



External Guidance - FPP Assessment Application Wizard guidance

Document Version Number: 0.2

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1. Scope

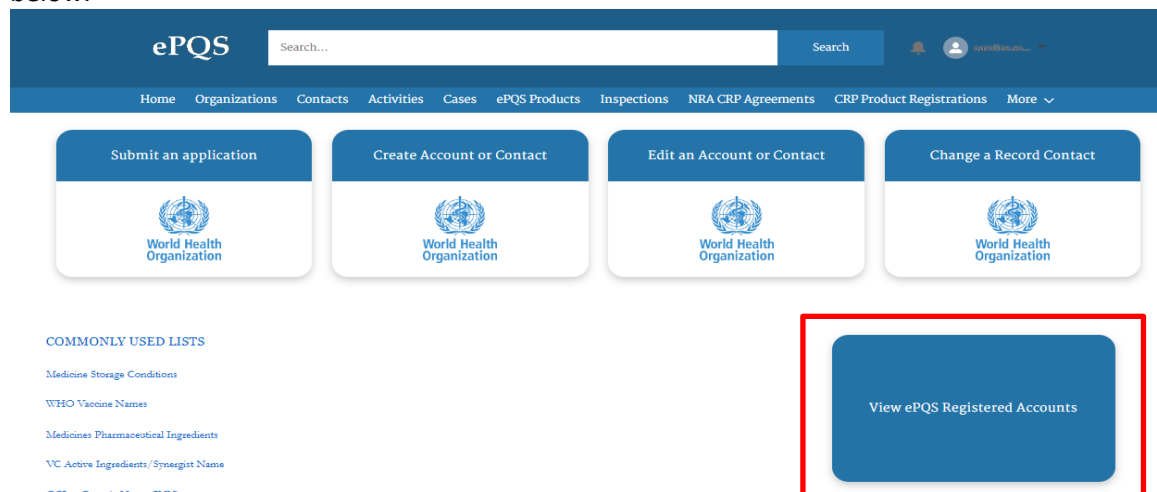
This guidance covers submitting an application(s) for FPP assessment via the WHO ePQS Portal. The applications include new dossier submissions, requalification applications, and additional information. The guidance provides step-by-step instructions on how to use the Portal Application Wizard to create, submit, receive feedback, and respond to queries on the portal.

2. Prerequisites

Access the application wizards via the ePQS Portal – <https://who.my.site.com/ePQS/s/login/>. The WHO must grant you access to the portal before you can use it. To seek registration, apply via the form on the Portal landing page.

Some types of applications have prerequisite conditions. For instance, one can only create a requalification application if the respective prequalified product exists in the ePQS system for the applicant account.

Many wizards include steps requiring the applicant to select an account from the ePQS database. For instance, when an applicant wishes to create a 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 below.



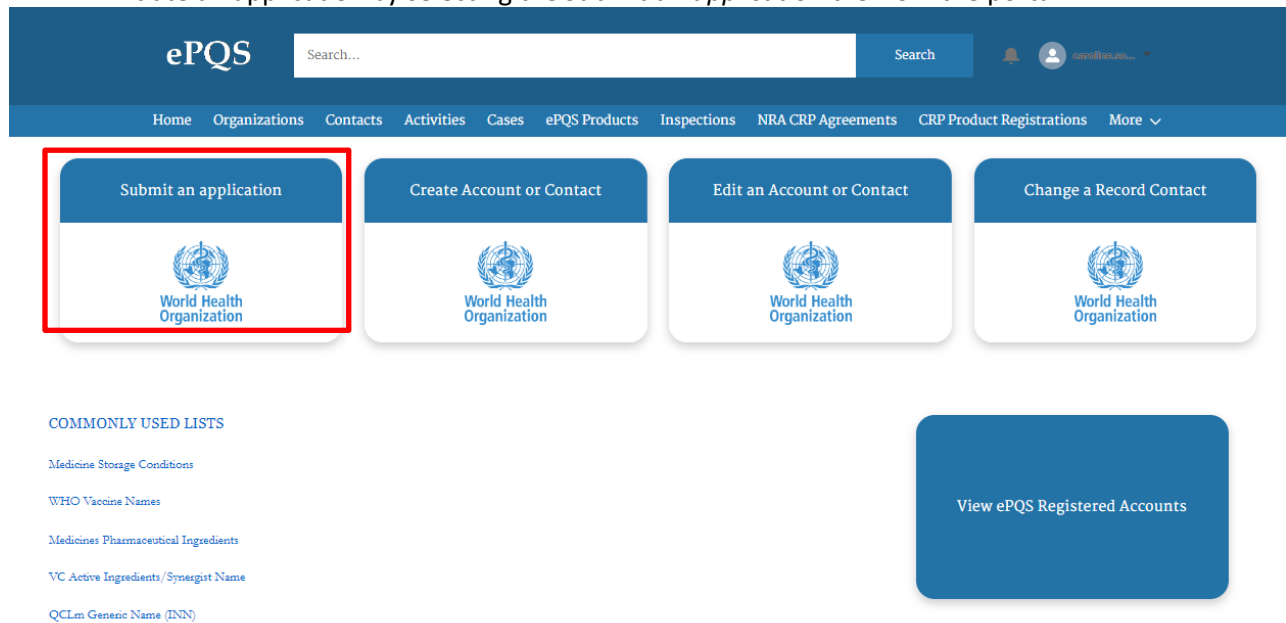
3. Accessing the Portal

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

4. Wizard steps

4.1 Wizard commencement

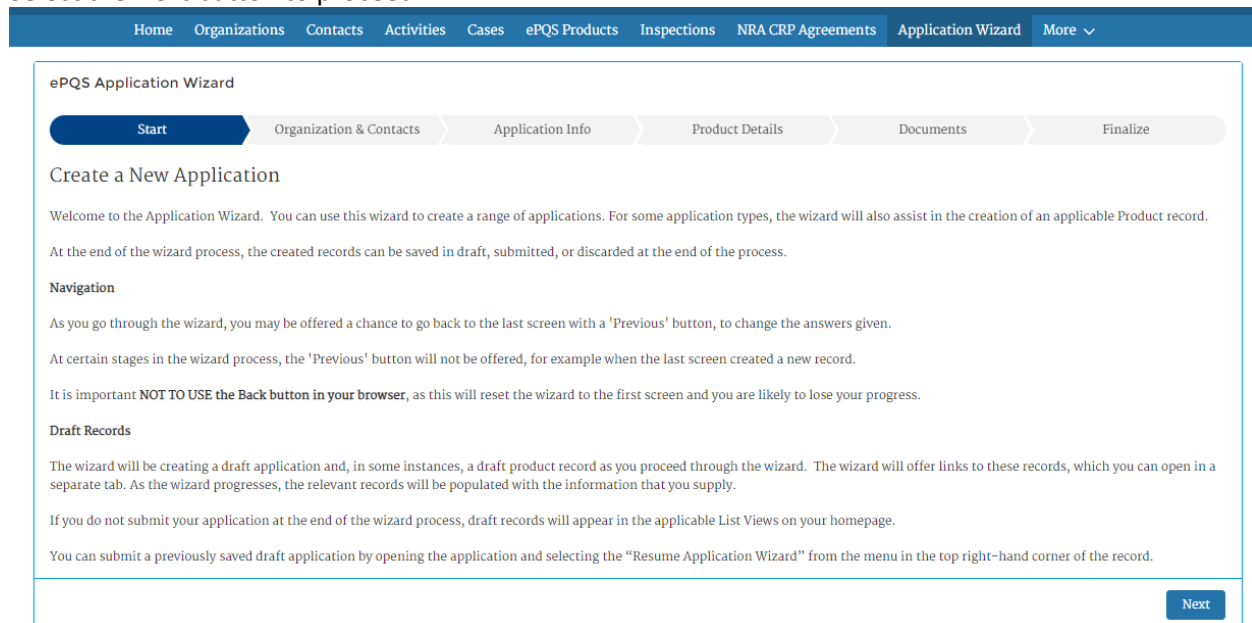
Initiate an application by selecting the *Submit an application* tile from the portal.



