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1. Scope

This guide outlines the procedures and best practices for the submission of annual report and supporting documents. This ensures streamlined processing, improved efficiency, and consistent quality control.

2. Prerequisites

Applications wizards are accessed via the ePQS Portal – <https://who.my.site.com/ePQS/s/login/>.

Therefore access to the ePQS portal must be granted first. To seek registration apply via the form on the Portal landing page above.

Some types of applications have prerequisite conditions. For instance, a post-prequalification change application can only be created if there exists in the ePQS system at least one accepted or prequalified product for the applicant account.

Many wizards include steps that require the applicant to select an account from within the ePQS database. For instance, when an applicant wishes to create a product site for a product, or nominate a reference authority. Users can verify these accounts exist before commencing an application by referring to the spreadsheet available from the “View ePQS Registered Accounts” tile, as indicated in figure 1.

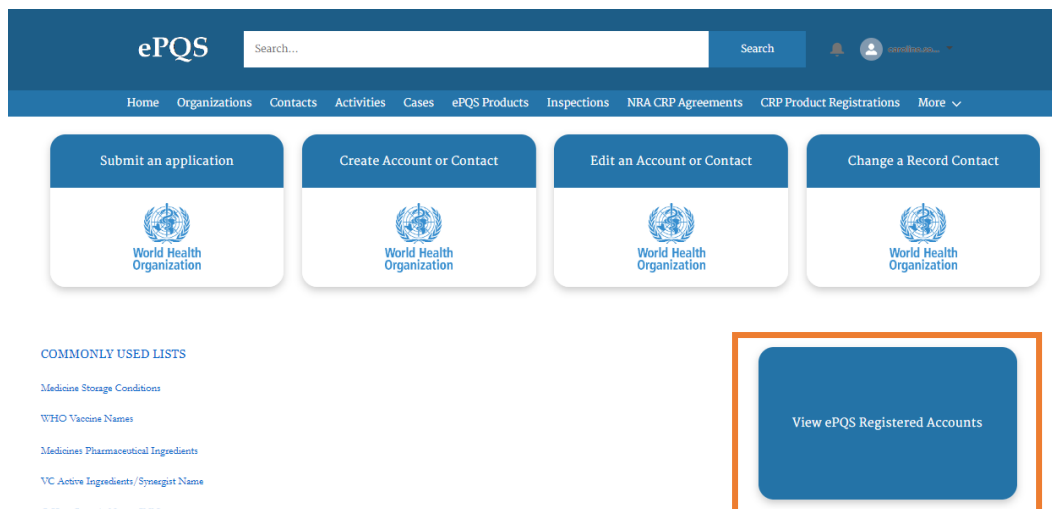


Figure 1: The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts”

3. Accessing the Portal

Applications wizards are accessed via the ePQS Portal – <https://who.my.site.com/ePQS/s/login/>.

