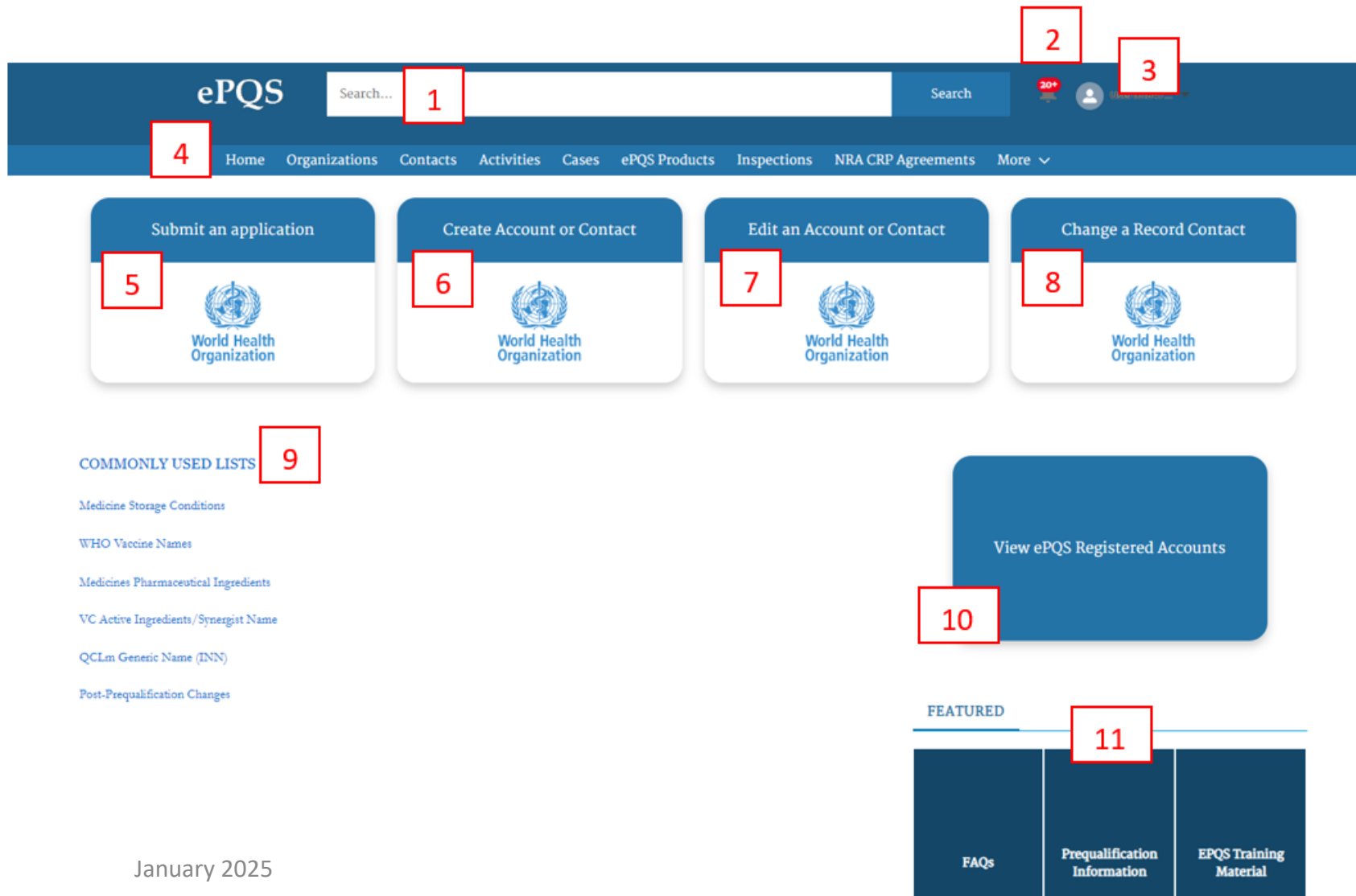
5) Application wizard

This initiates the creation of a new application

6 to 8) Contacts and Accounts

These menu items download the relevant forms for completion.

4. ePQS navigation – Homepage map



9) Commonly Used Lists

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

For instance, as part of the FVP application wizard the applicant will be asked to nominate a WHO Vaccine Name. If the applicant is unfamiliar with the possible WHO Vaccine Names, they can review these from this list.

10) View ePQS Registered Accounts

Account (Organisation) records are important records referred to on product, application, inspection and product site records.

During the wizard process, if an account is not present in the ePQS database, it will not be possible, for instance, to create a manufacturing site (Product Site) for a product.

11) FAQ and training materials

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

4. ePQS navigation – My profile



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

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



4. ePQS navigation – My profile



“My profile” appearance.

ePQS

Search...

Search

clic

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

Name

Title

Email

Address

About Me

Manager

Company Name

Active

Contact

Phone

Mobile

Home

My Profile

My Account

Logout

January 2025

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 displays the ePQS website interface. At the top, there is a dark blue header bar containing the ePQS logo, a search bar with the placeholder text "Search...", and a "Search" button. To the right of the search bar is a user profile icon with a dropdown arrow. Below the header bar is a horizontal navigation menu with the following items: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Products. Below the navigation menu are four large, rounded rectangular buttons, each featuring the World Health Organization logo and a specific action: "Submit an application", "Create Account or Contact", "Edit an Account or Contact", and "Contact". To the right of these buttons, a dropdown menu is open, showing the following options: Home, My Profile, My Account (highlighted with an orange border), and Logout. The "My Account" option is the focus of the slide.

4. ePQS navigation – My account



“My account” appearance.

5 sub-tabs appear:

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

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

ePQS

Search...

Search

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

Account

+ Follow New Note DocuSign Arms Tobacco Disclosure Update Published Information

Account Record Type Address (2) Email

Details Related Preview Documents Document Download Document Submission

Account Information

Organization UID Account Owner

Legal Name Primary Contact

Account Name Phone

Parent Account Email

Account Record Type

Description

Address Information

WHO Country Information

General Details

Related Links

PQT Information

Account Usage - Collaborators

System Information

4. ePQS navigation – Related



“Related” provides a list of all records in ePQS related to a user’s account.

