World Health Organization

External Guidance – APIMF Procedure Application Wizard guidance

Document Version Number: 1.2

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1. Scope

This guidance covers the submission of an application for the Active Pharmaceutical Ingredient Master File (APIMF) Procedure via the ePQS Portal Wizard.

2. Prerequisites

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

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 if 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.

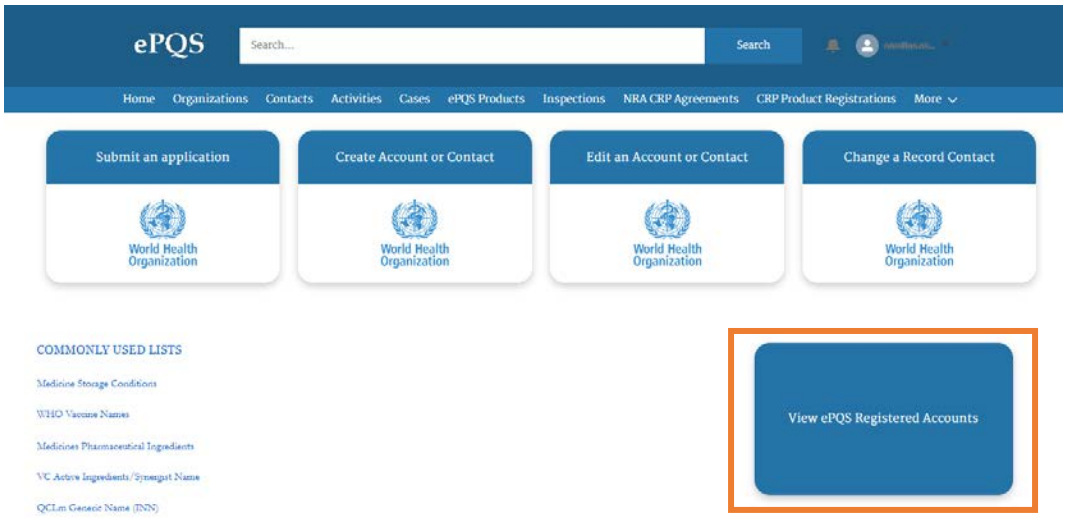

Figure 1: The existence of an Account within the ePQS system can be determined by selecting the indicate - "View ePQS Registered Accounts"

3. Accessing the Portal

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

4. Wizard steps

4.1. Wizard commencement

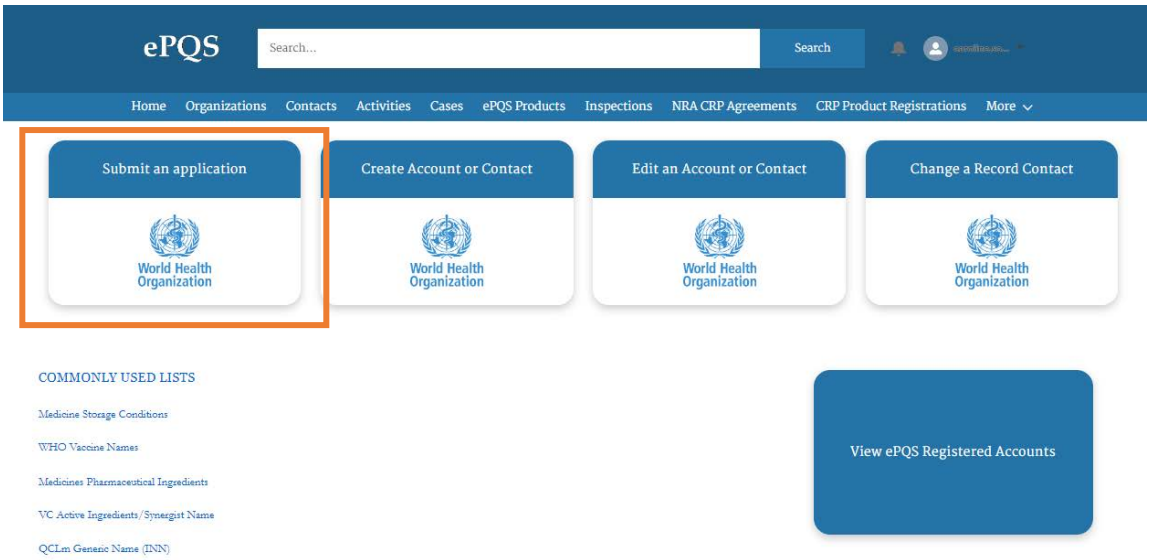

Figure 2: Commence the application process by selecting the Submit an Application tile

An application can be initiated by selecting the *Submit an Application* tile 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 directly on a screen requesting the nomination of the contacts for this application, figure 3. The system will offer for selection, any contact associated with this account.

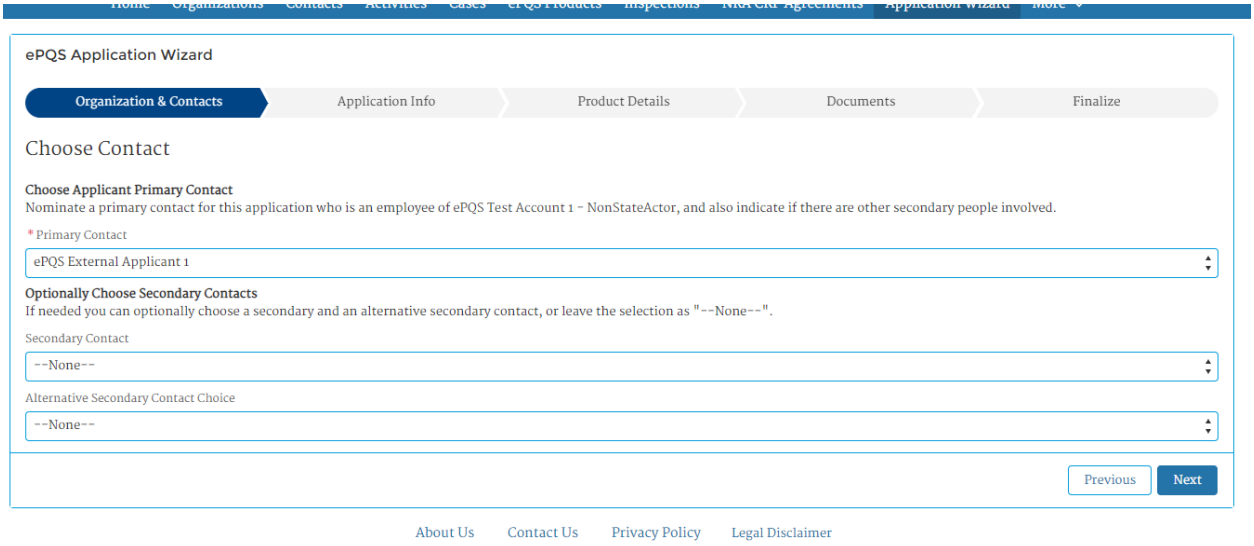

Figure 3: As part of the preliminary application steps, Applicants will be asked to nominate contacts for the application, and if applicable the product.

You will then be prompted to select the product type that you wish to lodge an application for.

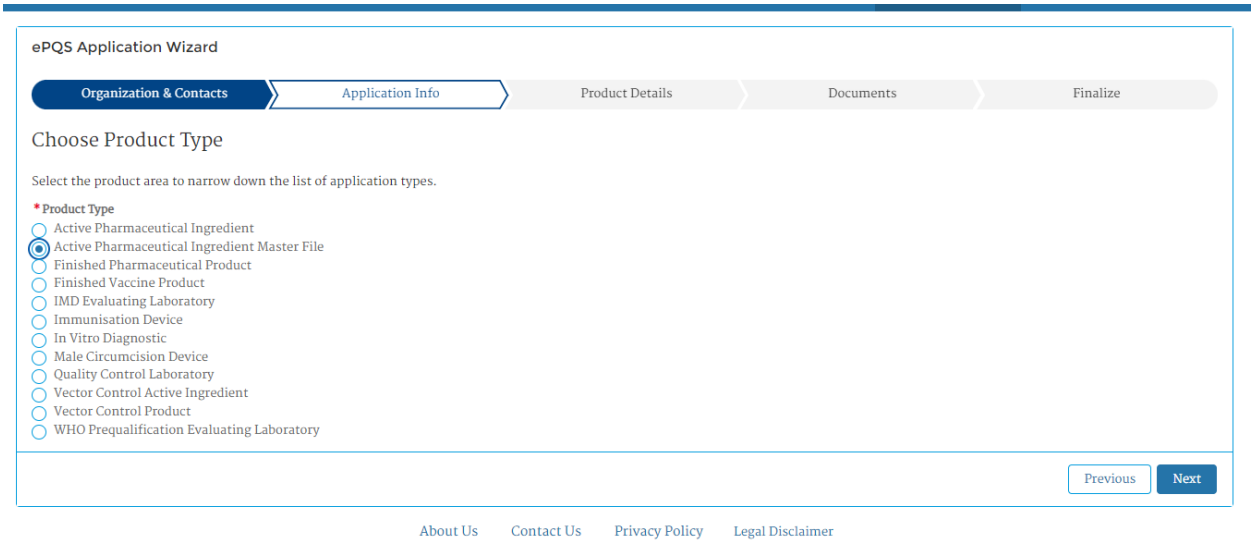

Figure 4: You must first select the associated product type, before selecting the application type.

