

External Guidance - FPP Post-prequalification Change Application Wizard guidance Document Version Number: 1.0

1. Contents

1.	Contents1
2.	Scope
3.	Prerequisites
4.	Accessing the Portal 2
5.	Wizard steps3
4	.1 Wizard commencement
4	.2 Wizard Selection
	4.2.1 Subtype: eCTD-Baseline
4	.3 eCTD or non-eCTD7
4	.4 Entering application-specific wizard details7
6.	Document uploading10
5	.1 eCTD document upload10
5	.2 Common document upload steps
7.	Submitting the application
8.	Upon Submission15
7	.1 Notifications
9.	Saving as Draft and recommencing16
10.	Acceptance for assessment17
11.	Receiving and responding to questions17
1	0.1 Receiving requests for additional information17
1	0.2 Responding to requests for additional information18
12.	Record monitoring

2. Scope

This guidance covers the submission of an application for FPP Post-prequalification Change/Variation Application via the ePQS Portal Wizard. The guidance provides step-by-step instructions on how to use the ePQS Portal Application Wizard to create, submit, receive feedback, and respond to queries on the WHO ePQS portal regarding FPP Post-prequalification Change application.

3. Prerequisites

Applications wizards are accessed via the ePQS Portal –<u>https://who.my.site.com/ePQS/s/login/</u>. Therefore, access to the ePQS portal must be granted first. To seek registration, apply via the form on the Portal landing page above.

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."

4. Accessing the Portal

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

5. Wizard steps

4.1 Wizard commencement

ePQS Search.		Search	🐥 🙆 errottauron *
Home Organizations Cont	acts Activities Cases ePQS Products Ins	pections NRA CRP Agreements CRP Proc	luct Registrations More 🗸
Submit an application	Create Account or Contact	Edit an Account or Contact	Change a Record Contact
World Health Organization	World Health Organization	World Health Organization	World Health Organization
DMMONLY USED LISTS			
edicine Storage Conditions			
HO Vaccine Names		Vie	ew ePQS Registered Accounts
edicines Pharmaceutical Ingredients			
C Active Ingredients/Synergist Name			
CLm Generic Name (INN)			

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 from the portal as indicated in Figure 2.

4.2 Wizard Selection

Having passed the initial "Create a New Application screen", the system may prompt you to confirm the Applicant organization that is making the application. This occurs if you are a registered user that is associated with more than one Account.

More commonly, you will arrive on a screen requesting the nomination of the contacts for this application, as shown in Figure 3. The system will present any contact associated with this account for selection. Please note that, the contacts do not need to be ePQS portal users, although it is likely they are.

Organization & Contacts	Application Info	Product Details	Documents	Finalize
Choose Contact				
Choose Applicant Primary Contact Nominate a primary contact for this applic	cation who is an employee of ePQS Test .	Account 1 - NonStateActor, and also inc	dicate if there are other secondary peop	le involved.
* Primary Contact				
ePQS External Applicant 1				
Optionally Choose Secondary Contacts If needed you can optionally choose a seco	ndary and an alternative secondary con	tact, or leave the selection as "None-	⁰ ,	
Secondary Contact				
Secondary Contact None				
Secondary Contact None Alternative Secondary Contact Choice				
Secondary ContactNone Alternative Secondary Contact ChoiceNone				
Secondary ContactNone Alternative Secondary Contact ChoiceNone				

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Figure 3: As part of the preliminary application steps, Applicants will be asked to nominate contacts for the application, and if applicable the product.