This includes:

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

The screenshot shows the ePQS interface. At the top, there's a search bar and navigation links. The 'Related' tab is highlighted in the top navigation bar. Below the navigation bar, there's a section for 'Account' with links like '+ Follow', 'New Note', 'DocuSign Arms Tobacco Disclosure', and 'Update Published Information'. The main content area is titled 'Details' and 'Related'. It lists several categories of records related to the user's account:

- Notes (0)
- Related Contacts (2) - Includes a table with columns: Contact Name, Direct, Active, Start Date.
- Case (Applications) (6+)
- Products (Applicant Organization) (6+) - Includes a table with columns: WHO Product ID, Product Name, Vaccine Abbreviated Name, Product Status.
- Product Sites (6+)
- Inspections (0)
- CRP Product Registrations (0)
- CRP Product Registrations (NRA Organisation) (0)
- NRA CRP Participations (NRA Organization) (0)
- Files (0) - Includes an 'Add Files' button and an 'Upload Files' button.
- Account History (0)

At the bottom, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

4. ePQS navigation – Documents



“Preview documents” is a reference library of all documents related to a user’s account.

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

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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a navigation menu. The navigation menu includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. A user profile dropdown menu is open, showing options for Home, My Profile, My Account (highlighted with an orange border), and Logout. Below the header, there is a section for 'Account' with a table of account records. The table has columns for Account Record Type, Address (2), and Email. To the right of the table are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Disclosure'. Below the account section, there is a tabbed interface with four tabs: Details, Related, Preview Documents (highlighted with an orange border), Document Download, and Document Submission. The 'Preview Documents' tab is active, showing a 'box' search bar and a table of documents. The table has columns for Name, Modified, and Size. It lists two folders: 'External correspondence' and 'Submitted Documents', both with a modified date of 'Fri Apr 12 2024' and a size of '0 Byte'.

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

4. ePQS navigation – Documents



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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a user profile dropdown menu. The dropdown menu is open, showing options: 'Home', 'My Profile', 'My Account' (highlighted with an orange border), and 'Logout'. Below the header is a navigation bar with links: 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', and 'CRP Product Registrations'. The main content area features a 'Document Download' tab, which is highlighted with an orange border. Below this tab is a 'box' search bar with the text 'Search files and folders'. A list of documents is shown, including 'External correspondence' and 'Submitted Documents', both modified on 'Fri Apr 12 2024' and having a size of '0 Byte'. At the bottom, there is a selection bar showing '0 Selected' and a confirmation button with a checkmark.

4. ePQS navigation – Documents



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

ePQSSearch...Search

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

Account

+ FollowNew NoteDocuSign Arms Tobacco DisclosureU

Account Record TypeAddress (2) ▼Email

HomeMy ProfileMy AccountLogout

DetailsRelatedPreview DocumentsDocument DownloadDocument Submission

Upload to Account Submission

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

Next

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

4. ePQS navigation – Documents



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

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

Upload to Account Submission



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

Cancel

Upload

Next

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.



4. ePQS navigation – Forms



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

The screenshot displays the ePQS homepage. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a 'Search' button. To the right of the search bar are icons for notifications and a user profile. Below the header is a navigation bar with the following tabs: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area features four large blue buttons, each with the World Health Organization logo and text: 'Submit an application', 'Create Account or Contact', 'Edit an Account or Contact', and 'Change a Record Contact'. The 'Create Account or Contact', 'Edit an Account or Contact', and 'Change a Record Contact' buttons are 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'. On the right side of the page, there is a large blue button labeled 'View ePQS Registered Accounts'.

4. ePQS navigation – Notes



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

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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a user profile icon. Below the header is a navigation menu with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registration. On the right side of the header, a dropdown menu is open, showing options: Home, My Profile, My Account (highlighted with an orange box), and Logout. In the main content area, there is a 'New Note' button (highlighted with an orange box) and a '+ Follow' button. Below the 'New Note' button is a large orange arrow pointing to a 'New Note' form. The form has a title 'New Note', a text area for 'Enter a note...', and a 'Share' button (highlighted with an orange box) at the bottom right. The form also includes a 'Related to' dropdown menu set to 'Current Record' and a 'Visibility Set by Record' label.

4. ePQS navigation – Organisations



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

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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a 'Search' button. Below the header is a navigation bar with several tabs: 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'CRP Product Registrations', and 'More'. The 'Organizations' tab is highlighted with an orange box. Below the navigation bar, the 'Accounts' section is visible, showing 'ePQS Accounts (Portal)' with a dropdown arrow. This dropdown menu is open, showing a list of 'LIST VIEWS': 'All Vx accounts', 'ePQS Accounts (Portal)' (which is selected and has a blue checkmark), 'Recently Viewed (Pinned list)', and 'Recently Viewed Accounts'. To the right of the dropdown menu, there is a search bar labeled 'Search this list...' and a 'Country (Physical)' dropdown menu.

4. ePQS navigation – Contacts



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

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

The screenshot shows the ePQS web application interface. At the top, 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 tabs: Home, Organization, **Contacts** (highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation menu, the main content area displays the 'Contacts' section. A dropdown menu is open, showing 'All ePQS Contacts (Portal)' (selected), 'Recently Viewed (Pinned list)', and 'Recently Viewed Contacts'. The main content area shows a table with 2 items, titled 'LIST VIEWS'. The table has columns for 'Account Name' and 'Account: Legal Name'. The data rows show 'Vestfrost Solutions' for both columns. The table also includes a search bar, a settings icon, a refresh icon, and a filter icon.

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

4. ePQS navigation – Activities



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

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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and user profile icons. Below the header is a navigation menu with tabs: Home, Organizations, Contact, **Activities** (highlighted with an orange box), Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows the 'External Activities' section with a 'Recently Viewed' dropdown menu (also highlighted with an orange box) and a list of 'LIST VIEWS'. The list includes: All Activities (Applications - Portal), All Activities (Inspections - Portal), My Activities (Portal), My Open Activities (portal), and **Recently Viewed (Pinned list)** (selected with a blue checkmark). A search bar for the list is visible on the right.