4.2 Wizard Selection: New Application

Please read the welcome note and follow the instructions provided.

Select the Next button to proceed.



Confirm the Applicant organization if you are a registered user associated with multiple accounts. Otherwise, nominate the contact(s) for the application. The system will offer any contact(s) associated with the account for selection. Note that the contacts do not need to be ePQS portal users.

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--

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

Choose the *product type* from the radio button and click next.

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

Choose the *Application type* from the radio button and click next.

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, with 'Application Wizard' highlighted. The wizard progress bar shows five steps: 'Organization & Contacts' (active), 'Application Info', 'Product Details', 'Documents', and 'Finalize'. The current step is 'Choose Application Type'. Below the title, it states: 'Based on the product type, here is the list of application types available.' A section titled '* Application Type' contains a list of radio buttons: 'Prequalification' (selected), 'Post-PQ Change', 'Alternative Listing', 'Emergency Use Listing (EUL)', 'Expert Review Panel (ERP)', 'New - Collaborative Registration Procedure - SRA', 'New - Collaborative Registration Procedure - WHO', and 'Requalification'. At the bottom right of the wizard box are 'Previous' and 'Next' buttons. Below the wizard box is a footer with links: 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

For prequalification, choose the *Application subtype* – either *Full assessment* or *Abridged*.

The screenshot shows the ePQS Application Wizard interface at the 'Choose Application Subtype' step. The top navigation bar and main navigation bar are identical to the previous screenshot. The wizard progress bar remains the same. The current step is 'Choose Application Subtype'. Below the title, it says: 'Please enter the following additional information:'. A section titled '* Application Subtype' features a dropdown menu with 'Full' selected. At the bottom right of the wizard box are 'Previous' and 'Next' buttons. Below the wizard box is a footer with links: 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

At this point, you will get a summary of the application details. Please confirm before proceeding to the next step.

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 menu 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 'Confirm Application Details'. It displays a summary of the application: Application Type: Prequalification, Application Subtype: Full, Product Type: Finished Pharmaceutical Product, Organization: Laurus Labs (Corp), and Primary Contact: Vaidyanathan N Iyer. A message states: 'By proceeding to the next step you will be creating a draft Mx FPP New Application. This draft application will be available in your List View of Cases.' At the bottom right of the wizard box are 'Previous' and 'Next' buttons. Below the wizard box is a footer with links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

After confirming the application details, a draft application is created. Details of the application can be viewed by clicking the case number (*PQ-FPP-2024-0010*) hyperlink.

The screenshot shows the 'ePQS Application Wizard' interface at the 'Continue Application' step. The top navigation bar and main navigation menu are identical to the previous screen. The wizard progress bar shows the same five steps. The current step is 'Continue Application'. It displays a message: 'A draft application has been created.' followed by: 'For reference the new application has the case number PQ-FPP-2024-0010. You can view the draft application details by following the link.' At the bottom right of the wizard box is a 'Next' button. Below the wizard box is the same footer with links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

For abridged applications, please enter additional application information, specifically the reference authority. Choose the applicable Reference Authority from the dropdown list.

Generally, the full assessment option does not require the reference authority details. However, it is possible to have partial reliance in some instances. Leave it as “None” if it is not applicable.

The screenshot shows the ePQS Application Wizard interface. The top navigation bar includes the ePQS logo, a search bar, and a user profile icon. Below this is a horizontal menu with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard (selected), and More. The main content area is titled 'ePQS Application Wizard' and features a progress bar with five steps: Organization & Contacts, Application Info (current step), Product Details, Documents, and Finalize. Under the 'Application Info' step, the section 'Additional Application Info' contains two dropdown menus. The first is labeled '* Product Subtype' and has 'Finished Pharmaceutical Product' selected. The second is labeled '* Reference Authority - If not applicable then leave choice unchanged as "--None--"' and has '--None--' selected. At the bottom right of the form are 'Previous' and 'Next' buttons. A footer bar at the very bottom contains links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

4.3 eCTD or non-eCTD

The applicant may choose to submit in non-eCTD or eCTD format.

The screenshot shows the 'Select Document Format' step of the ePQS Application Wizard. The progress bar now highlights 'Select Document Format' as the current step. The form contains two radio button options: 'eCTD' and 'Non-eCTD'. The 'Non-eCTD' option is selected. 'Previous' and 'Next' buttons are located at the bottom right of the form.

The choice between filing in eCTD (electronic Common Technical Document) format or non-eCTD format impacts the document uploading process at the end of the wizard.

Additionally, this decision influences the format of any subsequent submissions of additional information for a product under evaluation, as well as requalification applications associated with a prequalified product.

If a new application is submitted in eCTD format, all related submissions, additional information, and requalification applications must also be eCTD compliant, and the same applies if the initial application is made in non-eCTD format.

4.4 Entering application-specific wizard details

The following steps involve completing FPP product-related information.

4.4.1 Creating a new product.

Click on Next to access the product record.

The screenshot shows the 'ePQS Application Wizard' interface. The top navigation bar includes 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'Application Wizard', and 'More'. The wizard progress bar shows four steps: 'Organization & Contacts' (completed with a green checkmark), 'Product Details' (current step), 'Documents', and 'Finalize'. The main content area is titled 'Create a Product' and contains the following text: 'New Product', 'Since this is a Prequalification type application, a new product will be created of type:', a bulleted list with 'Finished Pharmaceutical Product (FPP)', and 'It will be linked to your application, PQ-FPP-2025-0046.' At the bottom right, there are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red rectangle. At the very bottom, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'. A small 'javascriptvoid(0);' error message is visible in the bottom left corner.

In the product details, add the following information. Please refer to the guidance provided below.

The screenshot shows the 'ePQS Application Wizard' interface at the 'Product Details' step. The top navigation bar is the same as the previous screen. The wizard progress bar shows 'Organization & Contacts' (completed), 'Product Details' (current step), 'Documents', and 'Finalize'. The main content area is titled 'Create a Product' and contains the following form fields: 'New Mx FPP Product Information Screen 1' (with a note 'Please fill out all required fields'), '* Therapeutic Area' (dropdown menu with 'Analgesics' selected), '* Target Population - if not applicable, select \'--None--\'' (dropdown menu with '(Not applicable)' selected), 'Co-packaging?' (radio buttons for 'Yes' and 'No', with 'No' selected), '* Type of Safety and Efficacy Data' (dropdown menu with 'Additional strength biowaiver' selected), and 'Product Description' (text area). The 'Next' button from the previous screen is still visible at the bottom right.

* Packaging Description

* Dosage Form

* Routes of Administration (Mx): To select multiple items, hold down the Ctrl (PC) or Command (Mac) key

Respiratory (inhalation)
Subconjunctival
Subcutaneous
Subdermal
Sublingual

* Shelf Life (months)

* Storage Condition Requirements

Administration Device

Next

<i>Therapeutic area*</i>	Select as applicable to your product from the drop-down list
<i>Target population*</i>	Select as applicable from the drop-down list. <ul style="list-style-type: none"> ○ Paediatrics population- if it is to be used in children ○ Paediatrics suitable- if children can use it but also other age groups ○ Other- if the above two options are not applicable.
<i>Co-packaging</i>	Select Yes or No as applicable. Choose Yes if the product contains more than one product packaged together
<i>Type of Safety and Efficacy Data*</i>	Select as applicable
<i>Product Description</i>	Free text, as described in section 2.3.P.1 of the QIS and QOS-PD.
<i>Packaging Description*</i>	Includes the packaging type and configuration, e.g., Blister, PVdC/PVC/Alu, 10x5. The configuration of 10x5 means 5 blisters, each containing 10 tablets.
<i>Dosage Form*</i>	Type as applicable e.g., Tablet, Film-coated.
<i>Route of administration*</i>	Select from the options provided.
<i>Shelf Life (months)*</i>	Type as applicable
<i>Storage Condition Requirements*</i>	Type as applicable
<i>Administrative device</i>	Type if applicable. E.g., syringe, applicator, measuring spoon

All sections marked with an asterisk (*) must be completed before you can proceed to the next step.