You will then be prompted to select the product type for which you wish to submit an application, as shown in Figure 4.

ePQS Application Wizard	Application Info	Product Details	Documents	Finalize
Choose Product Type		Troddet Details	Jocuments	Thurst
elect the product area to narrow down t	he list of application types.			
Product Type Active Pharmaceutical Ingredient Ma Active Pharmaceutical Ingredient Ma 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 Lab	ster File wratory			
				Previous

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

On the next screen you will be offered a list of the specific application type and then application subtype relevant to the product 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 applic	cation types available.			
Application Type Prequalification Post-PQ Change Alternative Listing Emergency Use Listing (EUL) Expert Review Panel (ERP) New - Collaborative Registration Procedure - V Requalification	SRA NHO			
				Previous Next

Figure 5: Then you will be offered the application type to select.

ePQS Application Wizard			
Organization & Contacts Application Info	Product Details	Documents	Finalize
Choose Application Subtype			
Please enter the following additional information:			
*Application Subtype			
AN			:
AN			
eCTD-Baseline			
IN IN			
Major			
Minor			
SRA-IN			

Figure 6: Then you will be offered the application type and application sub-type to select.

Note: where grouped variations application is involved, the application sub-type should be consistent with the overall change severity (i.e highest severity/risk type).

The system will then display a preview of the application you are planning to create. By proceeding, a draft application record will be created in the 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 Mx FPP Post-PQ Change. This draft applicatio 4 Application Type: Post-PQ Change 5 Application Subtype: AN 5 Product Type: Finished Pharmaceutical Product 5 Organization: ePQS Test Account 1 - NonStateActor 6 Primary Contact: ePQS External Applicant 1	ion will be available in your List View of Cases.		
			Previous Next

Figure 7: The system both summarizes the application to be created and enables checks to confirm its correctness.

Home	Organizations	Contacts	Activities	Cases	ePQS Products	Inspections	NRA CRP Agreements	Application Wizard	l More ∨	
ePQS Application	Wizard									
Organization	& Contacts) Ap	plication Info		Produ	ict Details	Docum	ients	Finalize	
Continue Appl	ication									
A draft application ha	s been created.				•					
For reference the new	application has the	e case number	r PQC-FPP-20	24-0258.	You can view the dr	aft application d	etails by following the lin	ς.		
		_			-					Next
·			Abo	outHe	Contact Us	Drivacy Dolicy	Logal Disclaimor			

Figure 8: A draft application record has now been created in the system [Note the assigned application number highlighted by the red rectangle].

You may save the application as a Draft application at this time and recommencing later as per section 9. This record can now be located via the global search bar or in the case list view using the assigned application number as shown in Figure 9.

ePQS	PQC-FPP-2024-0254		Search	🌻 🙆 angaatan -
	Q "PQC-FPP-2024-0254" in ePQS r			luct Registrations More N
Cases Recently Viewed v	00026770 Case			
17 items • Updated a minute ago	Don't see it?	Ask the community		\$*) III * (
Case Number 🗸 🗸 🗸	ePQS Case ID 🗸 🗸	Case Record Type	×	Status
1 00026770	PQC-FPP-2024-0254	Mx FPP Post-PQ Change		Draft

	ePQS	PQC-FPP-2024-0254		Search 🐥 🙆 respectives				
	Home Organi	zations Contacts Activities Cases	ePQS Products Inspections NRA CRP Agreements	CRP Product Registrations More 🗸				
17 items	Cases Recently Viewed	Ŧ	Q. Search	h this list	✓ ○ ▼			
1.0	Case Number	✓ ePQS Case ID	✓ Case Record Type	✓ Status	~			
1	00026770	PQC-FPP-2024-0254	Mx FPP Post-PQ Change	Draft	•			
2	00020782	PQC-FFF-2024-0252	MX FPP Post-PQ Change	Under Screening				
3	00026704	PQ-FVP-2024-0026	Vx FVP New Prequalification Application	Under Screening	•			
4	00026761	PQC-FPP-2024-0251	Mx FPP Post-PQ Change	Draft	•			
5	00026721	New-APIMF-2024-0012	Mx APIMF Application	Under Assessment	•			
6	00026747	New-APIMF-2024-0012-InRq-01	Inspection Request	Pending				
7	00026746	PQC-APIMF-2024-0095	Mx API Post-PQ Change	Draft	•			
8	00026745	PQ-FVP-2024-0032	Vx FVP New Prequalification Application	Draft	•			

Figure 9: A draft application record can be located via the global search bar and in the "Case list view."