4. ePQS navigation – Cases



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

Available **list views** include “Open cases”, “Closed cases”, “All” and “Recently viewed”.

The screenshot shows the ePQS web application interface. The top navigation bar includes the ePQS logo, a search bar, and a user profile icon. The main navigation menu has tabs for Home, Organizations, Contacts, Activities, Cases, PQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The 'Cases' tab is highlighted with an orange box. Below the navigation bar, the 'Cases' section is displayed. It includes a 'Printable View' button and a search bar. A dropdown menu is open, showing the following list views:

- ✓ All Cases (Portal)
- 1 All Closed Cases (Portal)
- 2 All Open Cases (Portal)
- 3 Recently Viewed (Pinned list)
- 4 Recently Viewed Cases

The main table displays a list of cases with columns for Application S..., WHO Pro..., Date Appl..., Date Appl..., and Date of Pr... The table shows four rows of data, all with the value 'Standard' in the 'Application S...' column and '01/01/1900' in the 'Date Appl...' column.

4. ePQS navigation – Products



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

The screenshot shows the ePQS web application interface. The navigation bar at the top includes the ePQS logo, a search bar, and a user profile icon. The main navigation menu is visible, with the 'ePQS Products' tab highlighted. Below the navigation bar, the 'ePQS Products' section is displayed, showing a dropdown menu for 'All Products (Portal)' with the following options:

- All Active Products (Portal)
- All Closed Products (Portal)
- All Products (Portal)** (selected)
- Recently Viewed (Pinned list)

The main content area displays a table of products. The table has the following columns: Product Subtype, Date of Preq..., Date of ..., and Date of Pro... The table contains three rows of data:

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

4. ePQS navigation – Inspections



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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a 'Search' button. Below the header is a navigation bar with various tabs: Home, Organizations, Contacts, Activities, Cases, ePQS Products, **Inspections** (highlighted with an orange box), NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, the 'Inspections' section is active. It features a dropdown menu for 'All Inspections (Portal)' (highlighted with an orange box) and a 'Recently Viewed (Pinned list)' option. To the right of the dropdown is a search bar labeled 'Search this list...' and three icons: a settings gear, a refresh icon, and a filter icon. Below these elements is a table with columns for 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.





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

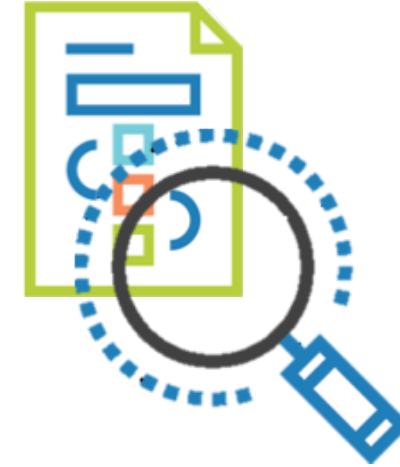
Verification of product data sheets

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 interface. At the top, there is a search bar and a navigation menu. The 'ePQS Products' tab is highlighted with a red box and the number 1. Below the navigation menu, the 'ePQS Products' section is visible, with 'IMDs (All)' selected, highlighted with a red box and the number 2. Below this, a table of products is displayed. The first row of the table is highlighted with a red box and the number 3. The table has columns for WHO Product ID, Applicant Organization, Product Status, Date of Application, Date of Prequalification, and Date of Product Cancellation.

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

5a. Verification of product data records



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

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

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

The screenshot shows the ePQS system interface. The top navigation bar includes links for Home, Accounts, Contacts, ePQS Products, Cases, Inspections, Reports, Dashboards, Application Wizard, and NRA CRP Participations. The 'ePQS Product' link is highlighted with a red box. Below the navigation bar, the product details for 'Immunisation Device' are displayed. The 'Related' sub-tab is highlighted with a red box and a red arrow pointing to it. The 'Information' section is expanded, showing various fields and their values.

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

Details **Related** Document Activity Chatter Audit Trail

Comments

Information

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

5a. Verification of product data records



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

Select the record displayed under “IMD Product Variant”



ePQS Product

+ Follow Edit Sharing Printable View

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

Details **Related** Document Activity Chatter Audit Trail

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

☐	Product Site ID	Product Site Status	Site	Site Activity	Activity Type(s)
1		Accepted		IMD Manufacture	Refrigerators and freezers

[View All](#)

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

☐	IMD Variant Ref.
1	

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

☐	Case Number	ePQS Case ID	Status	Application Type	Application Subty...	Date Application A...	Date of Prequalificat...
1			Prequalified	Prequalification	Standard	01/01/1900	05/06/2019

[View All](#)

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

Fees (0) [New](#)

Files (0) [Add Files](#)

USER TASK →

- To report incorrect data please use the templates on the following slide.**

Related		Details		Activity		Audit Trail	
Comments							
Comments							
Product Identification							
NDC origin Ref.		Supplier					
NDC Product ID		Manufacturer Reference					
Record Type	☒	Country of Manufacture					
Device Sub-category	☒						
Yield Unit	☒						
Product specifications - Main							
Temperature Zones	☒	Inp qualified regions					
Temperature Zones (Other)	☒	Auto-define					
Holdover time OR	☒						
Holdover time IR	☒						
Enclosure construction options							
Cold room size available (largest), m ²	☒	Drying system					
Cold room size available (smallest), m ²	☒	Drying material					
Fresher room sizes available (L-R)	☒	Shared wall construction					
Fresher room sizes available (L, R)	☒	Strip curtain available					
Door size options available	☒	Pressure release valve (PR only)					
Door frame heating available	☒	Floor panel heater mat (PR only)					
Panel insulation material	☒	Wall/Ceiling Panel/Finish					
Panel joining system	☒	Floor panel finish					
Panel finishing options	☒	Type of Framing Agent					
Product specifications - Equipment options							
Refrigerant	☒	ISO 9001/14001 verified					
Refrigeration unit mounting options	☒	ISO 9001/14001 certified (Other)					
Refrigeration unit types	☒	Electric Safety Compliant To IEC 60335-1					
Lighting system	☒	High-voltage protection					
Dry sharing	☒	Voltage/Frequency/Phasing optional?					
Cold climate protection OR	☒	Voltage Regulation Available?					
Expirator purge quantity OR	☒	Surge Protection Available?					
		Cut-off system					
Product specifications - Temperature monitoring & alarm options							
Temperature recording system	☒	Alarm system					
		ISO 14001 verified					
Warranty, installation and maintenance							
Warranty period (months)	12	Maintenance service					
		Installation service					
Quality standard							
Quality Standard		Specification Reference					
Quality standard (Other)	☒						
Verification							
Verification Laboratory	☒	Verification Report Reference					
Records							
Remarks for Publishing	☒	Last Modified By					
Created By	MCI Data Migration , 16/11/2023, 08:40						
Published Record Details							
Published Snapshot?	☐	Published Snapshot Reference					