PLEASE ENSURE YOU CHOOSE THE CORRECT OPTION. Choosing Active Pharmaceutical Ingredient Master File" means you will be offered to file an APIMF procedure application or an Amendment application. Choosing "Active Pharmaceutical Ingredient" means you will be offered to file an API Prequalification application.

On the next screen you will be offered a list of the specific application type(s) and then application subtype(s) (if this is relevant) relevant to the product type (figure 5).

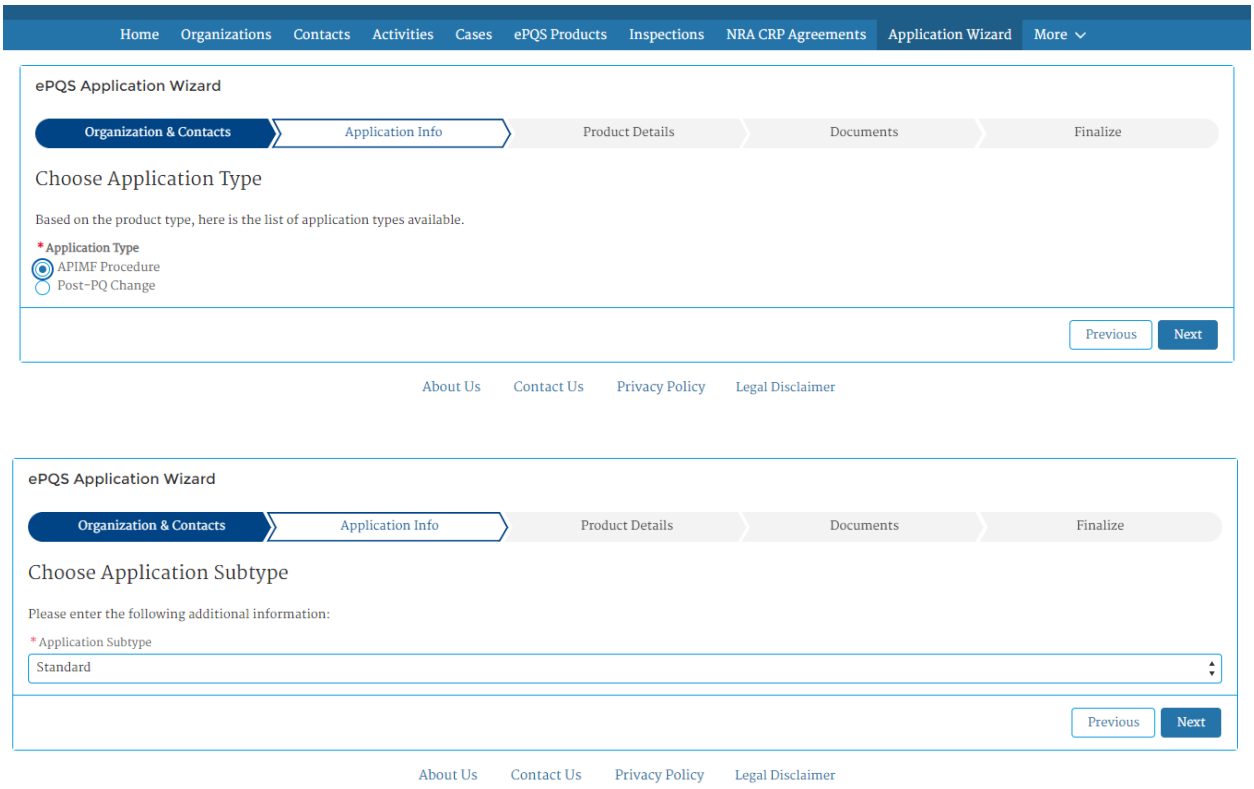

Figure 5: Then you will asked to select application type and sometimes application sub-type.

The system will then playback to you the application you are planning to create. By proceeding, the system will create a draft application record in the system.

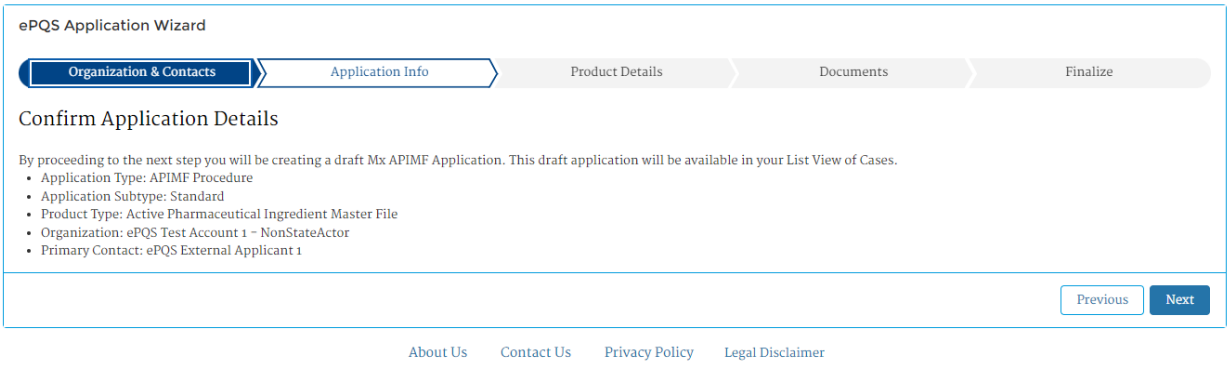

Figure 6: The system summarizes the application that is to be created.

Figure 7: A draft application record has now been created in the system.

This record can now also be located via the global search bar or in the case list view.

If the application sub-type you selected was Abridged, you will be asked to indicate the reference Authority. A picklist of options will be provided for selection.

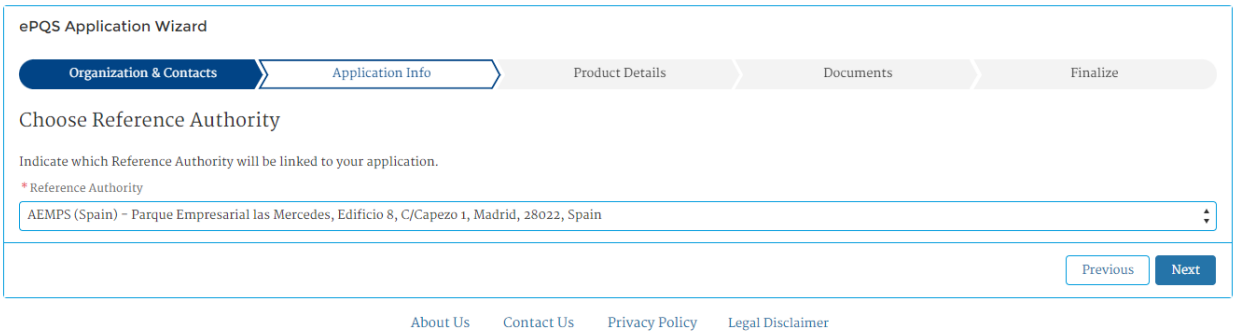

Figure 8: If an Abridged application was selected the applicant will be asked to select the Reference Authority.

4.3. eCTD or non-eCTD

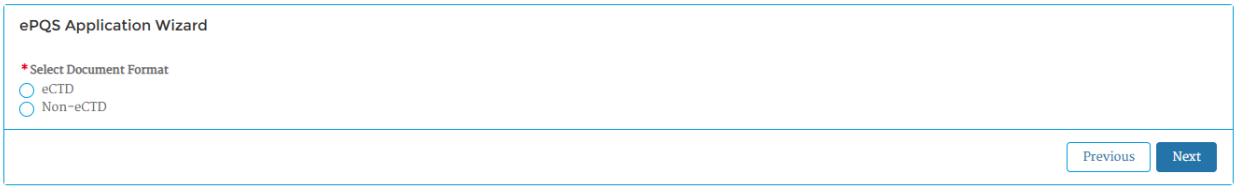

Figure 9: A decision is required if the dossier being filed is in eCTD or non-eCTD format.