4.2.1 Subtype: eCTD-Baseline

One of the application sub-types available for selection, as shown in Figure 5, is eCTD-Baseline. This subtype allows applicants to convert the dossier format of a prequalified product from non-eCTD to eCTD. Select eCTD-Baseline at the step depicted in Figure 5 to convert an associated product from eCTD noncompliant to eCTD compliant.

4.3 eCTD or non-eCTD

ePQS Application Wizard	
Select Document Format SCID Non-eCTD	
	Previous Next

Figure 10: A decision is required if the dossier being filed is in eCTD or non-eCTD format

The decision to file in eCTD or non-eCTD affects the document uploading steps at the end of the wizard. The decision to file in eCTD or non-eCTD also affects the prequalified products (dossier format) that may be associated with the Post-PQ Change application. A Post-PQ Change application in eCTD format requires all associated products (dossier format) to be eCTD compliant and vice versa.

4.4 Entering application-specific wizard details

The field for "Current Document Version Number" Figure 11 below may not apply to your application. In which case just enter "X' and click Next.

Home	Organizations	Contacts	Activities	Cases	ePQS Products	Inspections	NRA CRP Agreements	CRP Product Registratior	ns More 🗸
QS Resume Wiza	ard								
× .	\rangle	Ap	plication Info		Produ	act Details	Docum	nents	Finalize
dditional App	lication Info				_				
uunionui ripp	incution inno								
rrent Document Versio	on Number								
									Next
			Abo	aut He	Contact Us	Drivagy Doligy	Logal Diselaimor		

Figure 11: Additional Application Information; "Current Document Version Number"

The next steps involve completion of FPP Post-prequalification change product-related information.

As indicated in Figure 12, you will be offered three options under the Add Change Information. Selecting the "Add product that is the subject of the application option" will enable you to add the change-related product(s) as shown in Figure 13. At least one product needs to be added. To do so, select the radio button and click Next

ePQS Application Wizard					
Organization & Contacts	> ~	\rangle \checkmark	Post-PQ Changes	Documents	Finalize
Add Change Information	being changed, and also record the cl	lange types that apply			
Either Add products that are the subject of p Add one or more pieces of informatio No more at this time	oost-prequalification changes n about the change, including the typ	e			
					Next

Figure 12: Select "Add products that are subject to post-prequalification changes" to add the change-related product(s)

The system will provide a list of prequalified products of the applicant organization for selection. The list will display either eCTD or non-eCTD compliant products, depending on whether an eCTD or non-eCTD document submission format is selected (as shown in Figure 9).

ePOS Application	Wizard	Contacto			mopeetiono	The chain of the contents	Tipplication withard	
Organization & C	ontacts	~	\rangle	~	Post-Po	Q Changes	Documents	Finalize
Select Product	S							
Choose a product that	is the subject of a output of a state of a state of Prequalified of Prequalified of the state	c hange r Acceptable a	are available.					
only those with a state								
* Product(s): To select m	nultiple items, hold o	lown the Ctrl (PC) or Command (Mac) key				
*Product(s): To select m	ultiple items, hold o	lown the Ctrl (PC) or Command (Mac) key				
*Product(s): To select m	nultiple items, hold o	lown the Ctrl (PC) or Command (Mac) key				:
* Product(s): To select n	nultiple items, hold o	lown the Ctrl ()	PC) or Command (Mac) key				Previous Next

Figure 13: Select the change product(s) from the drop-down product list which records are linked to the applicant's account.

Note: once a product is added as shown in Figure 13, the Wizard returns to the selections in figure 12, therefore when multiple products are involved, the selection shown in Figure 12 and 13 can be repeated until all the products are added, then proceed to add information about the change.

ePQS Application Wizard					
Organization & Contacts	✓	\rangle \checkmark	Post-PQ Changes	Documents	Finalize
Add Change Information	e being changed, and also record the cha	nge types that apply			
Either Add products that are the subject of Add one or more pieces of informati No more at this time	post-prequalification changes on about the change, including the type				
					Next

Figure 14: Select "Add one or more pieces of information about the change" to add the change type.