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 website interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a user profile icon. Below the header is a navigation bar with links: Home, Organizations (highlighted with an orange box), Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar are four white buttons with blue headers and WHO logos: 'Submit an application', 'Create Account or Contact', 'Edit an Account or Contact', and 'Change a Record Contact'. On the left side, 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)'. On the right side, there is a blue button with the text 'View ePQS Registered Accounts' (highlighted with an orange box).

5b. Accessing registered accounts



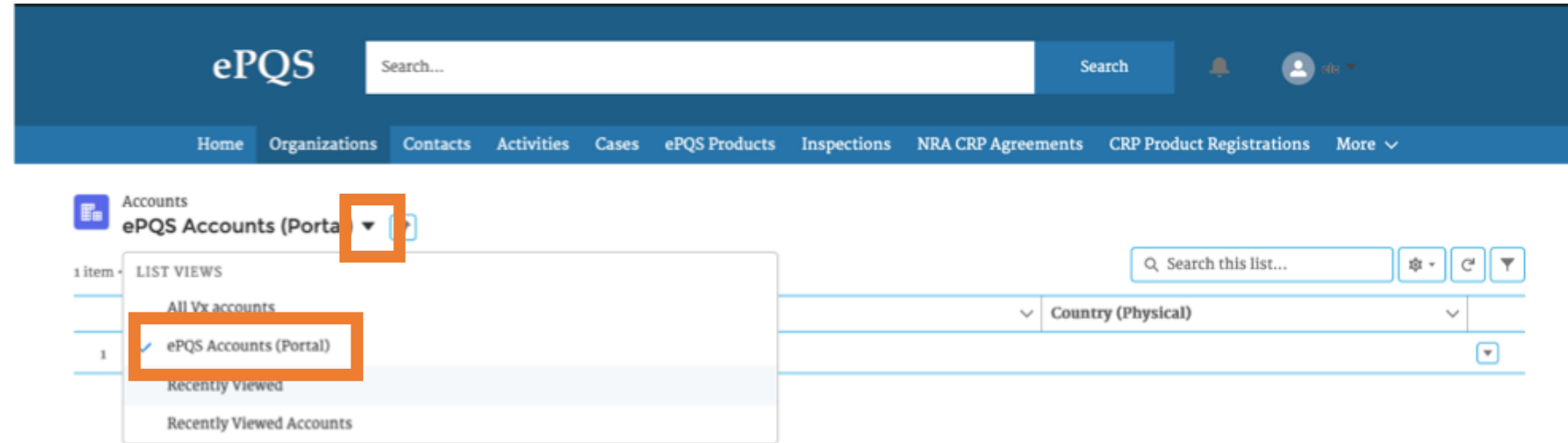
Users may select different **list views**.

Recommended: “**ePQS Accounts**”.

Users should **review each record** that appears in the list:

Account types include:

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



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

5b. Accessing registered accounts



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

- Report any errors or issues to the IMD-PQS Secretariat:
pqsinfo@who.int &
huckerbyg@who.int

The screenshot displays the ePQS (Electronic Product Quality System) interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a user profile dropdown menu. The main navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Products. The central content area shows an 'Account' record for a 'Non-State Actor'. It includes fields for 'Account Record Type', 'Address (2)', and 'Email'. To the right of these fields are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Dis'. Below the account details, there is a section titled 'Details' with 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 bottom of the page features a footer with links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.



5c

Correct record visibility

5ci. Correct record visibility



1. Users should click on their profile icon, and select **“My Account”**.

2. Then, click on the sub-tab **“Related”**.

The screenshot displays the ePQS application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a user profile icon. The user profile icon is highlighted with an orange box and a red circle containing the number '1'. A dropdown menu is open from this icon, showing options: 'Home', 'My Profile', 'My Account' (highlighted with an orange box), and 'Logout'. Below the header, there is a navigation bar with various tabs. The 'Account' section is active, showing a list of account records. The 'Related' sub-tab is highlighted with an orange box and a red circle containing the number '2'. Below the sub-tabs, there is a list of account information categories, including '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 displays the ePQS 'Related' sub-tab interface. The top navigation bar includes 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'CRP Product Registrations', and 'More'. The 'Related' sub-tab is active, showing a list of record types related to the user's account. The records are organized into sections, each with a count in parentheses:

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

The 'Related Contacts' section is expanded, showing a table with columns: Contact Name, Direct, Active, and Start Date. The 'Product Sites' section is also expanded, showing a table with columns: Product Site ID, Product Site Status, Site Activity, and Activity Type(s). The 'Case (Applications)' section is expanded, showing a table with columns: Case Number, ePQS Case ID, Status, and Last Modified Date/Time. The 'Products (Applicant Organization)' section is expanded, showing a table with columns: WHO Product ID, Product Name, Vaccine Abbreviated Name, and Product Status. The 'Files' section has an 'Add Files' button and an 'Upload Files' button. The 'Account History' section is at the bottom.

5cii. Correct record visibility - Products



Products

Expand or click directly on the Products sub-tab.

