External Guidance – Instructions for submitting a PSF for WHO's Prequalification Assessment of IVDs

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SUBMISSION OF A PRESUBMISSION FORM for WHO's PREQUALIFICATION ASSESSMENT OF IVDs

1. Scope

This guide outlines the procedures for the submission of an PSF by a manufacturer on the ePQS portal.

2. Prerequisites

Applications wizards are accessed via the ePQS Portal – https://who.my.site.com/ePQS/s/login/.
This requires a grant of access to the ePQS portal first. To seek registration, apply via the form available from: https://who.my.site.com/ePQS/s/login/.

This application process includes a step that requires the applicant to select an account (the legal manufacturer) from within the ePQS database. Users can verify these accounts exist before starting an application by referring to the spreadsheet available from the "View ePQS Registered Accounts" tile, as indicated in figure 1.

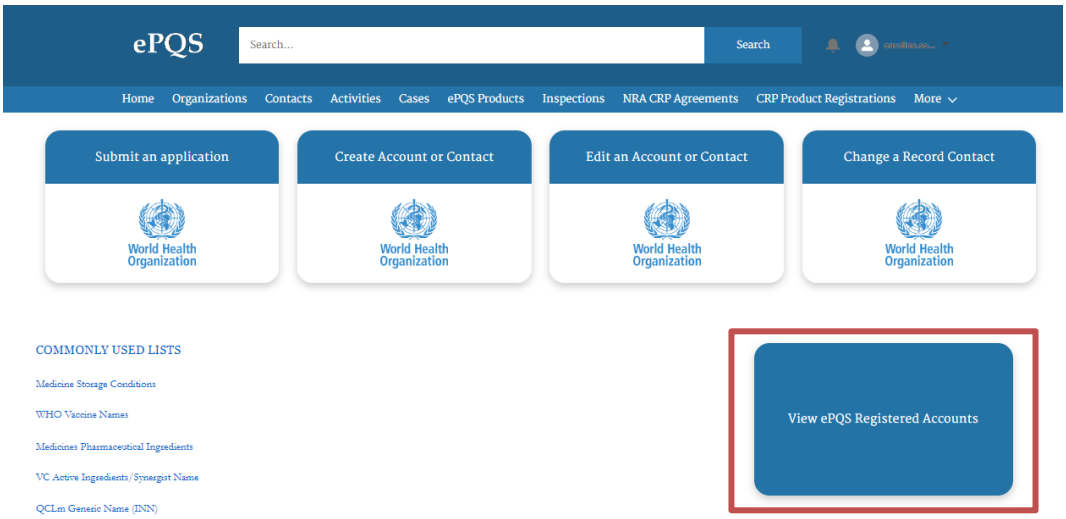


Figure 1 : The existence of an Account within the ePQS system can be determined by clicking on "View ePQS Registered Accounts".

3. Accessing the Portal

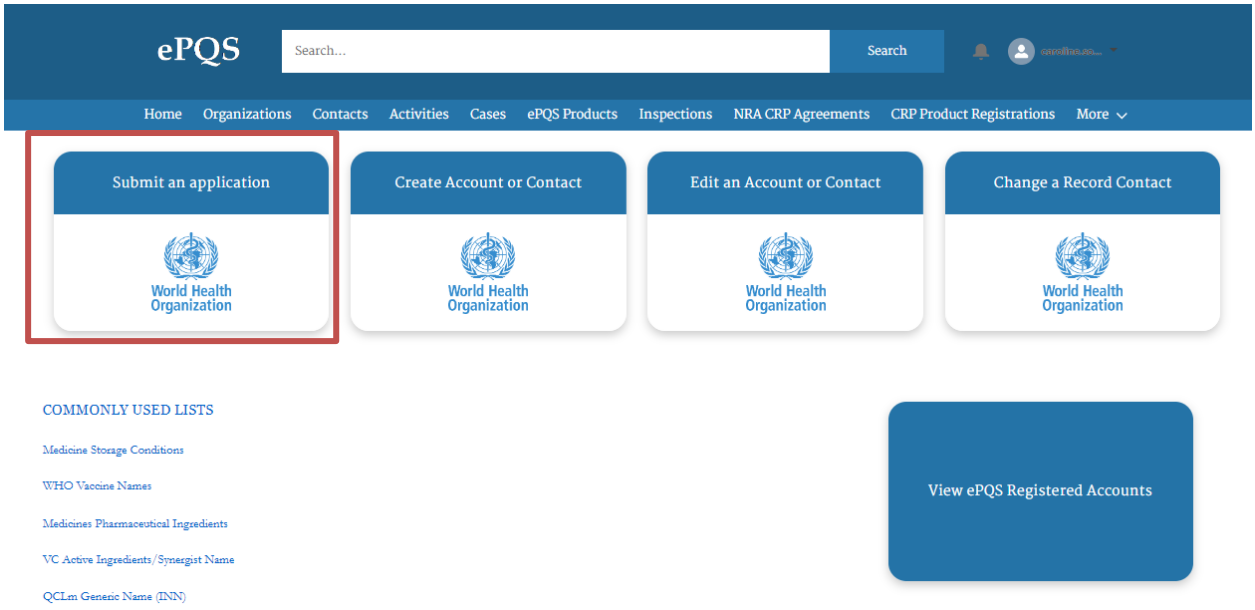
Application wizards are accessed via the ePQS Portal – Registered users can access the Portal at here: https://who.my.site.com/ePQS/s/login/