ePQS Application Wizard					
Organization & Contacts	~	> ~	Post-PQ Changes	Documents	Finalize
Add Change Info					
* Change Type					
Var eCTD-Baseline - Vmin					\$
					Previous Next

Figure 15: Select the change type from the drop-down list of variation/change types (AN, IN, Vmin, Vmaj or SRA-IN)

ePQS Application Wizard					
Organization & Contacts	> ~	\rangle \checkmark	Post-PQ Changes	Documents	Finalize
Add Change Info					
Change Description					
					Previous Next



Note: once the description of the selected change type is added as shown in Figure 16, the Wizard returns to the selections in Figure 12. Therefore, if a grouped variation application is involved, the selections shown in Figures 14 and 15 and change description (Figure 16) can be repeated until all the changes are added. Then proceed to add the overall change information. Similarly, additionally affect products can be added repeatedly as necessary.

To exit the Add Change Information section and proceed to "add the overall change information", select the "No more at this time" (Figure 17) below and click Next.

170077013	Organizations	Contacts	Activities C	cases ePQS Products	Inspections	NRA CRP Agreements	Application Wizard	More V
QS Application	Wizard							
Organization & C	ontacts	4	\rightarrow	× .	Post	PQ Changes	Documents	Finalize
dd Change In	formation							
au enunge m								
her	e products that are	being changed	, and also recor	d the change types that.	thbia			
Add products that	are the subject of p	ost-prequalific	ation changes					
Add one or more p No more at this tin	leces of informatio ne	n about the cha	inge, including	the type				
								Next

Figure 17: Select "no more at this time option' to exit the "Add Change Information" and proceed to add the overall description of the change(s).

Next, you will be asked to add an overall description of the change application.

ePQS Application Wizard				
Organization & Contacts	> ~	Post-PQ Changes	Documents	Finalize
Add Overall Change Info				
Enter the following before finalising the	e application			
* Description of Changes Requested				
xxxxxxxxx				
				6
				Next

Figure 18: Add the description of all the requested change(s).

Please enter a concise summary of the change application, noting that a full description should be present in application document

After adding the Overall Change Information (description of changes requested), click Next and proceed to application document upload step (Figure 19).

6. Document uploading.

5.1 eCTD document upload

	Home	Organizations	Contacts	Activities	Cases	ePQS Products	Inspections	NRA CRP Agreements	CRP Product Registrations	More 🗸
ePQS Res	sume Wiz	ard								
You are upl	oading docu	ments to Case#PQ	C-FPP-2024-	0261						
										Previous Next
										I I CYIOUS NEAR
				Abo	ut Us	Contact Us	Privacy Policy	Legal Disclaimer		

Figure 19: Initial document upload screen

If submission in eCTD format is intended, the system will display information that the applicant should use to complete the module 1 envelope for their dossier. The wizard may be paused at this stage and resumed once the dossier sequence file has been published.

ePQS Application Wizard				
eCTD Submission Module 1 Informat	tion			
Below are the Module 1 values requir Salesforce Case Id : 00028353 Application Type : Post-PQ Change Application SubType : eCTD-Baseline Contact-email : avuir Organization Name :	red for your eCTD submission envelop	pe. You can select and copy these val	ues before proceeding to the next ste	p to upload your zip file.
Product ID V	Product Type 🗸 🗸	Product SubType V	Product Assessment Procedure 🗸 🗸	Product Name 🗸
	Finished Pharmaceutical Product	Finished Pharmaceutical Product	Prequalification - Full	Artesunate Powder for solution for injection 120 mg
	Finished Pharmaceutical Product	Finished Pharmaceutical Product	Prequalification - Full	Zinc (sulfate) Tablet, Dispersible 20mg
				Previous Next

Figure 20: Information is provided for the applicant to complete their module 1 envelope information

Next, the system displays the exact name (as shown in Figure 21) the submitted file should be named. The dossier for each application submission should be formatted in "Zip" file format.

ePQS Application 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):	
2 of 2 items	
FileNames:	~
PQC-FPP-2025-0024	
PQC-FPP-2025-0024_DI011	
	Previous Next