The screenshot shows the ePQS web application interface. The top navigation bar includes a search bar and a menu with options: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The 'ePQS Products' tab is selected. Below the navigation bar, there is an 'Account' section with a 'Follow' button and a 'New Note' button. The main content area displays a list of tabs: Details, Related, Preview Documents, Document Download, and Document Submission. The 'Related' tab is active, showing a list of related items. The 'Products (Applicant Organization) (6*)' item is highlighted with an orange border. Below this, there is a table with columns: WHO Product ID, Product Name, Vaccine Abbreviated Name, and Product Status. The table is currently empty. At the bottom of the page, there is a footer with links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

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

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

- ePQS

Search

Home

Organizations

Contacts

Activities

Cases

ePQS Products

Inspections

NRA CRP Agreements

CRP Product Registrations

More

Accounts >

Products (Applicant Organization)

29 items • Updated a few seconds ago

New

⚙️

↺

⏏️

	WHO Produc... ▾	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.

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

January 2025

The screenshot displays the ePQS web application. 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** (highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area is titled 'Contacts' and shows 'All ePQS Contacts (Portal)' with a search bar and a table. The table has 2 items, sorted by Name, filtered by All contacts, and updated 2 minutes ago. The first row of the table is highlighted with an orange box and contains the text '1 YOUR NAME'. The second row is partially visible with the number '2'.

1	YOUR NAME				
2					

5d. Personal use folder



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

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

The screenshot displays the ePQS web application interface. At the top, there is a dark blue header with the 'ePQS' logo, a search bar, and a user profile icon. Below the header is a navigation menu with tabs: Home, Organization, **Contacts** (highlighted with an orange box), Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows a 'Contact' record with fields for Job Title, Account Name, Phone (2), Email, and Contact Owner. Below these fields are tabs: Details, Related, **Preview Documents** (highlighted with an orange box), Download Documents, Preview Mx Documents, and Download Mx Documents. The 'Preview Documents' tab shows a 'box' interface with a search bar and a folder named **YOUR Personal Folder** (highlighted with an orange box). To the right of the folder name is a '+' icon (highlighted with an orange box) for uploading documents. Below the folder, there is a message: 'There are no items in this folder.' At the bottom of the page, there are links for 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



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

IMPORTANT

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).

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--

IMPORTANT

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>)

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

* ISO 9001/13485 certified

* ISO 14001 certified

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

5e. Application submission procedure



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 maintenance
- ✓ Quality Standard

Quality Standard

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

Specification Reference

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

00AwaitingNewOrganisation -

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
Refrigerated vehicles and accessories

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.

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



ePQS Application Wizard

Organization & Contacts ✓ ✓ ✓ Documents Finalize

Upload Documents

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

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

When finished, click **Next**.



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

CancelUpload

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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.

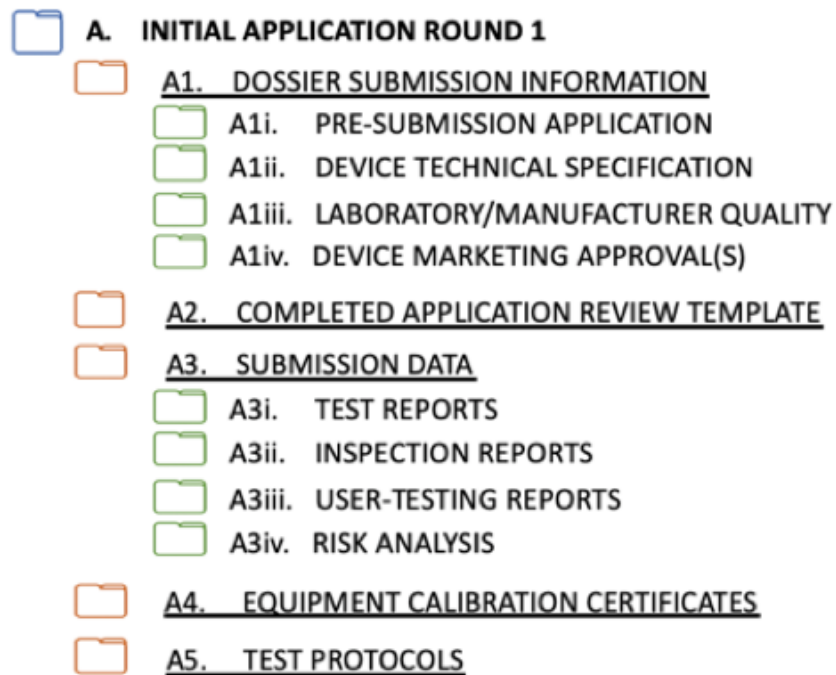
The Prequalification Guidelines can be downloaded from: <https://extranet.who.int/prequal/key-resources/documents/imd-pqs-guidelines-prequalification-applicants-prequalification-holders>

5e. Application submission procedure

MANDATORY folder structure



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



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.

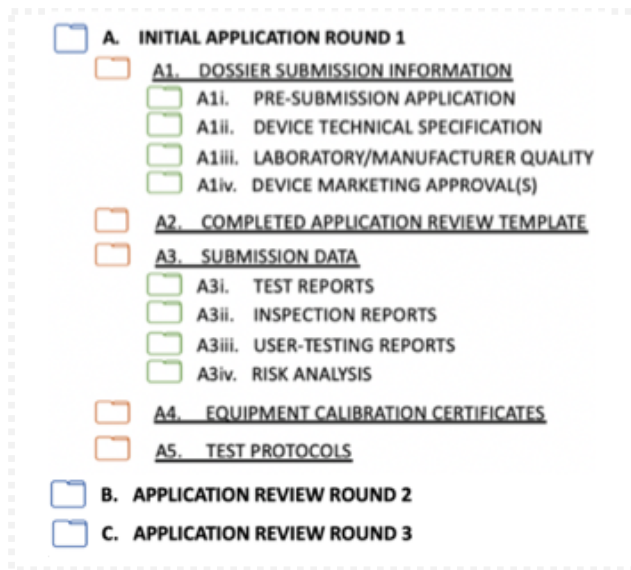
• **CLICK HERE TO DOWNLOAD THIS FOLDER STRUCTURE IN PRE-FORMATTED .ZIP FORMAT:**
<https://extranet.who.int/prequal/key-resources/documents/imd-pqs-epqs-mandatory-folder-structure>