The decision to file in eCTD or non-eCTD affects the document uploading steps at the end of the wizard.

4.4. Entering application-specific wizard details

For the APIMF application wizard, the next steps involve completion of APIMF product-related information.

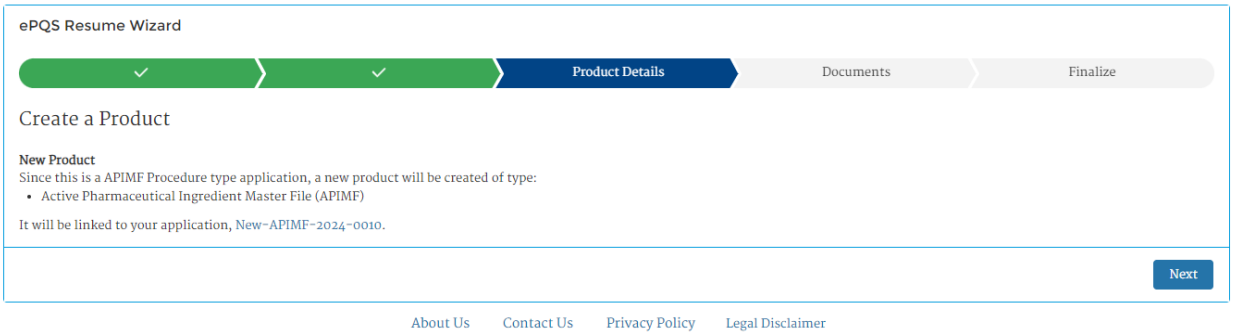

Figure 10: As a next step in the APIMF application wizard, an APIMF Product record is created.

As indicated in figure 11, you will be asked to add the active pharmaceutical Ingredient. Note, that once the first two letters of the API are entered, the system will begin to offer options for selection.

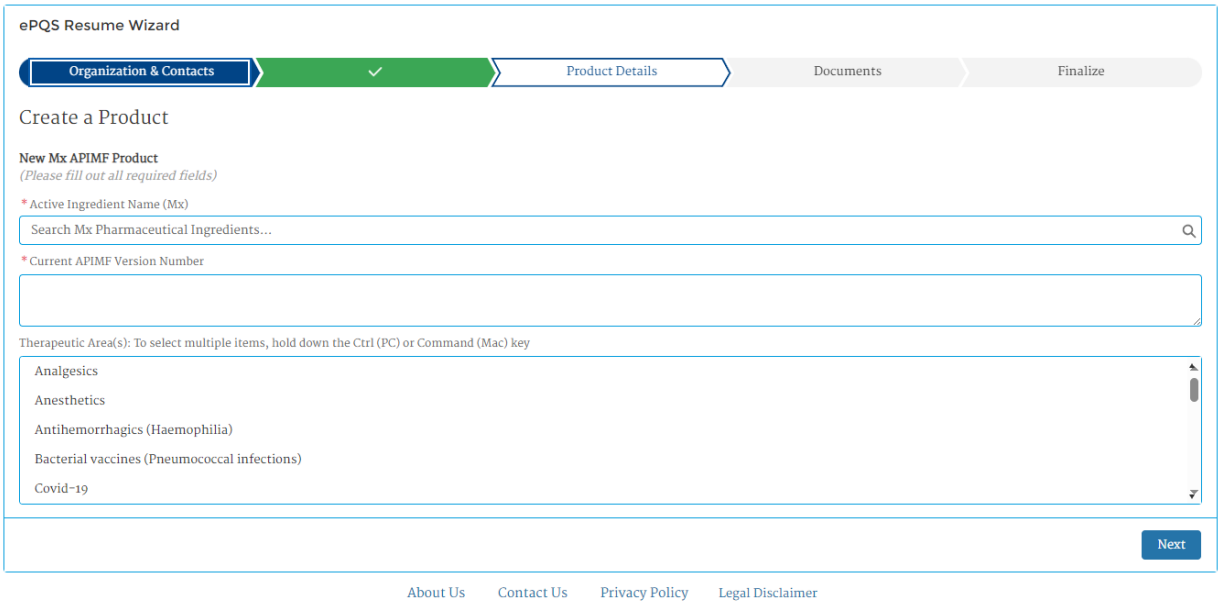

Figure 11: Information relating to the API, version number, and relevant therapeutic area should next be entered.

You will also be asked to enter the APIMF version number for the submission, and to select one or more therapeutic areas the API pertains to.

On the next screen, figure 12, you have the opportunity to go back to correct the entered information, by selecting “previous”.

Figure 12: By selecting the previous button you can correct the information entered in the previous screen.

By selecting Next, an associated APIMF product record is then created as per figure 13.

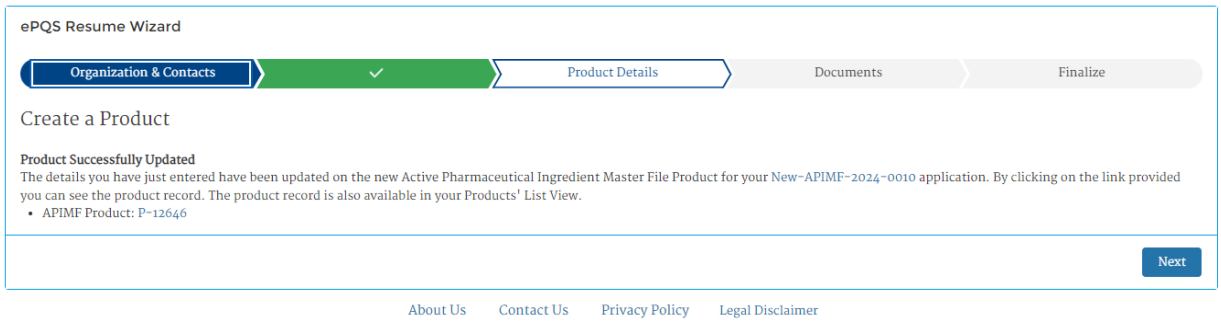

Figure 13: A new APIMF product record is created.

4.5. Product site creation

Once the Product record is created, you are then offered the opportunity to create product site records for the sites undertaking various activities. It is expected that every product must have at least one manufacturing site. To do so, select the Product site radio button and press Next (see figure 14). You will return to this screen eventually in case you need to create another product site.

For APIMF product records, it is required to create product site records for:

- all sites of API manufacture;
- all intermediate manufacturing sites that are not also API manufacturing sites; and
- any micronisation sites if they are not also API sites of manufacture.

Figure 14: Every APIMF product record must have at least one Product site record

The first step in the product site creation is to identify the Account/Organization representing the site. Enter at least the first three letters of the Account into the Site search field and press next. On the next screen (figure 15), the system will offer to you available accounts within the system matching the entry criteria, to choose from.

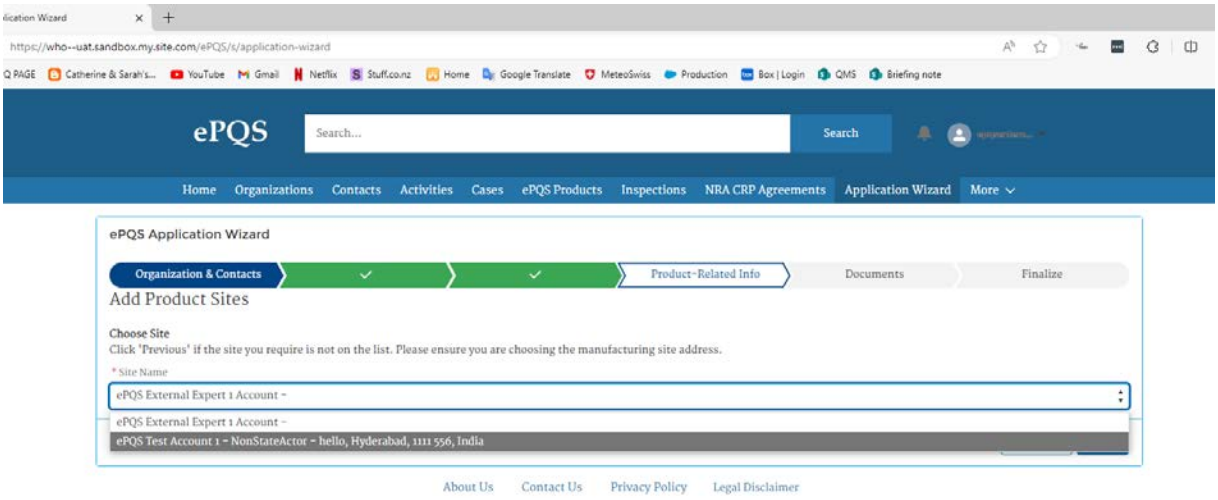

Figure 15: Based on the information entered into the site search field the system returns all accounts matching this name.