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Figure 21: The system provides the exact name to be used for the uploaded zip file

5.2 Common document upload steps

	Home	Organizations	Contacts	Activities	Canon	oPQS Products	Inspections	NRA CRP Ag	reements	CRP Product Rep	distrations	More ~
PQS Res	ume Wiz	ard										
Organii	ration & Co	mtacts	~	×		×.	>	×	>	Documents	\rightarrow	Finalize
Upload I	Docum	ents										
lease attact	s all suppo	rting documentation	on for your ap	plication belo	w. Either	drag-and-drop or a	elect one or mor	re files from you	r deaktop, a	ind then click Uploa	d to attach th	iem to this application.
fou can revi	ew the fold	ters for submission	in the next p	age. There you	i can also	rename, tag or tem	ove documents	You can return	to this screet	en to upload additio	nal documen	ts as part of this
Vhen finish	ed, click N	ext.										
							<u> </u>					
						Drag and dro	p mes and folder					
						Browsh your this	ALL OF SUMMA PLAN					
												trees and R. S. Spatian and

Figure 22: document upload screen

On the document upload screen, you can upload single files, multiple files, or folders. Click on **Next** once these are selected. You will be asked to confirm upload; you can also cancel and go back to the previous screen (Figure 23)

Upload F	ation a contacts		<u>></u>		>			Documents	\rightarrow	Finalize
opioau L	ocuments									
Please attach	all supporting documenta	tion for your app	lication below. Eith	ner drag-and-drop or s	elect one or mo	re files from your d	esktop, and	then click Uplo	ad to attach th	em to this application.
You can revie	w the folders for submissi	on in the next pa	ge. There you can a	lso rename, tag or rem	iove documents	You can return to	this screen t	o upload additie	onal document	s as part of this
suomission p	rocess, it you save the wa	nu as a dimit, m	en you recommen	e me mane you min o	are the opportu	intry to uprodu dita	terren docu	ments once ago	in berore man	submission.
When finishe	d, click Next.									
The Acc	D. 2024. Day. 2. Slides tio									~
0.0										~
									Ca	ncel Upload

Figure 23: Confirmation of the upload is required

	Contacts	~	<u> </u>	~	>	~	5	Documents		Finalize
Upload Docur	nents									
Please attach all supp	porting documentat	ion for your ap	plication below. I	lither drag-and-drop o	r select one or mo	re files from yo	ur desktop,	and then click Uple	oad to attach th	to this application.
You can review the fo	olders for submissio	n in the next p	age. There you ca	n also rename, tag or r	emove documents	. You can return	to this scre	en to upload additi	ional documen	ts as part of this
submission process.	If you save the wiza	rd as a draft, w	hen you recomm	ence the wizard you wil	I have the opporti	inity to upload a	and review d	ocuments once aga	ain before fina	submission.
When finished, click	Next.									
					0					
					~					
				Success! Your f Select More File	iles have been uplo es or Select More F	aded. olders				
									0	Upload

Figure 24: If the documents have uploaded successfully a confirmation screen will appear.

Home	Organizations	Contacts	Activities	Cases	ePQS Products	Inspections	NRA CRP Agreements	CRP Product Registrations	More ~
S Resume Wi	zard								
Organization & C	ontacts	~	X		×	\rangle	~ >	Documents	Finalize
ument Rev	iew								
e review the docu	ments and folders y	ou intend to	upload. You m	ay naviga	te through the fold	er structure, rer	aming and deleting folders	as necessary,	
ment type meta-	data may also be ad	led to individ	lual document	s by open	ng these document	ts and adding th	e metadata value via the do	cument menu that appears.	
XX Search	files and folders								
024-09-30-15:29									
Name					Modi	fied			Size
AGDD-2024	Day-2-Slides.zip				Toda	y by WHO_JWT			4.06 MB
									Preview
									Delete
									Download
									Rename
									Previous Next

Figure 25: document review screen where the uploaded files can be adjusted if necessary.