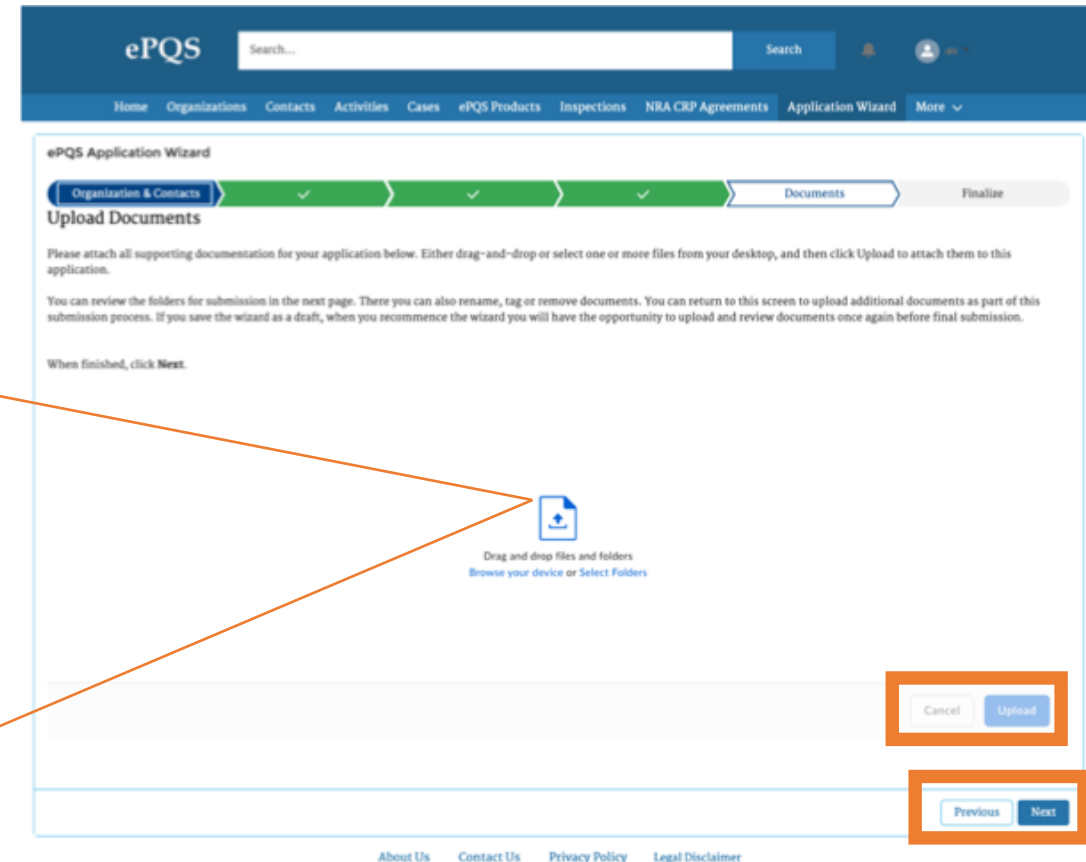
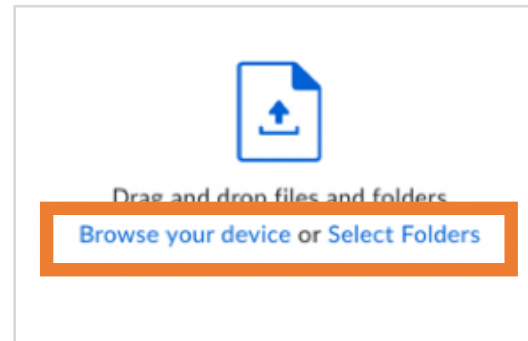
5e. Application submission procedure

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

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5e. Application submission procedure



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

ePQS Application Wizard

Organization & Contacts

✓

✓

✓

✓

Finalize

Review Application

It is important that you review your application prior to submission. Use the link provided to open it in a new tab and look at the information entered, and also review the related records (click on the Related sub-tab) of which you should be able to open those records too.

Case ID: [PQ-IMD-2023-0040](#)

Product or Laboratory ID: [P-15764](#)

Submit, Save or Discard

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

• Ready to submit?

☒ Yes

☐ No, save existing draft application and product (if applicable)

☐ No, discard this draft application and product (if applicable)

Previous

Next

5e. Application submission procedure



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

ePQS Application Wizard

Organization & Contacts

✓

✓

✓

✓

Finalize

Application Submitted

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

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

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

Next

5e. Application submission procedure



Receiving application feedback from the IMD team

During the course of the application assessment you may received 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 the specific submission/application:

The screenshot displays the ePQS application interface. At the top, a navigation bar includes links for Home, Organizations, Contacts, Activities, Cases (highlighted with a red box), ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and a More dropdown. Below the navigation bar, a case summary for 'Case PQ-IMD-' is shown, with a red box around the case icon. To the right of the case name are buttons for '+ Follow', 'Edit', 'Resume Application Wizard', and 'New Component(s)'. Below this, a table lists case details: Case Record Type (Vx IMD Application), Case Number, Status (Under Assessment), Applicant Organization, Date of Prequalification/Acceptance, and Case Owner (ePQS Vx IMD Queue). Below the table, a tabbed interface shows 'Details', 'Related', 'Activities', 'Preview Document', 'Document Download' (highlighted with a red box), and 'Document Submission'. The 'Document Download' tab displays a Box interface with a search bar and a list of files. A red box highlights a folder named 'Correspondence (External)' with the description 'Modified Wed Oct 29 2025 • 0 Byte'. At the bottom of the interface, a status bar shows '0 Selected' and a close button.