As mention in *Section 2 – Prerequisites*, a list of sites is available for review before commencing. If the site is new to the system, the applicant will need to request creation of the Account before commencing the application. It is also possible to leave the current application and recommence this later. See section 8.

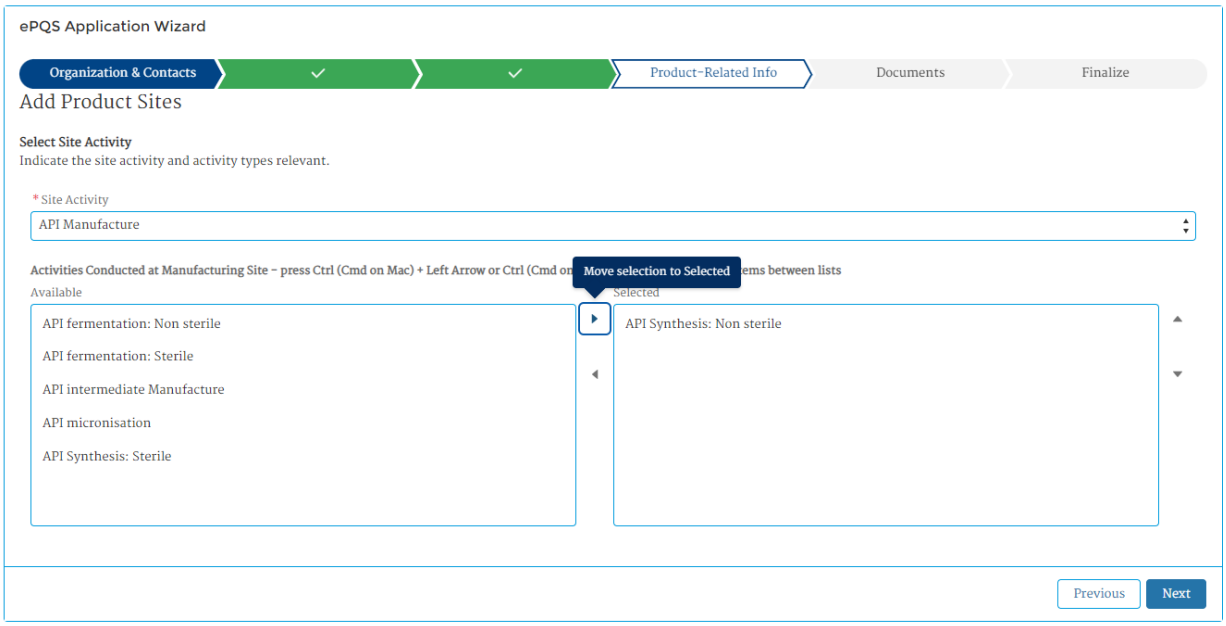

Figure 16: Next, indicate what activity the site is undertaking.

Having located and assigned the correct Account, you will then be asked to complete the type of activity that occurs at this site.

If intermediate manufacture is selected as an activity then you will be asked to enter the name of the intermediate.

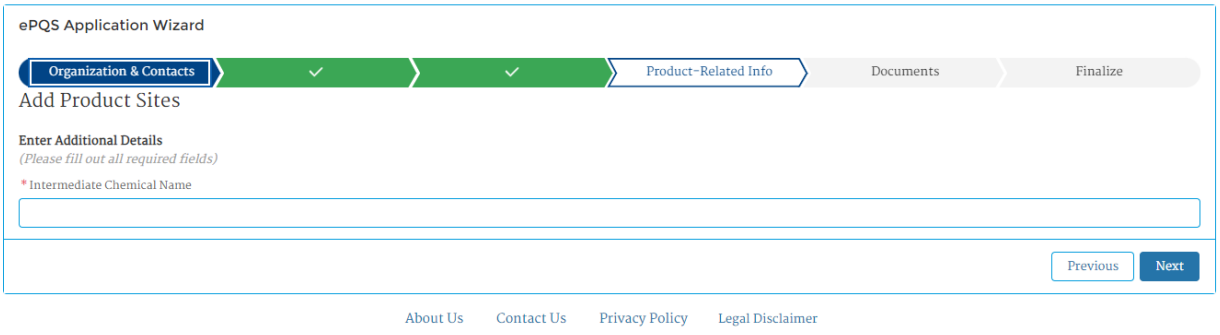

Figure 17: If the intermediate manufacture is selected as an activity then you will be asked to enter the name of the intermediate.

As indicated in Figure 19 the system will confirm the details for the product site record. Press next to create the record, or Previous to return for corrections.

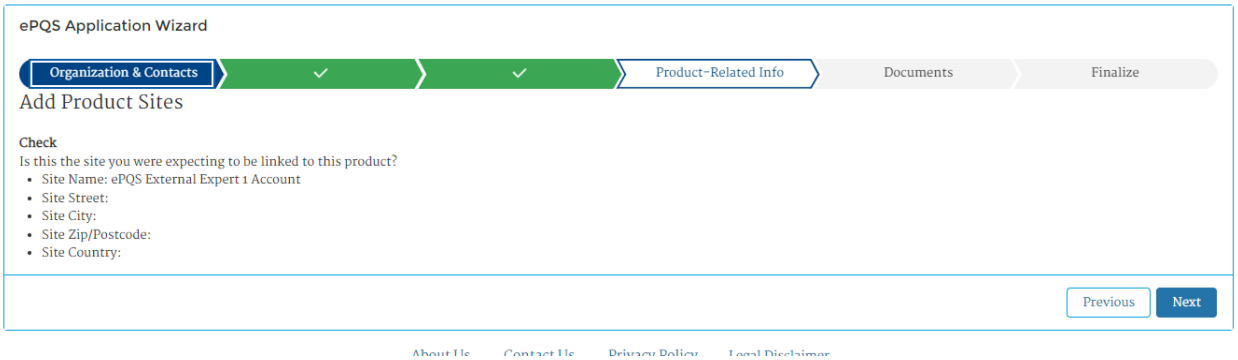

Figure 18: Press Next to confirm the details for the product site record and create the record.

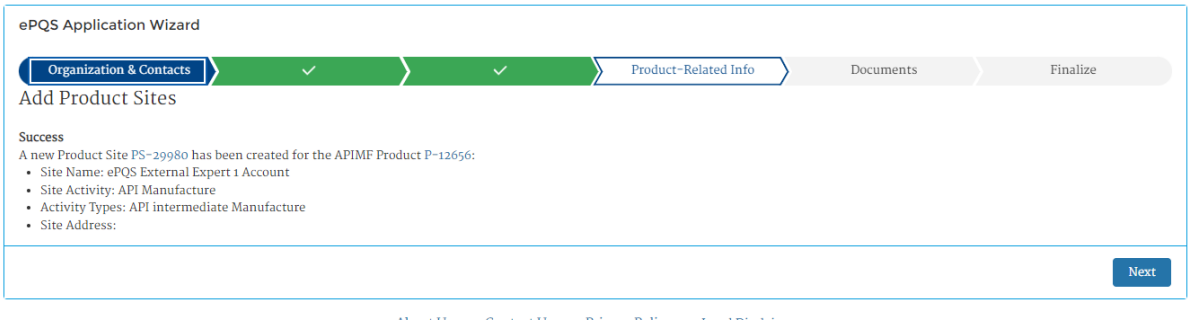

Figure 19: Confirmation of the sites creation should follow.

You will be informed that the Product site has now been created. This is also viewable on the product record, in the record's related list (figure 20)

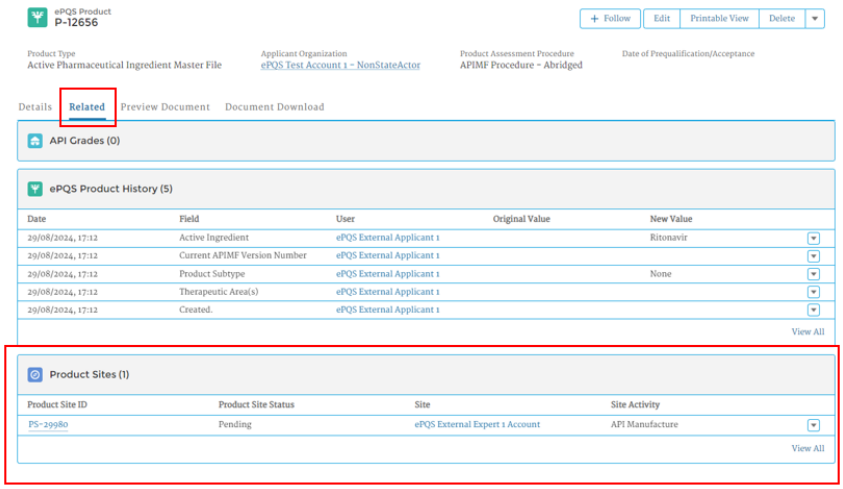

Figure 20: Once the site is created it can be seen on the draft Product record from the "related Tab.