Before moving to submission, you will be asked to review the files intended to be submitted. You can delete or rename the documents. You can also navigate through the uploaded folder structure to make more granular changes.

7. Submitting the application



Figure 26: Final screen before submitting the application

The final screen before submitting the application has three options. Save as a draft (see section 8), submitting, or discarding the application. If you discard the application, the application and product record will no longer be visible in the application and product lists. It can still be found via the global search bar. Periodically, the ePQS Admin officer will delete these records.

If submitting, click on the "Yes" option in Figure 26 and then click on Next.

- Organina	tion & Contacts		\rangle	\checkmark	· > · ·	~ >	~		Finalize
Applicati	on Submitted								
The applica	tion wizard has no	w finished - clicl	k on the Finish b	utton to be redi	rected to the de	tailed page of your s	submitted applica	tion.	
11						1.0. ,	11		





Figure 28: Currently there is a bug once you press finish. Simply refresh the page to continue in the portal

8. Upon Submission

Several changes are made to the application and product record once submitted. First, the ownership of the record changes to an internal assessment queue, meaning the record is no longer editable (see Figure 29). Second, the status of the application changes from Draft to Under Screening. Finally, the Date Application Submitted is entered by the system.

PQC-FPP-2024-0261	+ Pollow Edit Resume Application	(wizard New Component(s)
Case Record Type Case Number Status Applicant Mx FPP Post-PQ Change 00026881 Under Screening PQT Pha	Organization Date of Prequalification/Accepta rmaceuticals Inc (Corp)	ince
Details Related Activities Preview Document Document Download D	ocument Submission	
✓ General Details		
ePOS Case ID	Case Owner	
PQC-FPP-2024-0261	ePOS Mx FPP Oueue	1
WHO Application Number	status Indar Seraaning	
Product Type	And Area and Are	
Finished Pharmaceutical Product	PQT Pharmaceuticals Inc (Corp)	
Application Type	Applicant Organization (Legal)	
Post-PQ Change	PQT Pharmaceuticals Inc	
Application Subtype	Applicant Primary Contact	
00	Ambicant Secondary Contact	
	apprenti accounty source	
	Alternative Applicant Secondary Contact	
Change Details		
Overall Change Severity Rating Vmin		
Vanna		

Figure 29: Record ownership and status will change, and date the application is submitted is reflected in the system, once submitted.

If the submission is in eCTD format, the eCTD compliance field on the application record will be updated initially to Tentative. If eCTD validation step is successful, the eCTD Compliance will then be set to Yes. If the eCTD validation is unsuccessful, the eCTD Compliance value will remain as Tentative.

The application and product will now remain visible in the portal for on-going review.

7.1 Notifications

An email notification will be sent to the primary contact of the application to confirm the submission. Please note that this email only confirms the successful submission of the application, not its acceptance for assessment. Subsequently, an email acknowledging receipt of the application for assessment will be sent from [prequalvariation@who.int] following satisfactory screening of the application. If the submission is in eCTD format, an additional email notification will be received within approximately 30 minutes informing the applicant of the validation outcome of the submitted sequence. The eCTD validation report is placed in the Correspondence (External) folder of the application record as shown in Figure 30.

PQC-APIMF-2024-0	144		(+ Follow	Edit	Resume Application	Wizard	New Component(s)	
Case Record Type Mx API Post-PQ Change	Case Number 00027971	Status Under Screening	Applicant Organization eCTD Mx Account - ZM	Date of	Prequalifi	cation/Acceptance	Case 0 ePQS	wner Mx API Queue 🔊	
Details Related Activities	Preview Doo	ument Document Do	wnload Document Subm	ission					
PQC-APIMF-2024-0144									
Name			Modified					Size	
Correspondence (External)			Thu Dec 19 2024					226.88 KB	

Figure 30: eCTD validation reports are placed in the Correspondence (External) folder of the application

9. Saving as Draft and recommencing

Draft applications can be restarted from the application record by selecting the Resume Application Wizard button on the specific draft application.