Click **Next** after entering the above information.

4.4.1.1 Choosing a reference product for additional strength biowaiver.

On the next page, you will have the opportunity to either select an already prequalified product or choose a reference product application using BE data, from the drop-down list.

If not in the system, you should first create the product using BE data before creating the additional strength product record.

If applicable, you can enter the proprietary name at this stage. Click *Next* to continue.

The screenshot shows the 'ePQS Application Wizard' interface. At the top is a navigation bar with links: Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, Application Wizard, and More. Below this is a progress bar with five steps: Organization & Contacts (active, green), Product Details, Documents, and Finalize. The main heading is 'Create a Product'. Underneath, it says 'New Mx FPP Product Additional Information' and '(Please fill out all required fields)'. There is a text input field for 'Additional Strength Biowaiver' containing 'ANDA 077267 USFDA'. Below that is a text input field for 'Other Safety and Efficacy Studies'. Then, a text input field for 'Proprietary Name'. At the bottom right, there are two buttons: 'Previous' and 'Next'. The 'Next' button is highlighted with a red rectangle.

Upon completing the product details page, a product number is generated as P-xxxxx. Proceed to the next page to enter additional product-related information.

The screenshot shows the 'ePQS Application Wizard' interface after a successful update. The navigation bar is the same. The progress bar shows 'Organization & Contacts' as active (green) and 'Product Details' as the next step. The main heading is 'Create a Product'. Below it, it says 'Product Successfully Updated'. A message states: 'The details you have just entered have been updated on the new Finished Pharmaceutical Product for your PQ-FPP-2025-0046 application. By clicking on the link provided you can see the product record. The product record is also available in your Products' List View.' Below this message is a bulleted list: '• FPP Product: P-13718.' At the bottom right, there is a 'Next' button highlighted with a red rectangle. At the very bottom of the page, there are links: About Us, Contact Us, Privacy Policy, and Legal Disclaimer. A small 'javascript:void(0);' is visible at the bottom left.

4.4.1.2 Creating product components

The product component refers to the dosage units being submitted. Please click the fields for options and refer to the guidance provided below.

The screenshot shows the ePQS Resume Wizard interface. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area is titled 'ePQS Resume Wizard' and shows a progress bar with four steps: 'Product-Related Info' (active), 'Documents', and 'Finalize'. Below the progress bar, the section 'Create Product Components' is displayed. It includes a sub-section 'Create a New Component' with a note: '(Please fill out all required fields) It will be linked to the product P-13718.' The form contains the following fields: 'Component Type' (Active), 'Dosage Unit' (mg), 'Dosage Form' (Capsule, Soft, Rectal), 'Route of Administration' (Auricular (otic)), and 'Fixed Dose Combination Product (FDC)' (Yes/No). A 'Next' button is located at the bottom right of the form.

<i>Component type*</i>	Select as applicable to your product from the drop-down list. See below in 4.4.1.4 for co-packaged products.
<i>Dosage Unit*</i>	Select as applicable from the drop-down list
<i>Dosage Form*</i>	Select as applicable from the drop-down list
<i>Route of Administration*</i>	Select as applicable from the drop-down list
<i>Fixed Dose Combination Product (FDC)*</i>	Select Yes or No as applicable. If Yes, select the applicable number of active medicines from the drop-down list.

After all the details are added, a new component record with the reference number **PC-XXXX** is created. Click **Next** to continue adding ingredients for the components.

The screenshot shows the ePQS Resume Wizard interface. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area displays the 'ePQS Resume Wizard' progress bar with steps: Organization & Contacts (completed), Product-Related Info (current step), Documents, and Finalize. Below the progress bar, the title 'Create Product Components' is shown. A success message states: 'Success A new PC-05252 component has been created.' A 'Next' button is located at the bottom right of the form area. At the bottom of the page, there are links for About Us, Contact Us, Privacy Policy, and Legal Disclaimer.

4.4.1.3 Creating product ingredients

Please click the fields for options and refer to the guidance provided below.

The screenshot shows the ePQS Application Wizard interface. The top navigation bar includes links for Organization & Contacts (completed), Product-Related Info (current step), Documents, and Finalize. Below the progress bar, the title 'Create Product Ingredients' is shown. The section 'Enter FPP Ingredient Information' includes a note: '(Please fill out all required fields)'. The form contains the following fields:

- * Ingredient Type:** Radio buttons for Active (selected) and Inactive.
- * Active Ingredient:** A text field with a search icon and a 'Search All Result For...' button. The value 'Efavirenz' is entered.
- * Quantity:** A text field with the value '600.00'.
- * Unit:** A dropdown menu with 'mg' selected.
- Percentage of Component:** A text field with the value '35'.
- * Strength for Publishing:** A text field with the value '600mg'.

 At the bottom right, there are 'Previous' and 'Next' buttons.

Ingredient Type*	Start with the Active ingredient.
Active Ingredient*	Enter at least two characters in the field and click “Search all results for” then choose the correct API to populate the field.
Quantity*	Type amount of API or excipient per component up to two decimal places, e.g., 600.00.
Unit*	Select as applicable from the drop-down list.
Percentage of Component	Enter the percentage of the ingredient in the formulation.

<i>Strength for Publishing*</i>	<p>Enter the product strength.</p> <p>This is how the product strength will appear on the WHO Prequalification website, e.g., 600mg, with no decimal places.</p>
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If all the details are provided, the following page will appear after clicking Next.

[Home](#)
[Organizations](#)
[Contacts](#)
[Activities](#)
[Cases](#)
[ePQS Products](#)
[Inspections](#)
[NRA CRP Agreements](#)
[Application Wizard](#)
[More](#)

ePQS Application Wizard

[Organization & Contacts](#)
✓
✓
[Product-Related Info](#)
[Documents](#)
[Finalize](#)

Create Product Ingredients

Success
Efavirenz has been successfully created and added to your product.

[Next](#)

[About Us](#)
[Contact Us](#)
[Privacy Policy](#)
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Move to the next window to add more ingredients.

[Home](#)
[Organizations](#)
[Contacts](#)
[Activities](#)
[Cases](#)
[ePQS Products](#)
[Inspections](#)
[NRA CRP Agreements](#)
[Application Wizard](#)
[More](#)

ePQS Application Wizard

[Organization & Contacts](#)
✓
✓
[Product-Related Info](#)
[Documents](#)
[Finalize](#)

Create Product Ingredient

Add Further FPP Ingredients to the Same Component PC-05073?

* Choose one

☒ Yes, add more
 ☐ No

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

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Information for inactive ingredients (excipients)

For inactive ingredients, the process is similar to that for APIs. However, there is an additional field of *Reason for inclusion* where you should select the applicable option(s) from the provided list.

Additionally, there is no requirement to specify the strength for publication, as excipients are not published on the WHO PQ website.