You will then loop back to a screen asking if you wish to create another product site record. If all sites have been created select "I don't want to add any more…" to move to the document upload phase as indicated is figure 21.

Figure 21: You can move to the document upload phase by selecting "I do not want to…"

5. Document uploading

Figure 22: Initial document upload screen

5.1. eCTD document upload

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

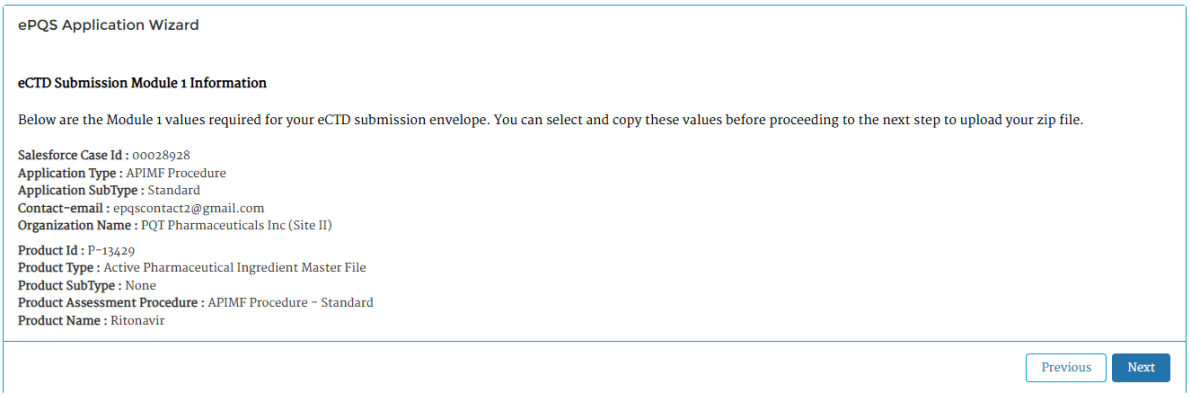

Figure 23: Information is provided for the applicant to complete their Module 1 Envelope information

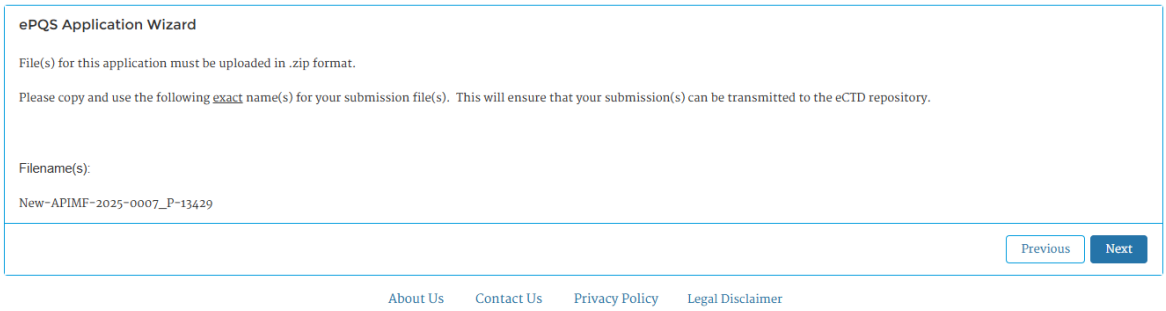

Figure 24: The systems provides the exact name to be used for the uploaded zip file

Next, the system displays the exact name the submitted file should be named. The dossier for a product should be formatted in a single ".zip" file.

5.2. Common document upload steps

The next steps are common to both eCTD and non-eCTD uploads.

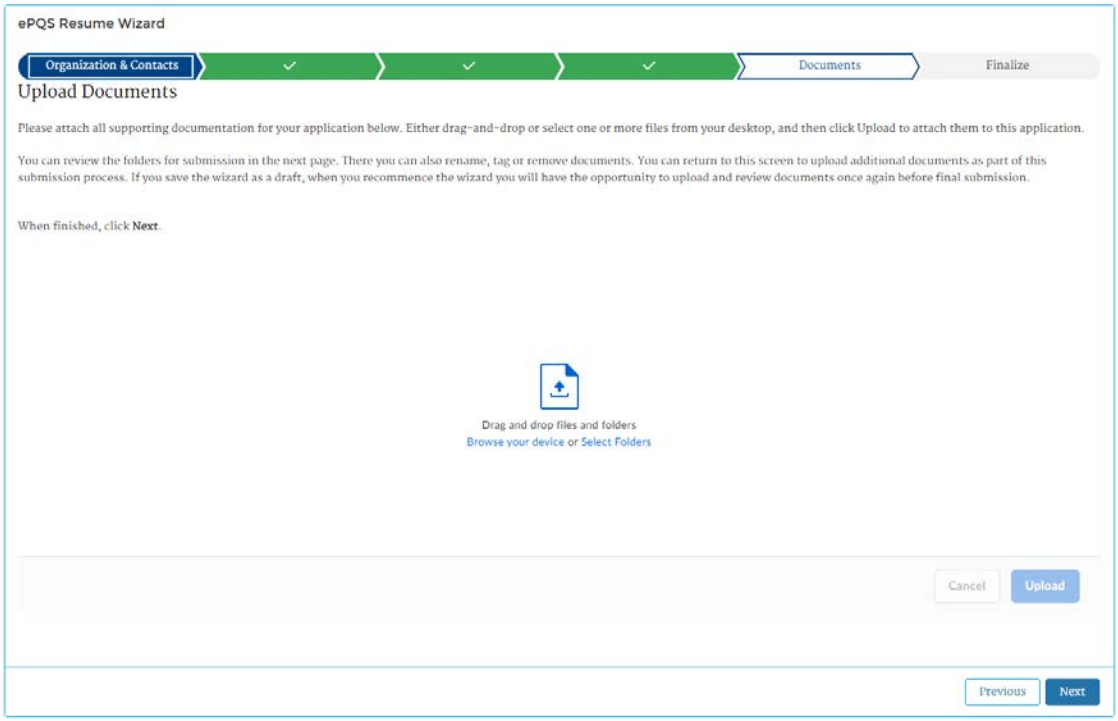

Figure 25: Document upload screen

On the document upload screen you can upload single files, multiple files or folders. Press next once these are selected.

Please note that non-eCTD dossiers should not be uploaded as a Zip file, but as folders or documents.

You will be asked to confirm upload, you can also cancel and go back to the previous screen (figure 26).