Home Organizations Contacts	Activities Cases e	PQS Products 1	inspections i	NKA CRP Agree	iments	CRP Pro	uct Registrat	nons	more ~		
Case PQC-FPP-2024-0261			+	Follow E	lit Re	sume App	ication Wizard	d Ne	w compo	nent(s)	¥
Tase Record Type Case Number Mx FPP Post-PQ Change 00026881	Status Under Screening	Applicant Organ PQT Pharmace	uzation euticals Inc (Co	Da orp)	te of Prequ	alification/	Acceptance				
ails Related Activities Preview Docum	nent Document Dov	vnload Docum	nent Submissi	ion							
General Details											
1000 m											
PQS Case ID			Case Owner								
PQS Case ID PQC-FPP-2024-0261			Case Owner ePQS Mx FPP Q	Jueue							È
VQC-FPP-2024-0261 VHO Application Number QC-FPP-2024-0261			Case Owner ePQS Mx FPP Q Status Under Screenin	Queue							£
AQS Case ID QC-FPP-2024-0261 VRO Application Number QC-FPP-2024-0261 roduct Type		>	Case Owner ePQS Mx FPP Q Status Under Screenin Applicant Organ	Queue ng nization							2
PROCEPTP-2024-0261 WHO Application Number PROC-FPP-2024-0261 Product Type Finished Pharmaceutical Product			Case Owner ePQS Mx FPP Q Status Under Screenin Applicant Organ PQT Pharmace	Queue ng nization euticals Inc (Corr	D)						2
VAUSCASE ID VAUSCASE ID VAUSCA		>	Case Owner ePQS Mx FPP Q Status Under Screenin Applicant Organ PQT Pharmace Applicant Organ	Queue ng nization uticals Inc (Corr nization (Legal)))						2
PROCERED 2024-0261 WHO Application Number PQC-FPP-2024-0261 Product Type Enished Pharmaceutical Product Application Type Post-PQ Change			Case Owner ePQS Mx FPP Q Status Under Screenin Applicant Organ PQT Pharmace Applicant Organ PQT Pharmace	Queue ng nization euticals Inc (Corr nization (Legal) uticals Inc	N)						£ /
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✓ Change Details

Figure 31: Select the resume application Wizard button to re-commence the application wizard (see also figure 9)

The application wizard when restarted commences from the next applicable section.

NOTE: There is a bug in the wizard currently. This means that upon resumption the user is taken directly to the document upload section. Please avoid closing the wizard before reaching the document upload steps. If this occurs for any reasons, please reach out to ePQS@who.int for assistance.

Should the application stay in draft for more than 60 days, an email reminder will be sent to the application's primary contact.

10. Acceptance for assessment

If the screening is satisfactory, the medicines prequalification team will accept the application for assessment. This results in the change in the status of the Application record to Under Assessment.

Subsequently, you will receive an acknowledgement email from the medicines prequalification team (PQTm) via <u>prequalvariation@who.int</u>, acknowledging the receipt of the application of the application in case of IN, Vmin and Vmaj subtypes of variation. This is usually accomplished within seven (7) days of receipt of your submission by the team.

This ends the initial steps in the wizard and initial application process.

11. Receiving and responding to questions

Receiving queries and uploading documents in response to the screening or assessment queries occur in the same manner.

10.1 Receiving requests for additional information

The application submitted is next reviewed internally to determine if it meets technical and procedural requirements.

In case further information is required, you will be contacted by the Medicines Prequalification Team (PQTm) by email or a letter.

In addition, you will notice that an Activity has been opened in the name of the primary contact (Figure 32). And, you will have been sent an email alerting you to this (Figure 33).



Figure 32: Outstanding task(s) could be accessed via the activity list

Please note that the activity described below has been assign to you.

- Activity Name: Request for Information (Screening)
- Component case Type:
- Component Case:
- Case number: 00026722
 WHO Product ID: P-12650

Should you require further information please log into ePQS, If you are unable to do so or should not be receiving these emails, please contact <u>contactepgs@who.int</u>

Figure 33: When an activity is assigned, an accompanying email is also sent

If a letter has been sent to you, a copy of this letter can be located in the Correspondence (External folder), which is accessible via the application record as indicated in Figure 34.