4. Wizard steps

Wizard commencement

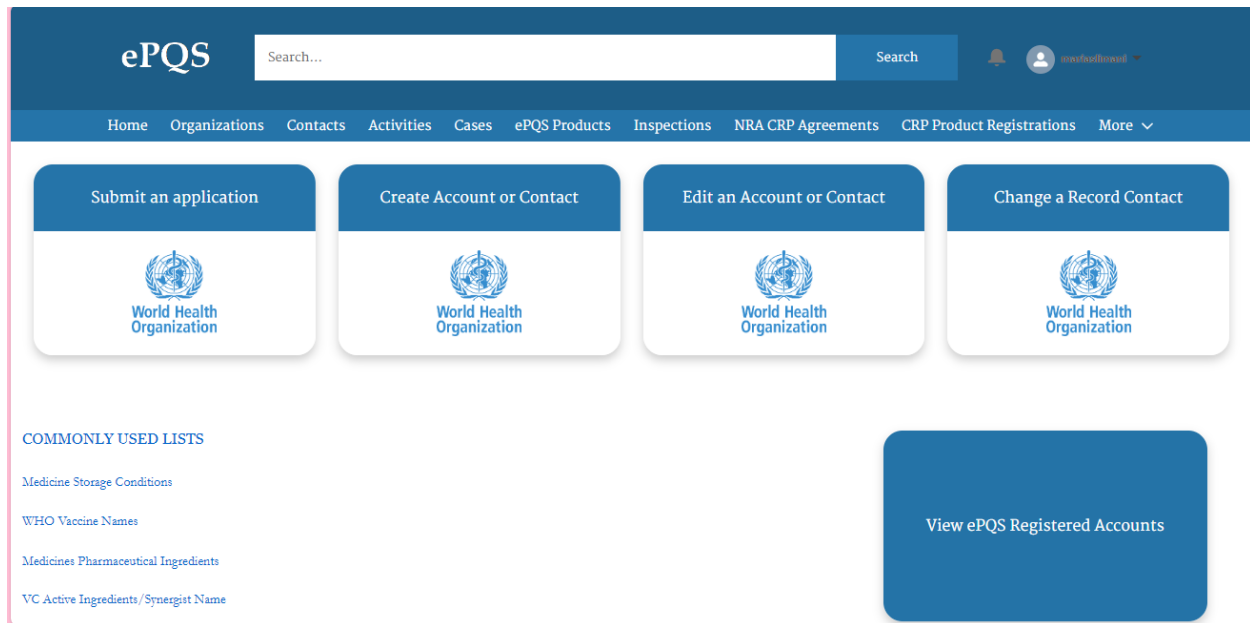


Figure 2: Commence the application process by selecting the Submit an application tile

An application can be initiated by selecting the Submit an application tile shown above, this opens up the “create a new application” page as shown below:

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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Figure 3: Create a new application page

Click next to open the “choose application type” page and select annual report as shown below.

Wizard Selection

Having passed the initial “Create a New Application screen”, the system will open the “choose a contact” page, use the drop-down arrow or search function to find and select the contact from the applicant organization, shown below:

Home
Organizations
Contacts
Activities
Cases
ePQS Products
Inspections
Archived Agreements
Application Wizard
More

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 ePQS Test Account 1 - NonStateActor, and also indicate if there are other secondary people involved.

* Primary Contact

ePQS External Applicant 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--

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Figure 4: You must first select the associated contact, before selecting the application type.

As part of the preliminary application steps, Applicants will be asked to nominate contacts for the application, and if applicable the product.

After choosing the contact, click next to open the “choose a product type” and select Quality Control Laboratory, as shown below:

The screenshot shows the ePQS Application Wizard interface. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. The wizard progress bar shows five steps: Organization & Contacts (active), Application Info, Product Details, Documents, and Finalize. The main heading is "Choose Product Type" with the instruction "Select the product area to narrow down the list of application types." Below this is a list of product types, each with a radio button. "Quality Control Laboratory" is selected. At the bottom right are "Previous" and "Next" buttons. The footer contains links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

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

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Figure 5: You must first select the associated product type, before selecting the application type.

The screenshot shows the ePQS Application Wizard interface. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. The wizard progress bar shows five steps: Organization & Contacts, Application Info (active), Product Details, Documents, and Finalize. The main heading is "Choose Application Type" with the instruction "Based on the product type, here is the list of application types available." Below this is a list of application types, each with a radio button. "Annual Report" is selected. At the bottom right are "Previous" and "Next" buttons. The footer contains links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

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
- ☒ Annual Report
- ☐ Technical Assistance

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Figure 6: Then you will offered the applicant application type and select annual report

Click next to open the “relevant products” page, as shown below:

The screenshot shows the ePQS Application Wizard interface. The top navigation bar includes the ePQS logo, a search bar, and a user profile dropdown. The main navigation bar lists: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. The wizard progress bar shows five steps: Organization & Contacts (active), Application Info, Product Details, Documents, and Finalize. The current step is titled "Relevant Products Found" and contains the text: "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." At the bottom right of the content area are "Previous" and "Next" buttons. The footer contains links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

Figure 7: Relevant Products found in the system (QCL)

Click next to open the “confirm application details” page, displaying:

- a) Application Type
- b) Product Type
- c) Organization
- d) Contact

As shown below:

The screenshot shows the ePQS Application Wizard interface at the "Confirm Application Details" step. The top navigation bar and main navigation bar are identical to Figure 7. The wizard progress bar shows the same five steps. The current step is titled "Confirm Application Details" and contains the text: "By proceeding to the next step you will be creating a draft QCLm Annual Report. This draft application will be available in your List View of Cases." Below this text is a bulleted list of application details: Application Type: Annual Report, Product Type: Quality Control Laboratory, Organization: [redacted], and Primary Contact: Maria Chimenti. At the bottom right of the content area are "Previous" and "Next" buttons. The footer contains links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