To create or edit a Contact or Account, please refer to **Creating or editing a Contact or Account.pdf**

4. New submission of PSF

4.1. Start a new application for a product to submit to prequalification assessment.

To submit a new PSF, the manufacturer must create an application for a product on the ePQS Portal Home page. This will create the folder structure in the ePQS environment for the submission of the documents related to the PSF. Please click on “Submit an application”:



4.2. Click on Create a New Application

Carefully read the information on this page.
Click NEXT.

4.2.1. Choose Applicant Primary Contact

Enter the name of the primary, secondary, and alternative secondary contacts, if applicable. If none are available, contact diagnostics@who.int with a new form https://extranet.who.int/prequal/key-resources/documents/external-form-new-epqs-portal-user
Click NEXT.

4.2.2. Choose the Product Type

Choose In Vitro Diagnostic.
Click NEXT.

4.2.3. Choose Application Type

Choose the product application type: Prequalification.
Click NEXT.

4.2.4. Choose Application Subtype

Choose Standard.
Click NEXT.

4.2.5. Confirm Application Details and Continue Application

Read the instructions carefully on this page and verify the information in the application.
Click NEXT, and a draft application will be created.
A reference case number will be provided, and the draft application can be viewed by clicking the link.
Click NEXT.

4.2.6. Additional Application Info

Select the Performance Evaluation option:
Option A – WHO's performance evaluation commissioned by the manufacturer and carried out by a Performance Evaluation Laboratory (PEL) selected by the manufacturer;
Option B – WHO's performance evaluation commissioned by WHO and carried out by a PEL selected by WHO.
If the Performance evaluation is not required, please select **Option 1** and follow to next step.

Click NEXT.

4.3. Create a Product

Please read the information provided on this page carefully.
Click NEXT.

The Create a Product page continues – and requests Further IVD Product Details.
Please complete each required (*) field, taking care to ensure that all relevant analyte details and analytes, specimen types, assay formats (e.g. if NAT, include NAT as well as any relevant additional definitions, such as NAT-qPCR, as relevant), and all regulatory versions of the product that apply to the product are selected.

If other versions of any of the required fields exist for your product, please record them in the "If Other" or "Other Regulatory Versions Which Exist" fields under each respective list.

If the product is a lateral flow device, please indicate the number of lines in the RDT. If another type of product is selected no additional information will be required.
Click NEXT.

An IVD Product number is assigned and is linked to the application.
Click NEXT.

4.3.1. Add Product Related Information

Add product sites for each relevant product site, and product codes for each configuration of the product to be submitted. Include all relevant information as required.

4.3.2. Add a product site

Enter the name of the site and search for the site name/company name/site address.
Click NEXT.
Select the site from the dropdown list.
Click NEXT.

If the desired site does not exist in the available list, please contact WHO Prequalification of IVDs at diagnostics@who.int to add additional manufacturing sites.

NOTICE to MANUFACTURERS
Please do not forget to create the product site. The product site is a **mandatory requirement** to schedule site inspections.

4.3.3. Select Site Activity

Select each/all of the activities conducted at the manufacturing site.
Click NEXT.
Then verify the product site name and address.
Click NEXT.
This updates the application. Click NEXT.