PQC-FPP-2024-03	17		(+ Follow Edit	Resume Application	on Wizard	New Component(s)	*
Case Record Type Mx FPP Post-PQ Change	Case Number 00027375	Status Under Assessment	Applicant Organization Ipca (Corp)	Date of Prequalific	ation/Acceptance	Case Ov	vner ti Ra 🔊	
tails Related Activitie	Preview Doc	ument Docement Down	nload Document Subm	ission				_
Search) files and folde	(%).							
PQC-FPP-2024-0317							(a	12
PQC-FPP-2024-0317	_		Modified				Size	

Figure 34 Formal correspondence is located in the applications external Correspondence folder. It can be previewed and downloaded.

10.2 Responding to requests for additional information

To upload documents in response to questions raised, proceed to the application and select the document submission tab.

Description Case PQC-FPP-2024-03	17			+ Follow	Edit	Resume Application Wizard	New Component(s)	•
Case Record Type Mx FPP Post-PQ Change	Case Number 00027375	Status Under Assessment	Applicant Organization	Date of F	requalific	ation/Acceptance Case O	wner	
Details Related Activitie	es Preview Docu	iment Document Down	lload Document Subm	nission				
Case Submission Wizard								
You can not upload document to	this case as it is in Dr	aft status.						
							Fin	ish
		About Us Cor	ntact Us Privacy Policy	/ Legal Disc	laimer			

Abbut 03 Contact 03 Privacy Poncy Degar Discianner

Figure 35: Documents can be uploaded via the application record, using the Document submission tab.

This initiates a short wizard to enable documents upload. The wizard functions in the same way as the document steps in the initial wizard. Note, like initial submission information, uploaded information cannot be seen once submitted.

In addition to any correspondence you might undertake with the assessment team, you can also signal the uploading of your response by changing the status of the activity to "actioned" as indicated in Figure 36.

✓ Information		
Related To (Case) 00027375		
Related To (Inspection)	Owner	
	Common Co	
Activity Name	Time Assignment	
Request for Information (Screening)	Manufacturer	
Due Date	- Status	2
	Actioned	Ŧ
Start Date	Activity Outcome	
08/10/2024		
End Date	Activity Phase	
	Under Screening	
	Response Date -	
✓ Case Information		
Case Record Type	Component Type	
Mx FPP Post-PQ Change	This field is calculated upon save	
This field is calculated upon save		
WHO Product ID		
This field is calculated upon save		
✓ System Information		
Created By	Last Modified By	
Vosaf 19815, 08/10/2024, 16:19	Yusuf IDRIS, 08/10/2024, 16:19	
	Record Type	
	ePQS Workflow Task	

Figure 36: By changing the status of the pending activity to Action, this signals to the assessment team a response has been submitted.

Upon responding to the request for additional data on the portal, you should also send an email to <u>FPPassessment@who.int</u> notifying the team of your response to the request for additional information. Subsequently, an email confirming the successful upload of your documents to the ePQS portal will be sent to you from <u>FPPassessment@who.int</u>.

Once your response has been reviewed, and assuming this is a valid response, then assessment team will change the status and outcome, and enter the end date as indicated in Figure 37.

External Activity EA-021904		Edit Change Owner
etails Related		
✓ Comments		
Comments		
< Information		
Related To (Case)		
00027375		
Related To (Inspection)	Owner	
		21
Activity Name	Time Assignment	
Screening of Application	WHO	
Due Date	Completed	a
Start Date	Activity Outcome :	
08/10/2024	Accepted	
End Date	Activity Ubase	
08/10/2024	Under Screening	
	Response Date	
 Case Information 		
Case Record Type Mx FPP Post-PQ Change	Component Type	
WHO Product ID		

Figure 37 Once the response is reviewed the activity will be further updated

This completes the response to a request for additional information.

12. Record monitoring.

Further guidance on other aspects of the portal will be provided in separate documents, but you can monitor the status of your applications, product and activities using the various list views available from the menu bar at the top of the portal landing page.