The screenshot shows the 'ePQS Application Wizard' interface. At the top, a progress bar indicates the current step is 'Product-Related Info', with 'Organization & Contacts' completed and 'Documents' and 'Finalize' pending. The main heading is 'Create Product Ingredients'. Below this, a sub-heading reads 'Enter FPP Ingredient Information' with a note '(Please fill out all required fields)'. The form contains several fields: 'Ingredient Type' with radio buttons for 'Active' and 'Inactive' (the latter is selected); a text field for 'Inactive Ingredient' with a search icon and a placeholder 'Methylcellulose'; 'Quantity' with a value of '300.00'; 'Unit' with a dropdown menu showing 'mg'; and a 'Reason for Inclusion' dropdown menu with options: 'Co-Solvent', 'Desiccant', 'Diluent' (which is highlighted), 'Disintegrant', and 'Dispersant'. Below this is a 'Percentage of Component' field with a value of '18'. At the bottom right, there are 'Previous' and 'Next' buttons.

Repeat the process until all the ingredients are added.

Note that there is no coating agent in the excipients list. For coating ingredients, e.g., *Opadry red*, select the ingredient as *Colourant*, and enter the reason for inclusion as *Coating agent*.

When done, choose *No* on the window for "Add further ingredients to the same component PC-xxxxx," and move to the next window to create more components if applicable.

4.4.1.4 Creating additional components

Create additional components if the products are co-packaged (containing more than one dosage unit in a pack). A separate component is required for each product included in the package.

Here are some examples:

- i. A co-pack containing 2 active products, such as Nirmatrelvir tablets and Ritonavir tablets, requires the creation of a separate component for each product, resulting in a total of **2** components
- ii. A co-pack containing an active product and a placebo as in some hormonal contraceptives, such as Ethinylestradiol/Levonorgestrel Tablet co-packaged with placebo tablet, requires the creation of a separate component for each product, resulting in a total of **2** components.
- iii. A co-pack that includes one active product and two diluents necessitates the creation of a separate component for each, leading to a total of **3** components.

The addition of ingredients for additional components should be repeated as described above in 4.4.1.2.

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 (completed), Product-Related Info (current step), Documents, and Finalize. The main heading is 'Create Product Components'. Below it, the text asks 'Do you want to create more Components for your FPP Product P-13025?'. There are two radio button options: 'Yes, add more' (selected) and 'No'. At the bottom right, there are 'Previous' and 'Next' buttons. At the very bottom, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

4.4.1.4 Creating product packaging

Enter packaging information as applicable to your product and click **Next**.

The screenshot shows the 'ePQS Application Wizard' interface at the 'Create Product Packaging' step. The top navigation bar is the same as the previous screenshot. The wizard progress bar shows five steps: Organization & Contacts (completed), Product-Related Info (current step), Documents, and Finalize. The main heading is 'Create Product Packaging'. Below it, the text says 'FPP Packaging Information' and '(Please fill out all required fields)'. There are several required fields with asterisks: 'Mx FPP Packaging Type' (text input with 'Bottle; HDPE'), 'Pack Size' (text input with '28'), 'Configuration' (text input with '28x1'), 'Shelf Life (months)' (text input with '36'), 'WHO Listed Authority Shelf Life (months)' (text input), 'Storage Condition' (text input with 'Do not store above 30°C'), and 'WHO Listed Authority Storage Condition- if not applicable, select 'None'' (text input with '--None--'). There is also an 'In-use Shelf Life' text input field. At the bottom right, there are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red rectangle.

You will receive confirmation of the newly created packaging record with reference number *PP-xxxxx*.

The screenshot shows the 'ePQS Application Wizard' interface. At the top is a navigation bar with links: 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), a step with a checkmark, 'Product-Related Info', 'Documents', and 'Finalize'. The main heading is 'Create Product Packaging'. Below it, a 'Success' message states: 'A new Packaging item PP-06871 has been created and added to the Product.' A 'Next' button is located at the bottom right of the content area. At the very bottom of the page are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Select the product component(s) that uses the created packaging and click *Next*.

This screenshot shows the 'ePQS Application Wizard' at the 'Choose the relevant Component(s) for the Packaging Record' step. The progress bar is identical to the previous step. The main heading is 'Create Product Packaging'. The instruction reads: 'Choose the relevant Component(s) for the Packaging Record.' Below this is a dropdown menu labeled '* Product Component(s)' with 'PC-05073' selected. 'Previous' and 'Next' buttons are at the bottom right. The footer links remain the same.

You will receive a notification for successful linkage and click *Next* to continue.

The screenshot shows the 'ePQS Application Wizard' with a 'Success' message: 'The following Component(s) have been linked with your PP-06871 Product Packaging record: PC-05073;'. The 'Next' button at the bottom right is highlighted with a red rectangle. The progress bar and footer links are consistent with the previous steps.

Select *Yes* or *No* to add more components to the created packaging, if applicable. Click *Next* to continue.

[Home](#) [Organizations](#) [Contacts](#) [Activities](#) [Cases](#) [ePQS Products](#) [Inspections](#) [NRA CRP Agreements](#) [Application Wizard](#) [More](#) ▼

ePQS Application Wizard

Organization & Contacts

✓

✓

Product-Related Info

Documents

Finalize

Create Product Packaging

Do you want to add any more components to this Product Packaging?

Choose one

☐ Yes, add more

☐ No

Previous

Next

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Creating additional packaging records

When a product is packaged in more than one type of packaging, such as blisters and bottles, create a record for each pack type.

ePQS Application Wizard

Organization & Contacts

✓

✓

Product-Related Info

Documents

Finalize

Create Product Packaging

Do you want to create more Packaging records for your FPP Product P-13025?

* Choose one

☐ Yes, add more

☐ No

Previous

Next

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

4.4.1.5 Creating product site(s) records

4.4.1.5.1 Adding a FPP manufacturing site(s)

Enter the site name and click next.

[Home](#) [Organizations](#) [Contacts](#) [Activities](#) [Cases](#) [ePQS Products](#) [Inspections](#) [NRA CRP Agreements](#) [Application Wizard](#) [More](#) ▼

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-13025:

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

Previous

Next

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

Select the applicable site address from the drop-down list and click Next.

[Home](#) [Organizations](#) [Contacts](#) [Activities](#) [Cases](#) [ePQS Products](#) [Inspections](#) [NRA CRP Agreements](#) [Application Wizard](#) [More](#) ▼

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

Laurus Labs Limited (Plot No. 22 D & E) 1 - Plot No. 22 D & E, APSEZ De-Notified Area, Gurajapalem Village, Rambilli Mandal,, Visakhapatnam, 531011, India

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Next

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Select the site activity and the activities conducted at this site and click Next.

[Home](#) [Organizations](#) [Contacts](#) [Activities](#) [Cases](#) [ePQS Products](#) [Inspections](#) [NRA CRP Agreements](#) [Application Wizard](#) [More](#) ▼

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

FPP Manufacture

Activities Conducted at Manufacturing Site - press Ctrl (Cmd on Mac) + Left Arrow or Ctrl (Cmd on Mac) + Right Arrow to move items between lists

Available

Drum manufacturer

FPP manufacture: Terminal Sterile

Liquid, powder, gel (non sterile)

Microbiological release testing

Packaging only

Physicochemical release testing

Terminally sterilised FPP manufacture

Selected

Solid oral dosage form

Previous

Next

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Review the site information to confirm the entered details, then click *Next*.