Figure 8: Confirm application page

Click next to confirm the application details, a draft application is created, with a system assigned case number (AR-QCL-20XX-000X), as shown below:

The screenshot shows the ePQS Application Wizard interface. The top navigation bar includes the ePQS logo, a search bar, and a user profile dropdown. The main navigation bar lists various sections: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. The Application Wizard progress bar shows five steps: Organization & Contacts, Application Info, Product Details, Documents, and Finalize. The current step is Application Info, which displays the message: "Continue Application. A draft application has been created. For reference the new application has the case number AR-QCL-2024-0045. You can view the draft application details by following the link." The case number "AR-QCL-2024-0045" is circled in blue. A "Next" button is located at the bottom right of the wizard.

Figure 9: A draft application record has now been created in the system and assigned a case number AR-QCL-20XX-000X

Click next to open the “link to existing laboratory” page and use the drop-down arrow to search and select the appropriate quality control laboratory, as shown below:

The screenshot shows the ePQS Application Wizard interface at the "Link to an Existing Laboratory" step. The progress bar indicates that "Organization & Contacts" is completed (marked with a green checkmark) and "Product Details" is the current step. The main content area displays the heading "Link to an Existing Laboratory" and a label "* Product". Below this is a dropdown menu with the selected option "Morocco-LNCM - LNCM (Morocco) - LNCM (Morocco)". At the bottom right of the wizard, there are "Previous" and "Next" buttons. The footer of the page includes links for "About Us", "Contact Us", "Privacy Policy", and "Legal Disclaimer".

Figure 10: Link application to a QCL

Click next twice to open the “upload documents” page, where the annual report and supporting documents are uploaded, as shown below:

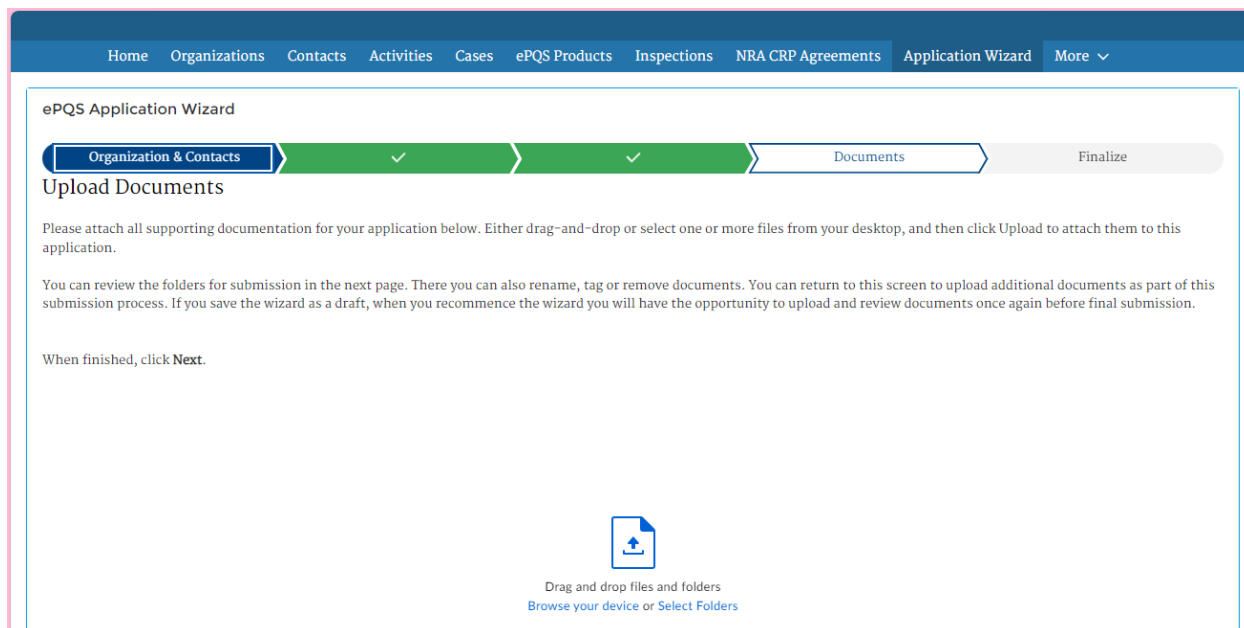


Figure 11: Upload Documents Page

After uploading the annual report and supporting documents, click next to open the “document review” page where you can preview, download, delete or rename the file(s), as shown below:

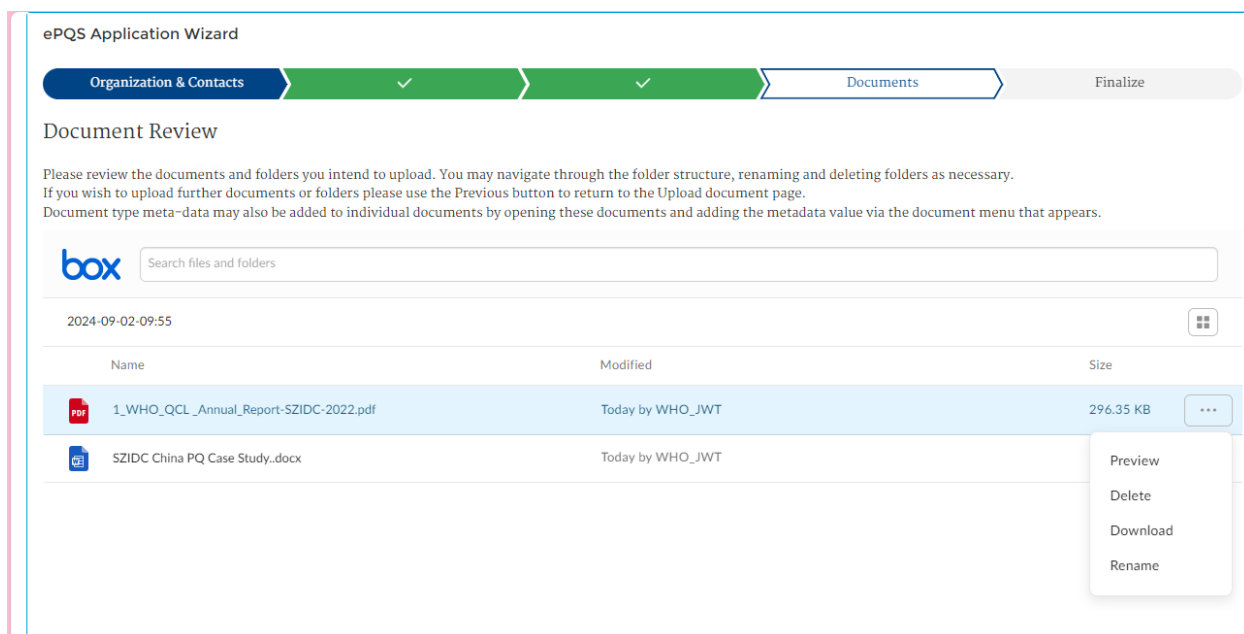


Figure 12: Documents review page

Click next to open the “review application” page, where links to the case (Application details) and product lab. i.d. (QCL/Applicant organization details) are provided for easy/quick access for review. After reviewing, there is the “ready to submit” section with three options, as shown below:

The screenshot shows the ePQS Application Wizard interface. At the top, there is a navigation bar with the ePQS logo, a search bar, and a user profile dropdown. Below the navigation bar is a horizontal menu with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. The main content area is titled "ePQS Application Wizard" and features a progress bar with four steps: "Organization & Contacts", "Review Application", "Ready to Submit", and "Finalize". The "Review Application" step is currently active. Below the progress bar, the text reads: "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." Below this, the Case ID is "AR-QCL-2024-0046" and the Product or Laboratory ID is "Morocco-LNCM". A section titled "Submit, Save or Discard" asks the user to choose whether they are ready to submit, if they need more time to save the draft, or if they want to discard it. The "Ready to submit?" section has three radio button options: "Yes" (selected), "No, save existing draft application and product (if applicable)", and "No, discard this draft application and product (if applicable)". At the bottom right, there are "Previous" and "Next" buttons.

Figure 13: Review application page

Click Yes and next to submit the application, the “application submitted” page is opened and click finish to complete the application process, as shown below:

The screenshot shows the ePQS Application Wizard interface after the application has been submitted. The progress bar now shows four steps: "Organization & Contacts", "Review Application", "Ready to Submit", and "Finalize". The "Ready to Submit" step is currently active. Below the progress bar, the text reads: "Application Submitted. The application wizard has now finished – click on the Finish button to be redirected to the detailed page of your submitted application." At the bottom right, there is a "Finish" button. Below the main content area, there is a footer with links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

Figure 13: Application submitted page