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”:

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

 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 ▼	
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:

HomeOrganizationsContactsActivitiesCasesePQS ProductsInspectionsNRA CRP AgreementsCRP Product RegistrationsMore

External Activity
EA

EditChange Owner

DetailsRelated

Comments

Comments

Information

Related To (Case)

Related To (Inspection)

Activity Name
Request for Information

Due Date

Start Date

End Date

Owner

Time Assignment
Manufacturer

Status
In-Progress

Activity Outcome

Activity Phase
In Progress

Response Date

Case Information

Case Record Type
Component

WHO Product ID

Component Type
Dossier Assessment

System Information

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

Last Modified By
Gemma HUCKERBY, 20/11/2025, 21:01

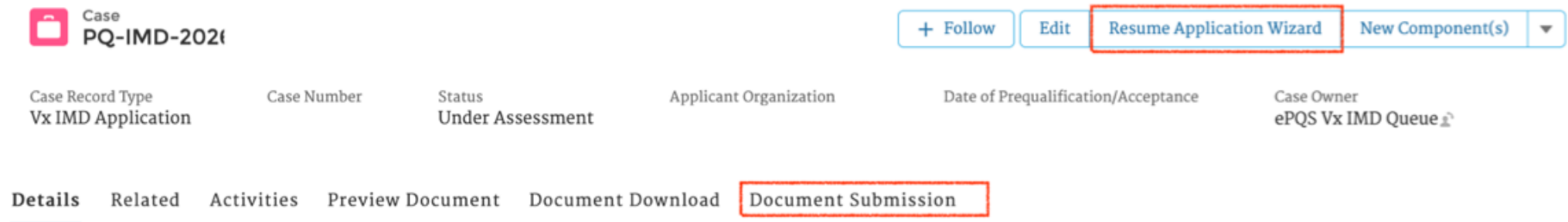
Record Type
ePQS Workflow Task

5e. EDITING your dossier POST-submission

IMPORTANT

AFTER submitting your dossier you can upload documents at any time using the “Documents submission” tab.

You may also **EDIT** or **COMPLETE** dossier data at any time using the “Resume application wizard” button.



NOTE: you can no longer edit or upload documents **AFTER** a product is prequalified.

- In you require data corrections for prequalified products see slide 60.
- For post-prequalification variations see slide 104-.



5g

Post-PQ variation submission

5g. 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.

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5g. Post-PQ variation submission procedure



Applicants will first be prompted to select the relevant contacts:

ePQS Application Wizard

Organization & Contacts

Application Info

Product Details

Documents

Finalize

Choose Contact

Choose Applicant Primary Contact
Nominate a primary contact for this application who is an employee of Vaccine UAT External Test Account 1, and also indicate if there are other secondary people involved.

* Primary Contact

Vaccine UAT External Contact 1

Optionally Choose Secondary Contacts
If needed you can optionally choose a secondary and an alternative secondary contact, or leave the selection as "--None--".

* Secondary Contact

--None--

* Alternative Secondary Contact Choice

--None--

Previous

Next

5g. 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

5g. Post-PQ variation submission procedure



Select “**Post-PQ Change**” as the application type:

ePQS Application Wizard

Organization & Contacts

Application Info

Product Details

Documents

Finalize

Choose Application Type

Based on the product type, here is the list of application types available.

* Application Type

☐ Prequalification

☒ Post-PQ Change

☐ Reassessment

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5g. 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.

A screenshot of the 'ePQS Application Wizard' interface. It features a horizontal progress bar with five steps: 'Organization & Contacts' (active), 'Application Info', 'Product Details', 'Documents', and 'Finalize'. Below the progress bar, the title 'Choose Application Subtype' is followed by the instruction 'Please enter the following additional information:'. A dropdown menu for '* Application Subtype' is open, showing two options: 'Type A(Administration)' and 'Type B (Technical)'. At the bottom right of the form, there are 'Previous' and 'Next' buttons.

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5g. Post-PQ variation submission procedure



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

ePQS Application Wizard

Organization & Contacts

Application Info

Product Details

Documents

Finalize

Relevant Products Found

For the specific product type selected, matching relevant prequalified or acceptable status products have been successfully found. You will be asked to link one to this application shortly.

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5g. Post-PQ variation submission procedure



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

ePQS Application Wizard

Organization & Contacts

Application Info

Product Details

Documents

Finalize

Confirm Application Details

By proceeding to the next step you will be creating a draft Vx IMD Post-PQ Change. This draft application will be available in your List View of Cases.

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

Previous

Next

5g. Post-PQ variation submission procedure



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

It provides an **application case number**. It is recommended to make a physical note of this number.

ePQS Application Wizard

Organization & Contacts

Application Info

Product Details

Documents

Finalize

Continue Application

A draft application has been created.

For reference the new application has the case number [PQC-IMD-2024-0007](#). You can view the draft application details by following the link.

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5g. Post-PQ variation submission procedure



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

At this stage, select **“Add products...”**

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

5g. 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

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SECTION C – APPLICATION PROCEDURES

5g. 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

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5g. Post-PQ variation submission procedure



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

ePQS Application Wizard

Organization & Contacts

✓

✓

Post-PQ Changes

Documents

Finalize

Add Change Information

You will need to list the products that are being changed, and also record the change types that apply

Either

☐ Add products that are the subject of post-prequalification changes

☒ Add one or more pieces of information about the change, including the type

☐ No more at this time

Next

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5g. 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

5g. 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

5g. 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.

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5g. 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”**.

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

5g. 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

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5g. Post-PQ variation submission procedure



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

WHO requirements and guidance on eCTD documents can be found here:

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

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

ePQS Application Wizard

* Select Document Type

☐ eCTD

☒ Non-eCTD

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5g. Post-PQ variation submission procedure



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

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

5g. 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.

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5g. 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

5g. 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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5g. Post-PQ variation submission procedure



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

The status will be listed as **“Under Screening”**.

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

The screenshot displays the ePQS system interface for a case titled "Case PQC-IMD-2024-0007". The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, the case details are shown, including Case Record Type (Vx IMD Post-PQ Change), Case Number (00026713), and Status (Under Screening, highlighted with an orange box). The interface also features tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The main content area is divided into sections: General Details, Case Progress, and System Information. The General Details section includes fields for WHO Application Number, ePQS Case ID, Product Type, Application Type, Application Subtype, and Product Assessment Procedure. The Case Progress section includes fields for Date Application Submitted, Date Application Accepted For Assessment, Date Of Suspension, Date of Prequalification/Acceptance, Cancellation/Withdrawal/Rejection Reason, and Cancellation/Withdrawal/Rejection Date. The System Information section includes fields for Created By, Last Modified By, Case Record Type, and Record Status. The bottom of the page features a footer with links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

Case	Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance	Case Owner
PQC-IMD-2024-0007	Vx IMD Post-PQ Change	00026713	Under Screening			ePQS Vx IMD Queue

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

General Details

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

Case Progress

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

System Information

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



5h

Up/downloading of documents



5h. 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 web application interface. The top navigation bar includes the ePQS logo, a search bar, and a user profile icon. The main navigation menu has tabs for Home, Organizations, Contacts, Activities, Cases (highlighted with an orange box), PQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The 'Cases' section is active, showing a list of cases. A dropdown menu for 'LIST VIEWS' is open, showing options: All Cases (Portal) (selected), All Closed Cases (Portal), All Open Cases (Portal), Recently Viewed (Pinned list), and Recently Viewed Cases. The table below shows a list of cases with columns for Application S..., WHO Pro..., Date Appl..., Date Appl..., and Date of Pr... The table has 4 rows of data, all with 'Standard' in the Application S... column and '01/01/1900' in the Date Appl... columns. A 'Printable View' button is visible in the top right corner of the table area.