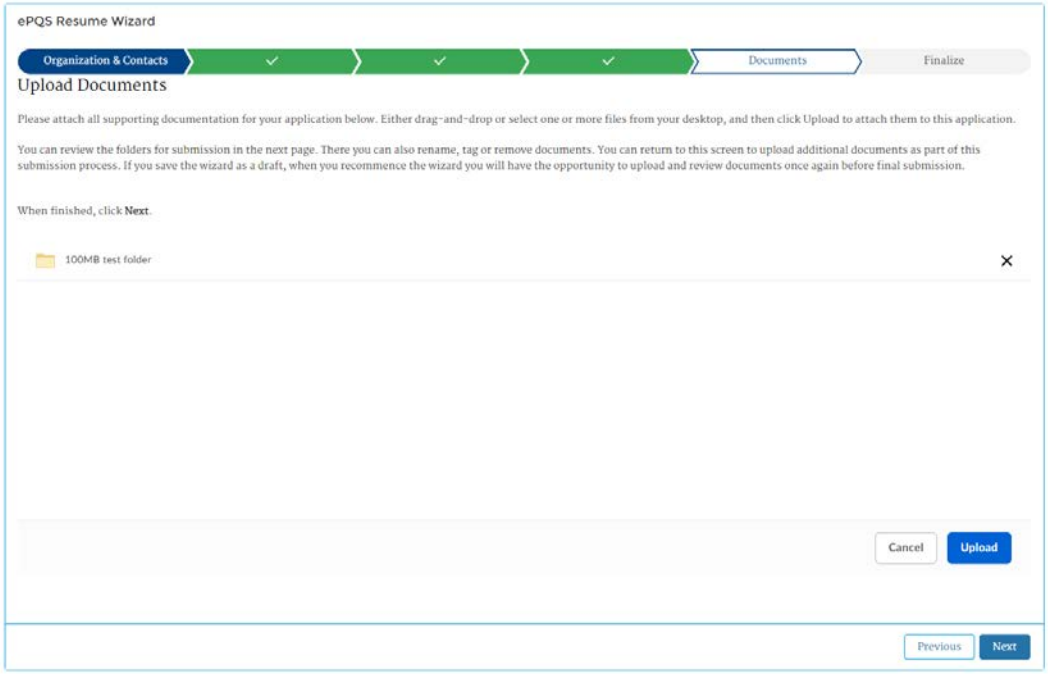

Figure 26: Confirmation of the upload is required

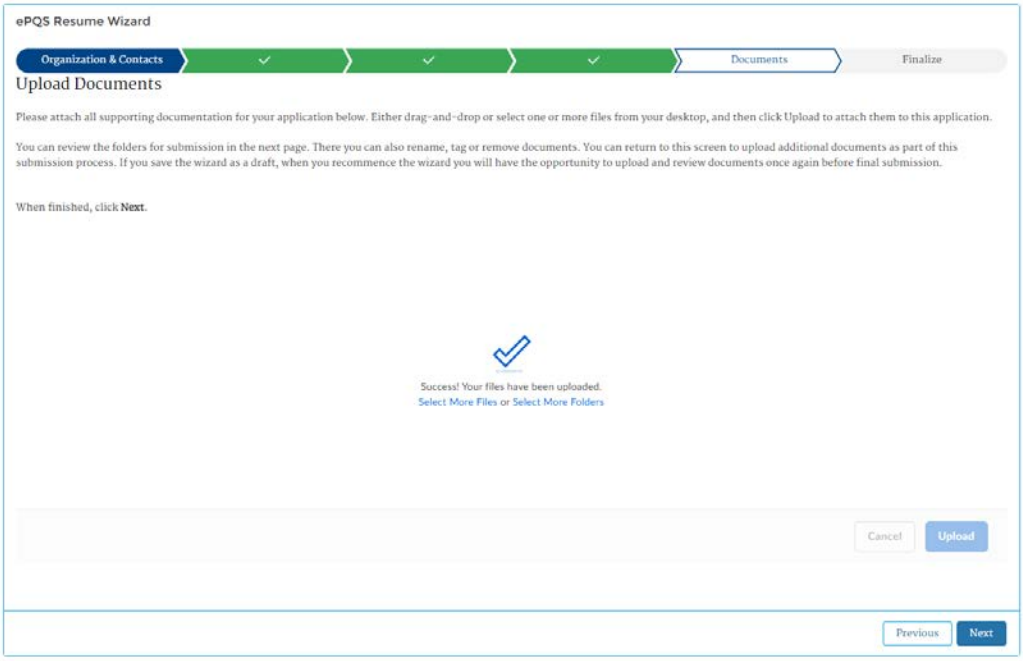

Figure 27: If the documents have uploaded successful a confirmation screen will appear

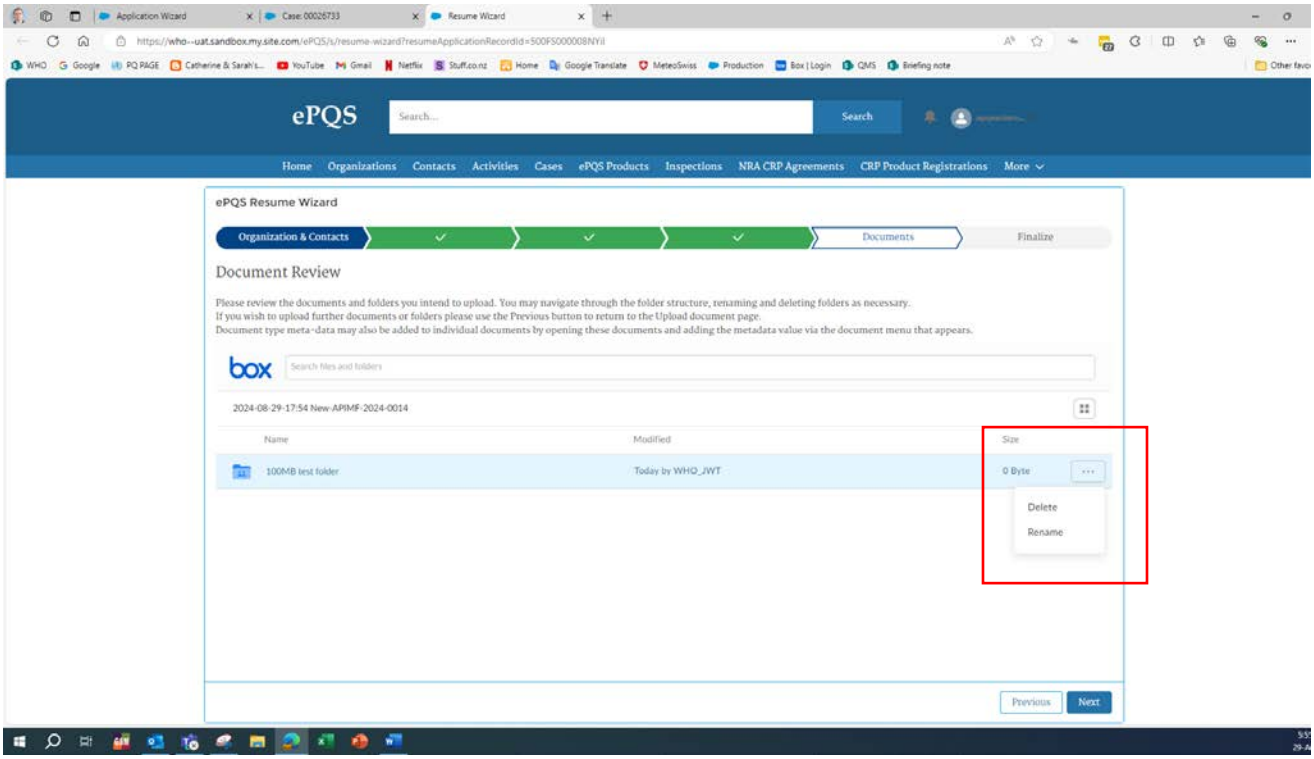

Figure 28: Document review screen where the uploaded files can be adjusted if necessary

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.

6. Submitting the application

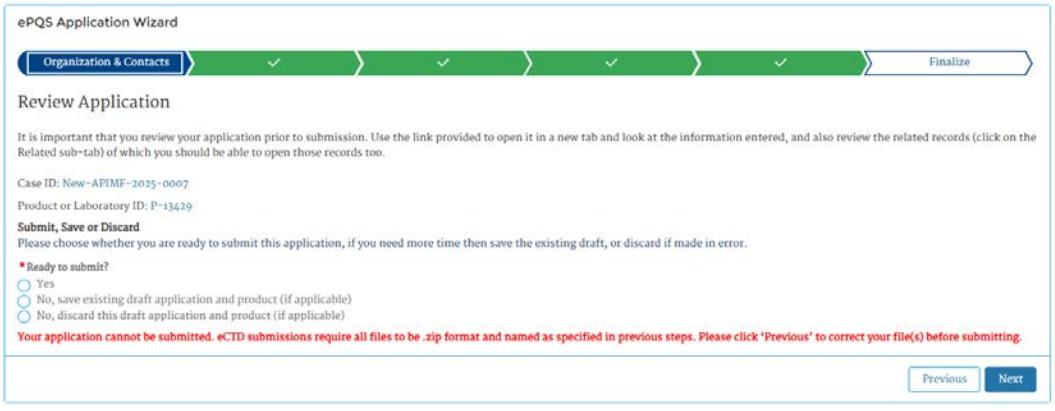

Figure 29: Final screen before submitting

The final screen before submitting 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.

The system will warn the applicant if the eCTD document requirements have not been met with respect to file name and the type and number of files. Press the "previous" button to move backwards in the wizard, back to the document upload step, to revise the files to be uploaded.