4.3.4. Create Product Codes

Enter separately for each product configuration the product code/catalogue number, the components included in the kit itself, the number of tests per kit (Packaging Size (tests)), and the Items Required But Not Provided with the kit, which are other reagents, controls not included with the kit, or, for example, a timer, pencil, or other things required to run the test/identify specimens.

Example of 2 different product codes:

Product Code/Catalogue Number:	ER56SK1	ER56SK100
Components/Configurations:	Single kit	Multi kit
Packaging Size (tests / kit):	1	100
Additional Kit Contents/Components:	1x specimen transfer device, 1x sterile lancet, 1x buffer vial, 1x Alcohol swab and 1x IFU	100x specimen transfer device, 100x sterile lancet, 5x buffer bottle, 100x Alcohol swab, 1x job aid and 1x IFU
Items Required but not Provided:	Timer	Timer, gloves and venous blood collection accessories

Product Code/Catalogue Number:
Components/Configurations:
Packaging Size (tests / kit):
Additional Kit Contents/Components:
Items Required but not Provided:

Click NEXT after entry of each new product code.
A screen will appear allowing you to view the product code just created by clicking the linked product code.

NOTICE to MANUFACTURERS
Please do not forget to create the product codes submitted for prequalification. That information will be made available for procurers.

When you have finished adding product codes and product sites, choose "I don't want to add any more product related information at this time".
Click NEXT.

4.4. Upload Documents

The Applicant is asked to upload documents to *Case# PQ-IVD-YYYY-XXXX*.
Please read carefully and follow the instructions provided on this page.

> The manufacturer must complete and submit to WHO a Presubmission form (using document PQDx_015), together with the necessary supporting documentation, to indicate the manufacturer's interest for an IVD to undergo WHO's Prequalification assessment. The Pre-submission form must be completed in accordance with the "Instructions for completion of the pre-submission form" (document PQDx_017).

The files will be stored in ***box*** (box, Inc. Cloud Storage Company) which is the integrated document management system in ePQS.

Portable Document Format (PDF) is the primary file format used for submitted documents. However, do not include any PDF that requires a password to open it. Use file names that are descriptive of a file's content and meaningful to dossier reviewers. The path length for each document submitted must not exceed 120 characters. The name can have spaces, dashes (not elongated dashes), underscores, and periods. However, the name of the file shall not contain any special characters or characters from another alphabet as they are not compatible with WHO's storage platform.

Once the files and/or folders have been uploaded.
Click NEXT.

4.5. Document Review

Please review the documents and folders you intend to upload.

Please read carefully and follow the instructions provided on this page.
Click NEXT.

5. Review Application:

Please carefully review your application prior to submission.
There are 3 options given under "Ready to submit?":

5.1. Ready to submit:

Choose "Yes" if you are ready to submit application now. Then click Next.

5.2. NOT Ready to submit yet?

You may decide to save the draft application for later submission.
Please select "No, save existing draft application and product". Click Next.

5.3. If you decide to discard the application:

Please select "No, discard this draft application and product"; all the information entered previously, and documentation uploaded will be lost and you will need to start again from the beginning. Then click Next.
Note: if you have saved the draft application but not yet submitted it, the application will appear in the portal with status "Under screening". However, PQ-IVD will not receive any notification and the application will not yet appear in the ePQS system until you have submitted the application. While the application is in draft and has not been submitted, the Case Owner will appear as the applicant.
To later re-start the application, in the portal, open the application case. Then click on "Resume Application Wizard".

6. Application submitted

The wizard has now finished.
Click Finish.
ePQS will redirect you to the case record for the product. You may make changes directly to this case record as needed using the pencil icon:

At this time, please also send an email to diagnostics@who.int indicating that your submission is complete. Please include the Case number provided to you, and the product name.

At this time the application case status is changed from "Draft" to "Under screening".

7. What happens next?

After you email WHO PQ-IVD at diagnostics@who.int to inform them that a new PSF has been submitted, PQ-IVD will send an email acknowledging receipt of the application and informing you of the reference number assigned to the Prequalification number (PQDx-XXXX-YYYY-00).

In the Portal, you will be able to access the Product (with PQDx-XXXX-YYYY-00 reference number automatically assigned during the creation of the product) in ePQS Products.

> ***Note:*** *in the portal, by default, the lists of Products, Cases or Activities only show those that were recently submitted/edited.*
> *You may change the lists by clicking on the arrow and selecting the appropriate list that you wish to see.*
> *To keep this list as the default list, click on the pin icon.*