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: Laurus Labs Limited (Plot No. 22 D & E) 1
- Site Street: Plot No. 22 D & E, APSEZ De-Notified Area, Gurajapalem Village, Rambilli Mandal,
- Site City: Visakhapatnam
- Site Zip/Postcode: 531011
- Site Country: India

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You will receive a notification of successful site entry. Click *Next* to continue.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Sites

Success
A new Product Site PS-29702 has been created for the Finished Pharmaceutical Product P-13025:

- Site Name: Laurus Labs Limited (Plot No. 22 D & E) 1
- Site Activity: FPP Manufacture
- Activity Types: Solid oral dosage form
- Site Address: Plot No. 22 D & E, APSEZ De-Notified Area, Gurajapalem Village, Rambilli Mandal, Visakhapatnam India 531011

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Add further information if applicable and click *Next* to continue.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Related Information

*Choose Product Related Information to Add to Application

- ☐ Component
- ☐ Ingredient
- ☐ Packaging
- ☐ Product Site
- ☐ I don't want to add any more product related information at this time

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4.4.1.5.2 Adding an API manufacturing site(s)

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
API Manufacture

Activities Conducted at Manufacturing Site - press Ctrl (Cmd on Mac) + Left Arrow or Ctrl (Cmd on Mac) + Right Arrow to move items between lists

Available	Selected
API fermentation: Non sterile	API Synthesis: Non sterile
API fermentation: Sterile	
API intermediate Manufacture	
API micronisation	
API Synthesis: Sterile	

Previous Next

API submission route.

Choose from the options in the drop down list: APIMF, API PQ, CEP and Full data, as applicable.

ePQS Application Wizard

Organization & Contacts ✓ Product-Related Info Documents Finalize

Add Product Sites

Additional Product Site Details
(Please fill out all required fields)

* API Submission Route
APIMF
API PQ
CEP
Full data

Complete this field.

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Full data option

ePQS Application Wizard

Organization & Contacts ✓ Product-Related Info Documents Finalize

Add Product Sites

Additional Product Site Details
(Please fill out all required fields)

* API Submission Route
Full data

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WHO Prequalified API (API PQ)

Select the linked WHO API PQ number in the format *WHOAPI-XXX*, from the drop-down list. Click *Next*.

[Home](#) [Organizations](#) [Contacts](#) [Activities](#) [Cases](#) [ePQS Products](#) [Inspections](#) [NRA CRP Agreements](#) [Application Wizard](#) [More](#) ▼

ePQS Application Wizard

Organization & Contacts

✓

✓

Product-Related Info

Documents

Finalize

Add Product Sites

Additional Product Site Details

(Please fill out all required fields)

* API Submission Route

API PQ

* API PQ Product Number – Only submitted products that have a product site that matches the site just previously chosen are available, where that product's status is not cancelled or withdrawn, and the product site is pending, acceptable or suspended

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Certificate of Suitability (CEP)

Enter the CEP number. Click *Next* to continue.

[Home](#) [Organizations](#) [Contacts](#) [Activities](#) [Cases](#) [ePQS Products](#) [Inspections](#) [NRA CRP Agreements](#) [Application Wizard](#) [More](#) ▼

ePQS Application Wizard

Organization & Contacts

✓

✓

Product-Related Info

Documents

Finalize

Add Product Sites

Additional Product Site Details

(Please fill out all required fields)

* API Submission Route

CEP

* CEP Number

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4.4.1.5.3 Adding a CRO site(s)

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
Clinical Research Organization

Activities Conducted at Manufacturing Site – press Ctrl (Cmd on Mac) + Left Arrow or Ctrl (Cmd on Mac) + Right Arrow to move items between lists

Available
CRO – Other

Selected
CRO – Bioanalytical
CRO – Clinical

Previous Next

Adding a CRO/BE study number(s).

The CRO study number can be found in the bioequivalence study report and in section 2 of the Bioequivalence Trial Information Form (BTIF).

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Site Details
(Please fill out all required fields)

CRO Study Number
axyl 1000

Previous Next

When done, click on *'I don't want to add any more product related information at this time.'* Click Next to continue.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Related Information

* Choose Product Related Information to Add to Application

☐ Component
☐ Ingredient
☐ Packaging
☐ New Active Site
☒ I don't want to add any more product related information at this time

Previous Next

5. Uploading documents.

5.1 eCTD document upload

You should upload documents in eCTD format if you have chosen submission by eCTD in Section 4.3.

Uploading documents

The screenshot shows a web browser window with the URL <https://who--uat.sandbox.my.site.com/ePQS/s/resume-wizard?resumeApplicationRecordId=500bW000008mkiK>. The page header includes the ePQS logo and a search bar. The main content area is titled "ePQS Resume Wizard" and contains the text "You are uploading documents to Case#PQ-2025-0047". Below this text is a large empty box for document upload. At the bottom right of the box are "Previous" and "Next" buttons. The footer contains links for "About Us", "Contact Us", "Privacy Policy", and "Legal Disclaimer".

For eCTD submission, the system will display information that the applicant should use to complete the module 1 envelope for their dossier. Copy the values displayed and click Next.

The screenshot shows the same web browser window as before, but the main content area now displays "ePQS Resume Wizard" and "eCTD Submission Module 1 Information". Below this, it states: "Below are the Module 1 values required for your eCTD submission envelope. You can select and copy these values before proceeding to the next step to upload your zip file." A red box highlights the following information:

- Salesforce Case Id : 00030243
- Application Type : Prequalification
- Application SubType : Abridged
- Contact-email :
- Organization Name : Ipca (Corp)
- Product Id : P-13722
- Product Type : Finished Pharmaceutical Product
- Product SubType : Finished Pharmaceutical Product
- Product Assessment Procedure : Prequalification - Abridged
- Product Name : null Tablet, Film-coated + Ritonavir Capsule, Soft, Rectal 100mg

At the bottom right of the box are "Previous" and "Next" buttons. The footer contains links for "About Us", "Contact Us", "Privacy Policy", and "Legal Disclaimer".

Carefully review the instructions on the following page and click *Next*.

The screenshot shows a web browser window with the URL <https://who--uat.sandbox.my.site.com/ePQS/s/resume-wizard?resumeApplicationRecordId=500bW000008mkiK>. The page is titled "ePQS Resume Wizard" and contains a search bar and 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 is enclosed in a red rectangular box and contains the following text:

ePQS Resume Wizard

File(s) for this application must be uploaded in .zip format.

Please copy and use the following exact name(s) for your submission file(s). This will ensure that your submission(s) can be transmitted to the eCTD repository.

Filename(s):

PQ-FPP-2025-0047_P-13722

At the bottom right of the box are two buttons: "Previous" and "Next". Below the box, there are links for "About Us", "Contact Us", "Privacy Policy", and "Legal Disclaimer".

See instructions under *section 5.2* below to complete the upload.

5.2 Common document upload

Initial document upload screen.

Upload documents according to your preferred choice.

You can upload single files, multiple files, or folders on the document upload screen. Once you have selected them, click *Next*.

The screenshot shows a web browser window with the URL <https://who--uat.sandbox.my.site.com/ePQS/s/resume-wizard?resumeApplicationRecordId=500bW000008TJ7W>. The page is titled "ePQS Resume Wizard" and contains a search bar and 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 is enclosed in a blue rectangular box and contains the following text:

ePQS Resume 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

At the bottom right of the box are two buttons: "Cancel" and "Upload". Below the box, there are links for "About Us", "Contact Us", "Privacy Policy", and "Legal Disclaimer".