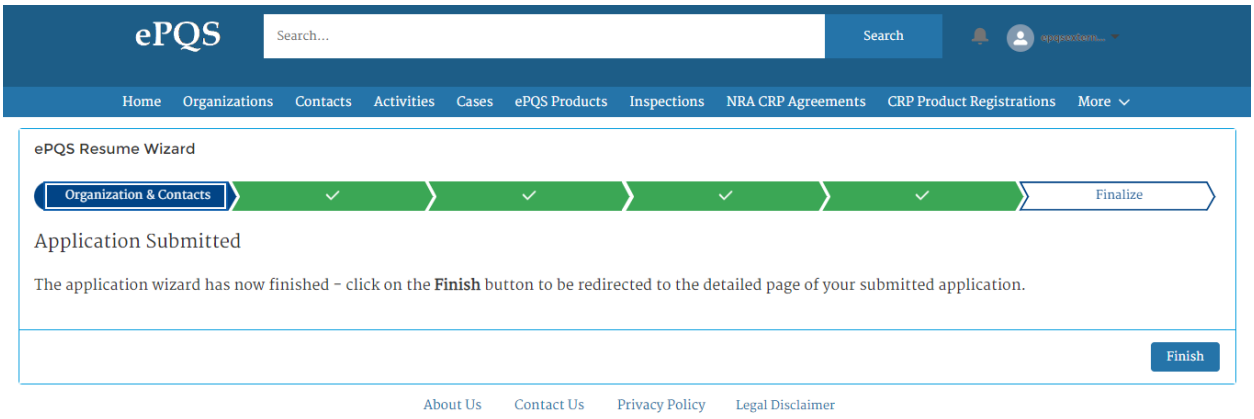

Figure 30: Confirmation screen

Currently there is a bug that displays "Invalid" once finished is selected. This can be disregard. Simply select a new list or refresh the screen.

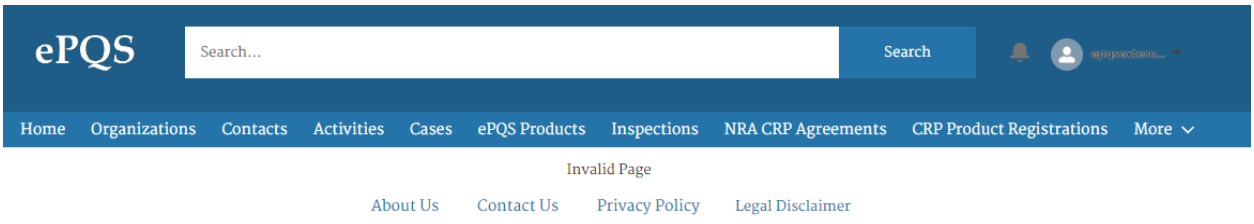

Figure 31: Currently there is a bug once you press finish. Simply refresh the page to continue in the portal

7. 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 32). Second, the status of the application changes from Draft to Under Screening. Finally, the Date Application Submitted is entered or updated by the system.

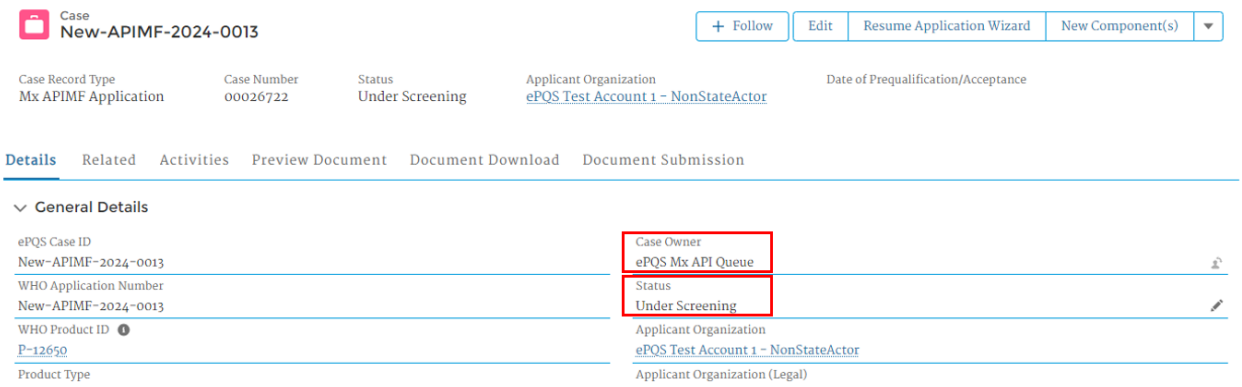

Figure 32: Record ownership and status changes once submitted

If an eCTD submission has been submitted, the eCTD compliance field on the application and product records 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 step is unsuccessful, the eCTD Compliance value will remain as Tentative.

7.1. Notifications

An email notification is sent to the Primary contact of the application confirming the submission of the application.

If an eCTD application has been submitted, a further 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 seen in figure 33.

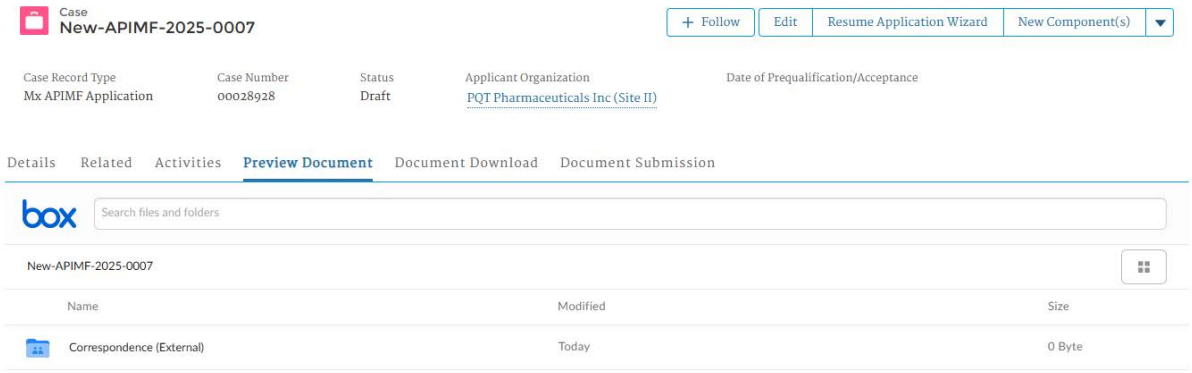

Figure 33: eCTD validation reports are placed in the Correspondence (External) folder of the application

8. Saving as a draft and recommencing

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

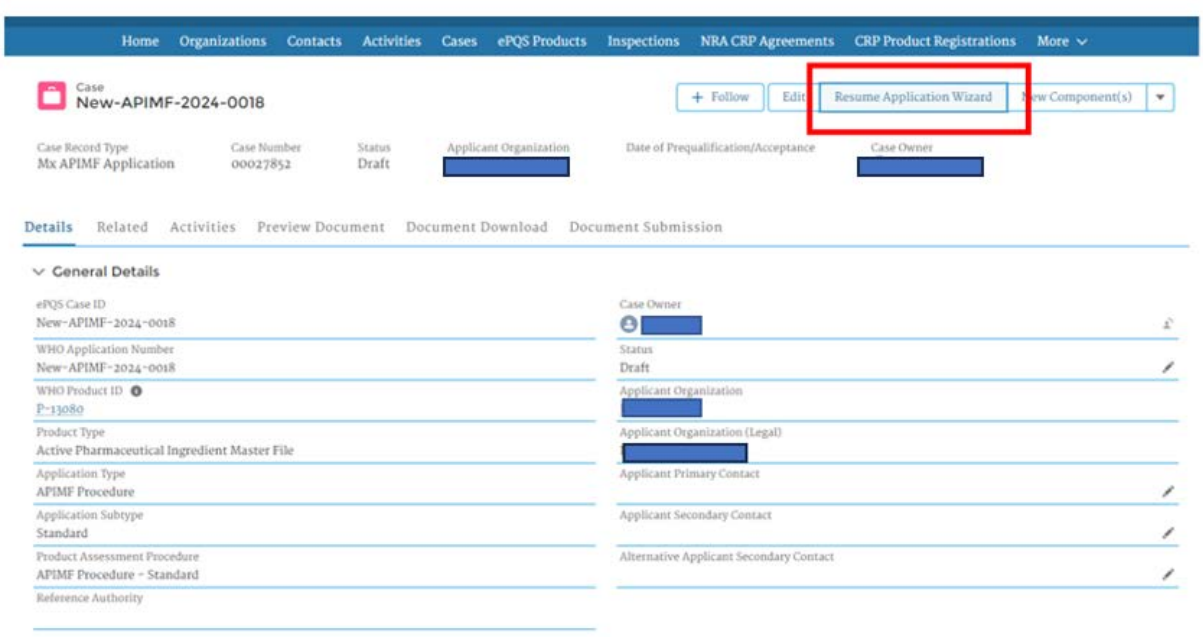

Figure 34: Figure 7: Select the Resume Application Wizard button to recommence the application wizard.

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.

9. Acceptance for assessment

If the screening is successful, the API Assessment group will accept the application for assessment. This results in the change in status of the Product and Application record to Under Assessment.

Subsequently, you will receive an email from the API assessment group confirming the acceptance of assessment of the application as per normal business processes.

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

10. Receiving and responding to questions

Receiving and uploading documents in response to screening or assessment queries occurs in the same manner as described below.

10.1. Receiving requests

The primary means for alerting an applicant that there are questions or information required is via email. In case further information is required, you will be contacted by the API group by email.