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

5h. 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.

The screenshot displays the ePQS web application interface. At the top, there is a search bar and a navigation menu with options: Home, Organizations, Contacts, Activities, **Cases** (highlighted with an orange box), ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation menu, a case card for 'Case PQC-IMD-2024-0007' is shown, with a pink folder icon. To the right of the case card are buttons for '+ Follow', 'Edit', 'Resume Application Wizard', and 'New Component(s)'. Below the case card, there is a table with columns: Case Record Type (Vx IMD Post-PQ Change), Case Number, Status (Under Screening), Date of Prequalification/Acceptance, and Case Owner (ePQS Vx IMD Queue). Below the table, there is a tabbed interface with tabs: Details, Related, Activities, **Preview Document** (highlighted with an orange box), Document Download, and Document Submission. The 'Preview Document' tab is active, showing a 'box' logo and a search bar. Below the search bar, there is a table with columns: Name, Modified, and Size. The table contains one row: 'Correspondence (External)' with a folder icon, 'Yesterday' for the modified date, and '0 Byte' for the size.

5h. 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 displays the ePQS web application interface. At the top, there is a dark blue header with the ePQS logo, a search bar, and a navigation menu. The navigation menu includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, and CRP Product Registrations. A user profile dropdown menu is open, showing options for Home, My Profile, My Account (highlighted with an orange border), and Logout. Below the header, the main content area shows the 'Account' section with a purple icon and the text 'Account Record Type Non-State Actor' and 'Email'. To the right of the account information are buttons for '+ Follow', 'New Note', and 'DocuSign Arms Tobacco Disclosure'. The 'My Account' button is highlighted with an orange border. Below this, there is a section for 'Document Submission' with tabs for 'Details', 'Related', 'Preview Documents', 'Document Download', and 'Document Submission' (highlighted with an orange border). The 'Document Submission' tab is active, showing a form titled 'Upload to Account Submission' with the text 'Welcome to Document Submission Wizard. Please click on **Next** to proceed for Account#Vestfrost Solutions'. A 'Next' button is located at the bottom right of the form. At the bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

5h. 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](#)



5i

**Viewing
assigned
activities**



5i. Viewing of assigned activities

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

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

ePQS

Search...

Search

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

External Activities

All Activities (Applications - Portal) ▾

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

Q Search this list...

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



5j

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

5j. Assignment of activities to applicants



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

ePQS Search... Search

Home Organizations Contacts Activities Cases ePQS Products Inspections NRA

Notifications

You don't have any notifications right now.

Submit an application

Create Account or Contact

Edit an Account or Contact

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

FEATURED

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SECTION D – TECHNICAL SUPPORT

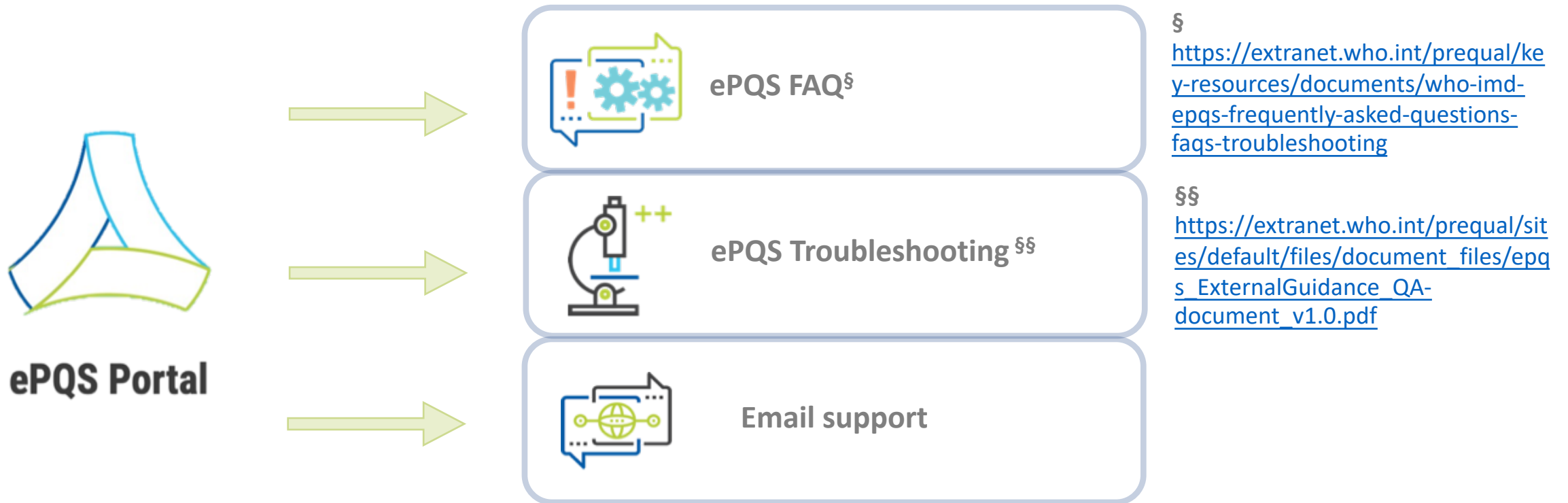


6

Additional technical support

6a. IMD-PQS Technical support

IMD-PQS provides the following additional support to new users.



6b. 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](#)

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