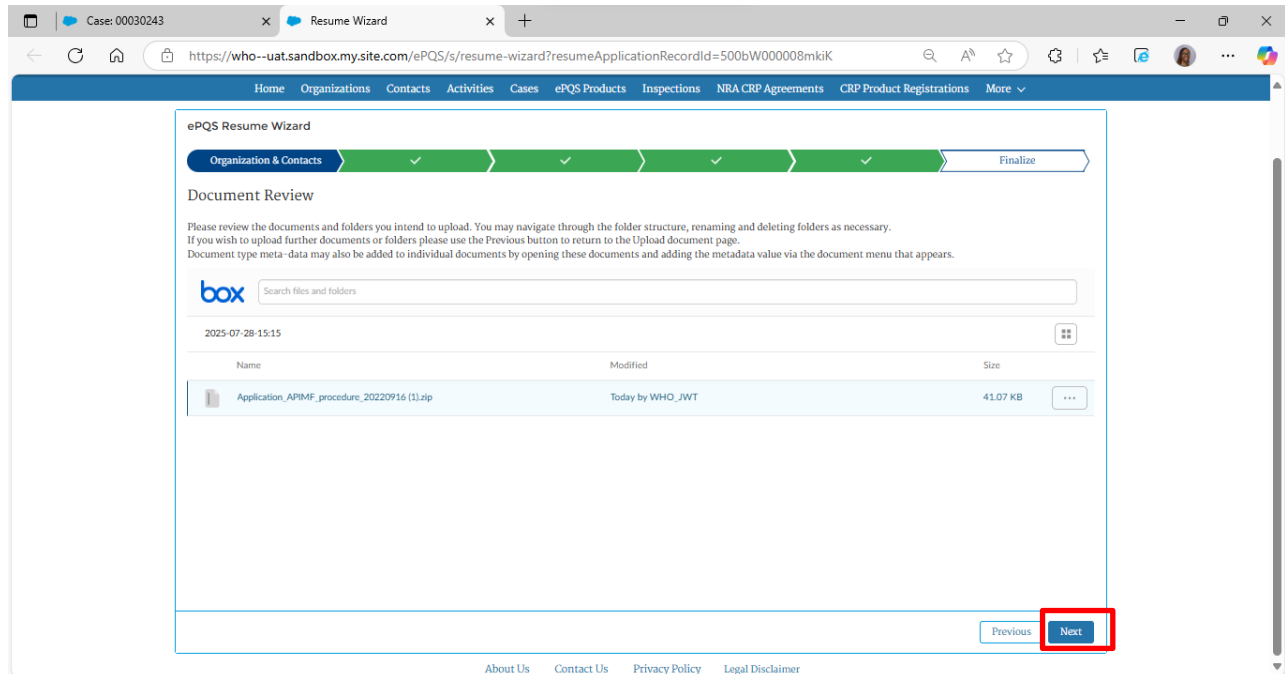
You will be asked to confirm the upload, but you can also cancel and return to the previous screen.

The screenshot shows the 'ePQS Resume Wizard' interface. At the top, a navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The wizard progress bar shows four steps: 'Organization & Contacts' (completed), 'Documents' (current step), and 'Finalize' (disabled). The 'Upload Documents' section contains 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. 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.' Below the instructions, a file named 'AGDD-2024-Day-2-Slides.zip' is shown with a close button (X). At the bottom right, there are 'Cancel' and 'Upload' buttons. At the very bottom, there are 'Previous' and 'Next' buttons.

Review the uploaded document(s)

Before submitting, you will be asked to review the files intended to be submitted. You can delete or rename the documents. You can also explore the folder structure that you uploaded to make more detailed changes.

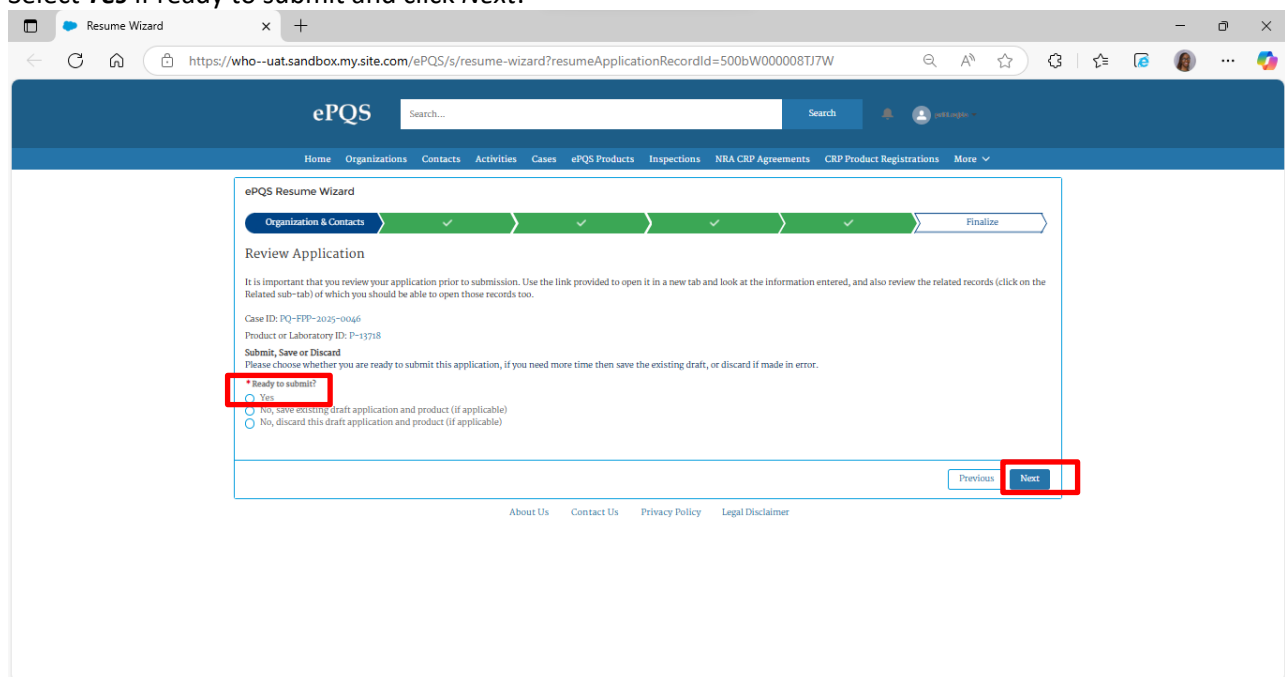
The screenshot shows the 'ePQS Resume Wizard' interface at the 'Document Review' step. The navigation bar and progress bar are the same as in the previous screen. The 'Document Review' section contains instructions: 'Please review the documents and folders you intend to upload. You may navigate through 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.' Below the instructions, there is a 'box' logo and a search bar labeled 'Search files and folders'. A table lists the uploaded documents. The first document is 'Application_APIMF_procedure_20220916 (1).zip', uploaded 'Today by WHO_JWT', with a size of '41.07 KB'. A red box highlights the document menu (three dots) next to the file name, which contains options: 'Preview', 'Delete', 'Download', and 'Rename'. At the bottom right, there are 'Previous' and 'Next' buttons. At the very bottom, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.



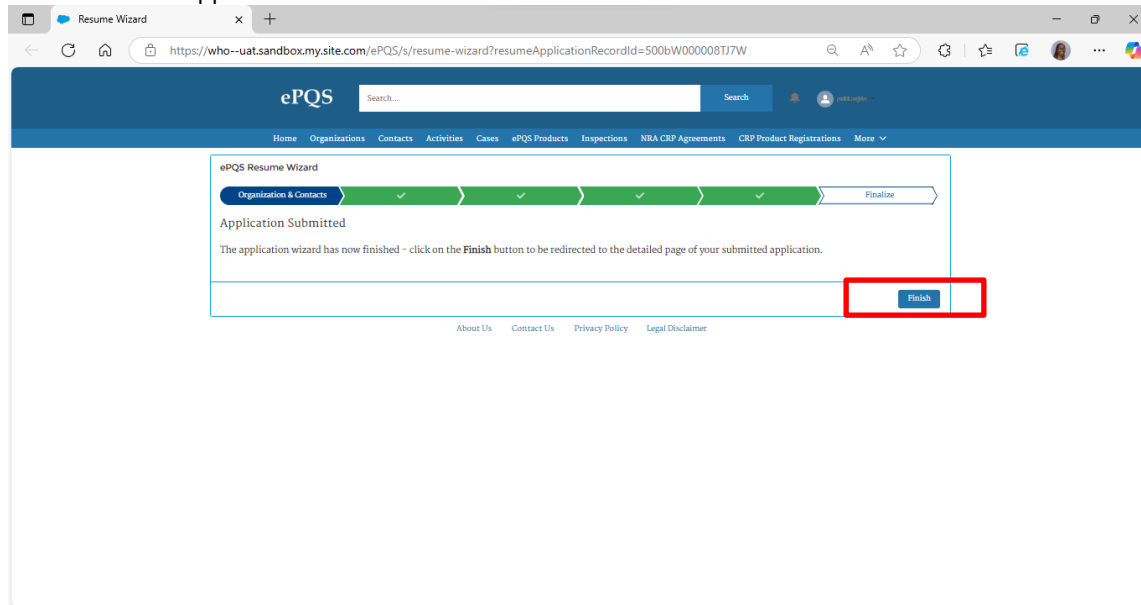
6. Submission

The final screen, before submission, has three options. *Submit*, *Save* (draft), and *Discard*. If you discard the application, the application and product record will no longer be visible in the application and product lists. However, you can find the information via the global search bar. The ePQS Admin officer will periodically delete these records.