If a letter has been sent with the email, a copy of this letter can be located in the Correspondence (External) folder, which is accessible via the application record as indicated in figure 35.

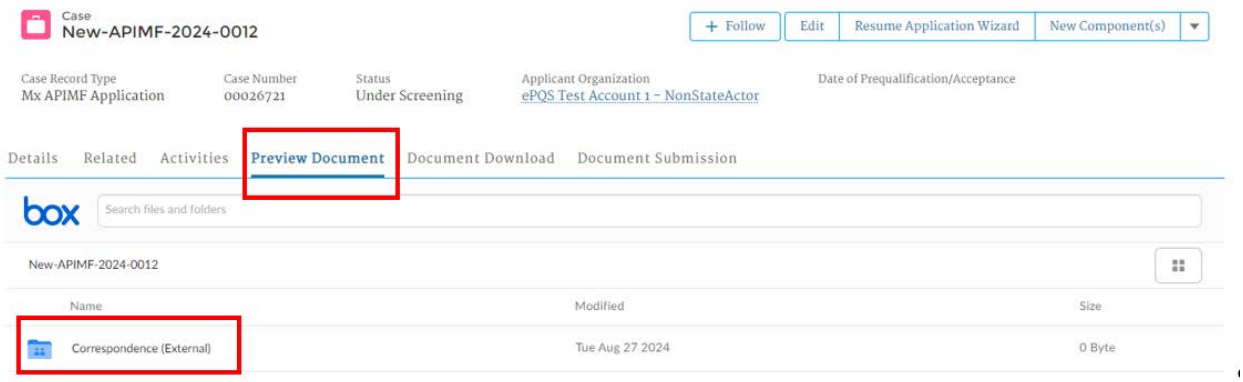

Figure 35: Formal correspondence is located in the applications external Correspondence folder. It can be previewed and downloaded.

In addition, you will notice that an Activity has been opened in the name of the primary contact (figure 36). And, the system will have been sent an email alerting the assignee to this (figure 37).

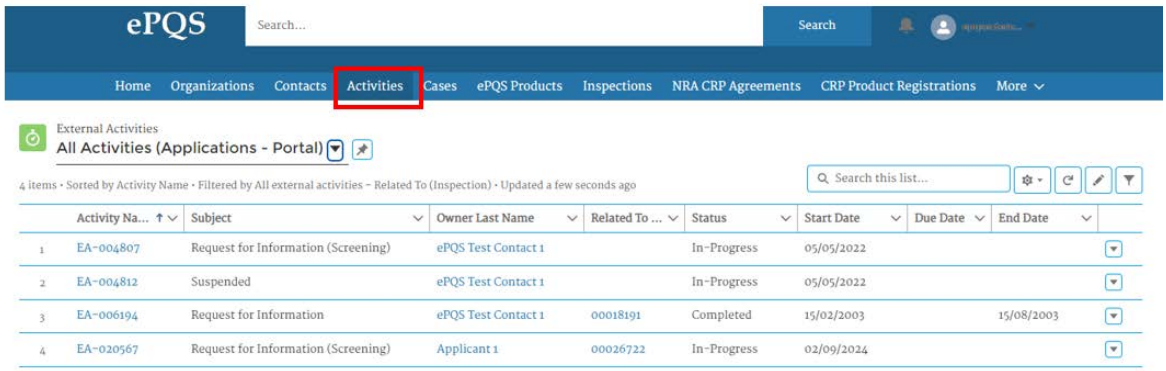

Figure 36: Outstanding tasks can be viewed via the activity list

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 contactepqs@who.int

Figure 37: When an activity is assigned an accompanying email is also sent

10.2. Responding to requests

To upload documents in response to questions raised, or in response to eCTD validation requests, proceed to the application and select the document submission tab. **Do not start a new application wizard.**

Figure 38: Documents can be uploaded via the application record, using the Document submission tab.

This commences a short wizard to upload documents. 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.

If the application was made in eCTD format, then subsequent responses must also be in eCTD. In such situations, the system will display the information for the Module 1 envelope and exact file name, as it did for the initial submission (see figure 23 and 24).

The system does not currently alert internal or external users when additional information is uploaded. This is being fixed. In the meantime, please ensure an email is sent to APIassessment@who.int alerting them that documents have been uploaded.

In addition to any correspondence you might send to the assessment team alerting them to the response, you can also signal your response by changing the status of the activity to “actioned” as indicated in figure 39.

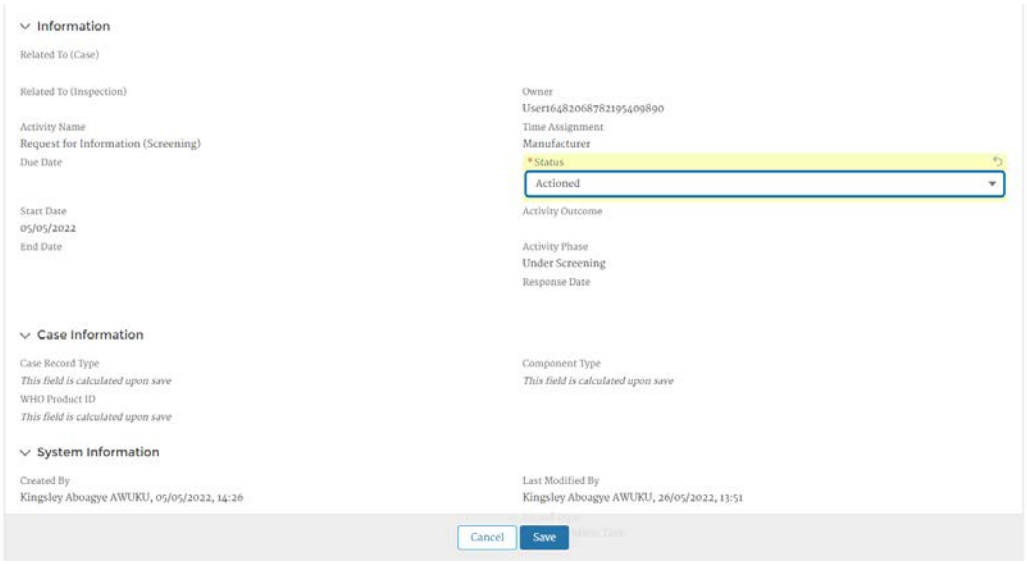

Figure 39: By changing the status of the pending activity to Action this signals to the assessment team a response has been submitted.

Once your response has been reviewed, and assuming this is a valid response, the assessment team will change the status and outcome of the activity, and enter the end date.

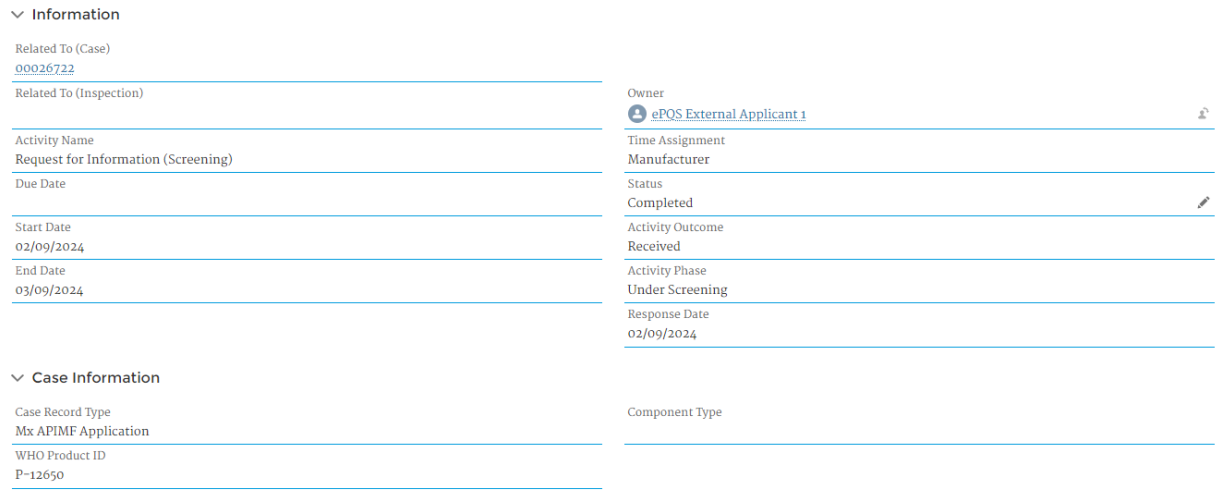

Figure 40: Once the response is reviewed the activity will be further updated

This completes the response to a request for screening information.

11. Record monitoring

Further guidance on other aspects of the portal will be provided in separate documents, but generally speaking 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