Select **Yes** if ready to submit and click *Next*.



Confirmation of application submission. Click *Finish*.



Currently, there is a bug that displays *Invalid Page* once *Finish* is selected. This can be ignored. Simply select a new list or refresh the screen.



Once the application and product record are submitted,

- The ownership of the record changes to an internal assessment queue, meaning you can no longer edit the record.
- The status of the application changes from *Draft* to *Under screening*.
- The system enters the date of application submission.
- The application and product record are visible in the portal for on-going review.
- The primary contact of the application will receive an email notification.

7. Saving as Draft and resuming

You can resume the application wizard several times. You do not have to complete the application in one go. However, please note that if the application remains in *Draft* for over 60 days, a reminder email will be sent to the application's primary contact.

To resume an application, click the **ePQS Products** button and select the application to resume from the displayed list.

The screenshot shows the ePQS Products application interface. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, **ePQS Products** (highlighted with a red box), Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, there is a search bar and a "Recently Viewed" section. The main content area displays a table of 6 items, updated a few seconds ago. The table has columns for ID, Status, Name, and Product. The first item is a draft application for Ipca (Corp).

ID	Status	Name	Product
1	Draft	Ipca (Corp)	
2	Under Screening	Ipca (Corp)	Amoxicillin Capsule, Soft, Rectal + Amoxicillin Capsule, Soft, Rectal 250mg + 250mg
3	Under Screening	Ipca (Corp)	Amoxicillin
4	Under Screening	Ipca (Corp)	Amoxicillin
5	Under Screening	Ipca (Corp)	Amoxicillin
6	Under Screening	Ipca (Corp)	Amoxicillin

Click on the *Original Application* number to access the case record.

The screenshot shows the ePQS Product page for P-13722. The page includes a search bar, navigation tabs (Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, More), and a header with the product name and ID. Below the header, there are tabs for Details, Related, Preview Document, and Document Download. The 'Information' section is expanded, showing various fields. The 'Original Application' number 00030243 is highlighted with a red box.

Field	Value
WHO Product ID	P-13722
Product Type	Finished Pharmaceutical Product
Product Assessment Procedure	Prequalification - Abridged
Basis for Alternative Listing	
Target Population	Other
Current QIS	
Product Status	Draft
Product Subtype	Finished Pharmaceutical Product
Responsible team	Medicines Team
Reference Authority	ANSM S.Denis (Evaluation)
Original Application	00030243
Applicant Organization	Ipca (Corp)
Applicant Organization (Legal)	Ipca Laboratories Ltd
Primary Contact	
Secondary Contact	
Alternative Secondary Contact	

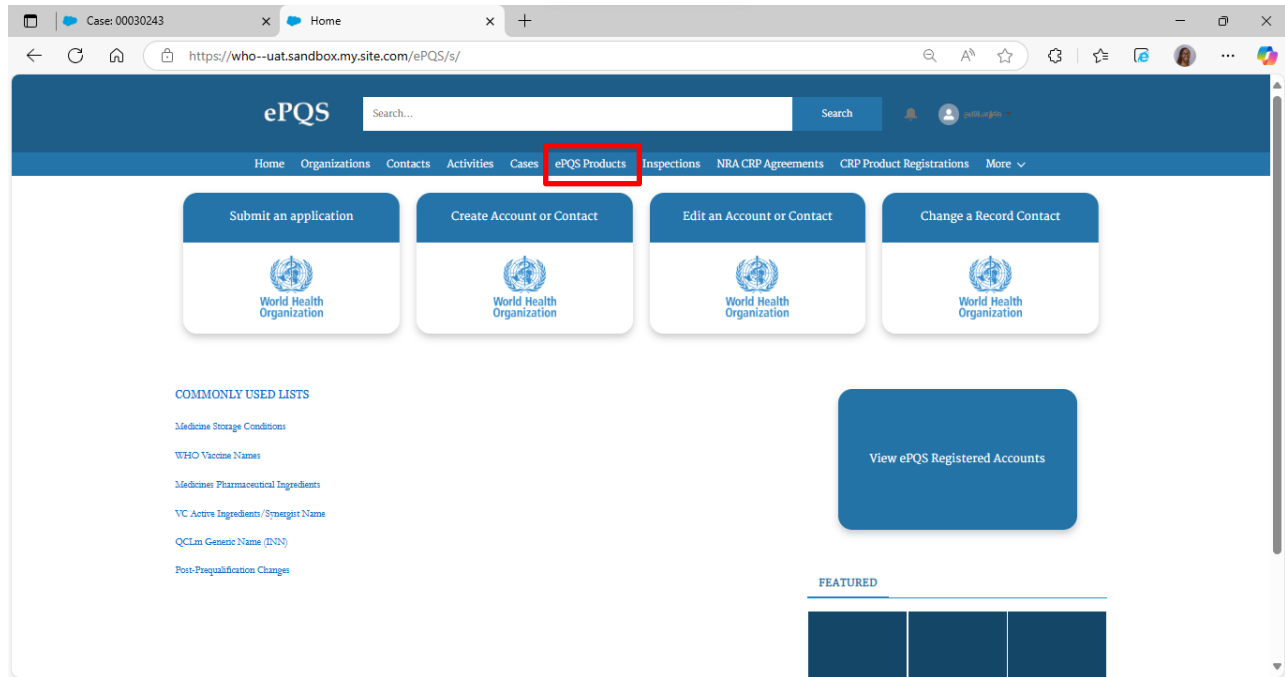
Select the *Resume Application Wizard* button to resume the application wizard. When restarted, the application wizard commences in the next applicable section.

The screenshot shows the ePQS Case page for Case: 00030243. The page includes a search bar, navigation tabs (Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, More), and a header with the case name and ID. Below the header, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'General Details' section is expanded, showing various fields. The 'Resume Application Wizard' button is highlighted with a red box.

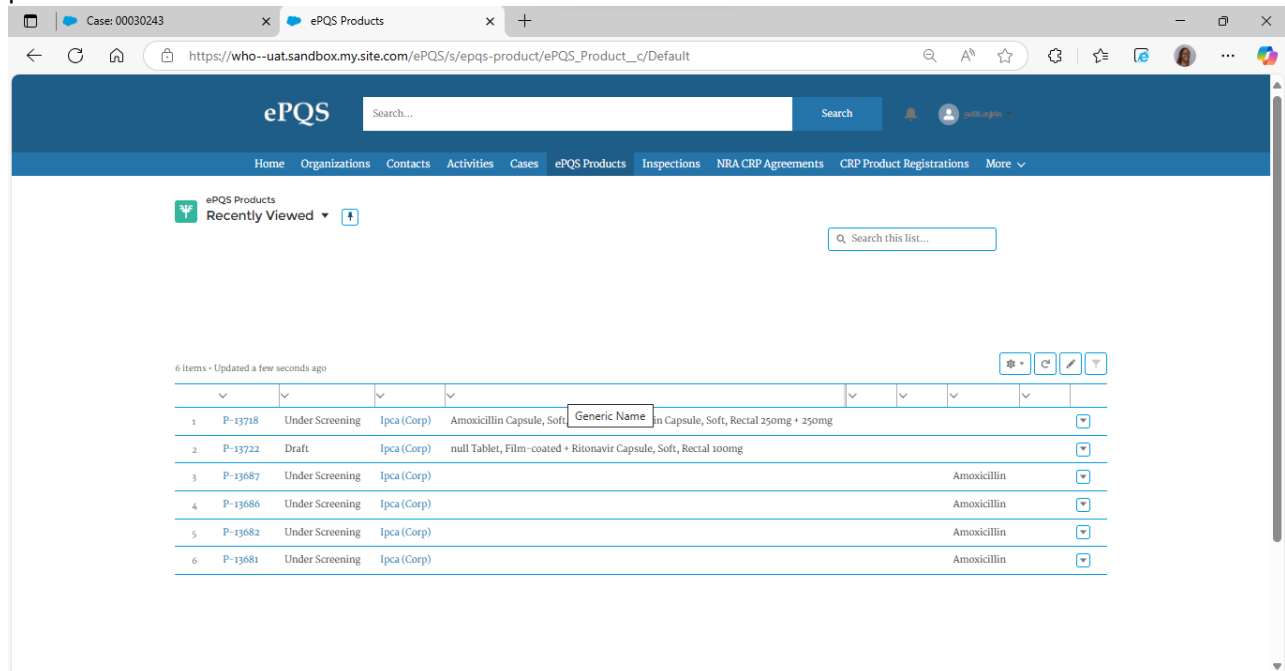
Field	Value
ePQS Case ID	PQ-FPP-2025-0047
WHO Application Number	PQ-FPP-2025-0047
WHO Product ID	P-13722
Product Type	Finished Pharmaceutical Product
Product Subtype	Finished Pharmaceutical Product
Application Type	Prequalification
Application Subtype	Abridged
Product Assessment Procedure	Prequalification - Abridged
Case Owner	Priti Rajda
Status	Draft
Reference Authority	ANSM S.Denis (Evaluation)
Applicant Organization	Ipca (Corp)
Applicant Organization (Legal)	
Applicant Primary Contact	
Applicant Secondary Contact	
Alternative Applicant Secondary Contact	
EOI Number	
Therapeutic Area(s)	

8. Submitting additional information and requalification

At the home page, select ePQS products



Then choose the application for which additional information or requalification information is to be provided from the list.



Click on the *Original Application* number to access the case record.

The screenshot shows the ePQS Product page for P-13722. The page has a blue header with the ePQS logo and a search bar. Below the header, there are tabs for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area displays product information for P-13722, including Product Type (Finished Pharmaceutical Product), Applicant Organization (Ipca (Corp)), Product Assessment Procedure (Prequalification - Abridged), and Date of Prequalification/Acceptance. Below this, there are tabs for Details, Related, Preview Document, and Document Download. The Details tab is selected, showing a list of product information. The 'Original Application' number 00030226 is highlighted with a red box.

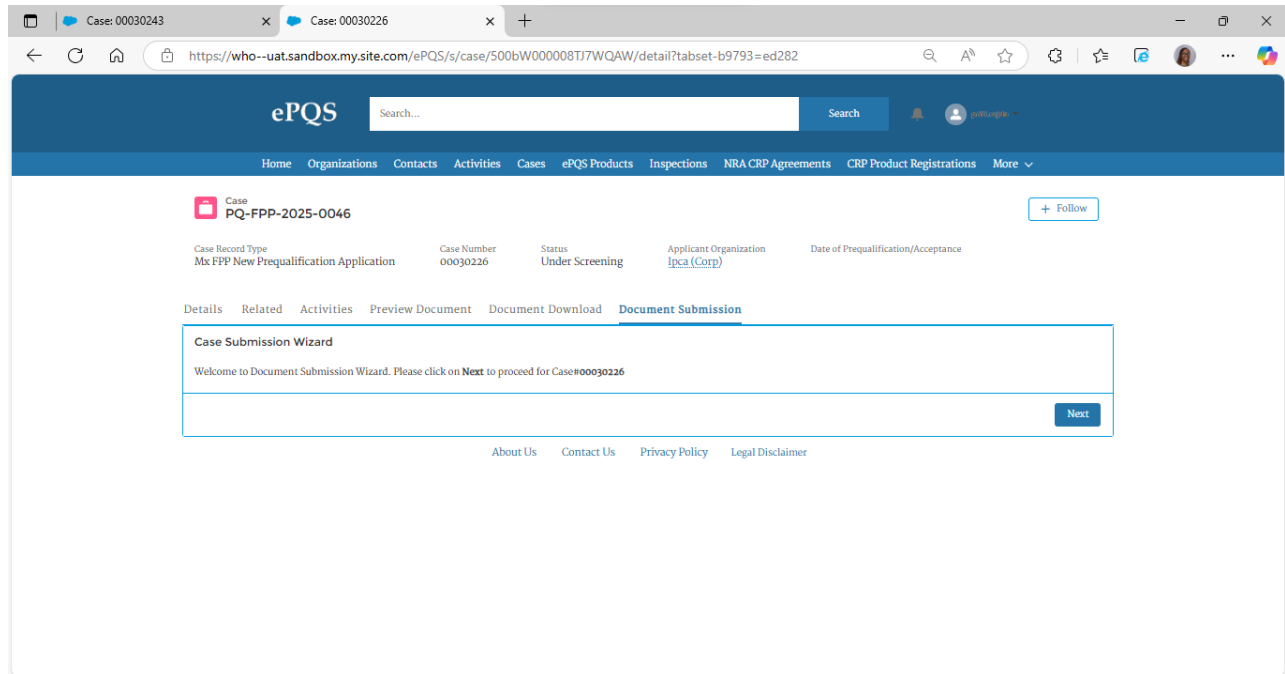
WHO Product ID	Product Status
P-13722	Draft
Product Type	Product Subtype
Finished Pharmaceutical Product	Finished Pharmaceutical Product
Product Assessment Procedure	Responsible team
Prequalification - Abridged	Medicines Team
Basis for Alternative Listing	Reference Authority
Target Population	ANSM S. Denis (Evaluation)
Other	Original Application
Current QIS	00030226
	Applicant Organization
	Ipca (Corp)
	Applicant Organization (Legal)
	Ipca Laboratories Ltd
	Primary Contact
	Secondary Contact
	Alternative Secondary Contact

On the Case record, click on the Document Submission tab.

The screenshot shows the ePQS Case page for PQ-FPP-2025-0046. The page has a blue header with the ePQS logo and a search bar. Below the header, there are tabs for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area displays case information for PQ-FPP-2025-0046, including Case Record Type (Mx FPP New Prequalification Application), Case Number (00030226), Status (Under Screening), Applicant Organization (Ipca (Corp)), and Date of Prequalification/Acceptance. Below this, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The Document Submission tab is highlighted with a red box.

Case Owner
ePQS Mx FPP Queue
Status
Under Screening
Reference Authority
Applicant Organization
Ipca (Corp)
Applicant Organization (Legal)
Ipca Laboratories Ltd
Applicant Primary Contact
Applicant Secondary Contact
Alternative Applicant Secondary Contact
EOI Number
Therapeutic Area(s)

This will create a short wizard to upload documents. The wizard functions in the same way as the document steps in the initial submission.



The assessment team will be notified of the uploaded documents by email.

9. Record monitoring.

Additional guidance on other features of the portal will be provided in separate documents. In the meantime, you can track the status of your applications, products, and activities by using the various list views available in the menu bar at the top of the portal's landing page.