

Guidance

ePQS Questions and Answers

Document Version Number: 1.0

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1. I have tried using the Post-PQ change wizard to file a change application, but the system states there are no relevant products (11 April 2025)

| Home Organizatio | ons Contacts Activities | Cases ePQS Products Insp | ections NRA CRP Agreements | Application Wizard More 🗸 | |
|---|------------------------------------|------------------------------------|---|---------------------------|--------|
| ePQS Application Wizard Organization & Contacts | Application Info | Product Deta | ils Document | s Finalize | |
| No Relevant Products | | | | | |
| For the specific product type selecte | d, no matching relevant prequalifi | ed or acceptable status products h | ave been found to be added - this appli | ation won't be created. | |
| | | | | Previous | Finish |

There are likely two reasons for this.

- If your user record is associated with more than one account, on the first screen of every wizard you will be asked to select which Account you are making the application for. This account must match the Application Organization account for the product(s) associated with the intended Post-PQ change applicant. Please check you have selected he appropriate Account at the beginning of the wizard.
- 2. The available products must have a status of either Prequalified or Accepted. If an eCTD application is being made the products must also be eCTD compliant.

2. I can use the wizard, but the documents are not uploading? (11 April 2025)

This is most likely due to a firewall setting. Please ask your company's IT department to permit access to Box, the underlying document management system. A call can be arranged with the ePQS manager if this is unsuccessful.

- *.box.com
- *.app.box.com
- *.ent.box.com #"ent" only required if you are a <u>Box Verified Enterprise</u> account
- *.box.net
- *.boxcdn.net
- *.boxcloud.com



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3. I can not determine which products my Post-PQ change application relates to? (11 *April 2025*)

Unfortunately, the field on the Post-PQ Change record that indicates the products associated with the application, is not currently visible to external users. We are hoping this bug will be rectified. In the meantime, if you have any doubts please approach the relevant assessment team for a correlated list of applications and products.

4. I have tried recommencing the wizard for a draft application, but I am unable to do so? (*11 April 2025*)

This might be because you did not create the original application. When an application is first created, the creating-user "owns" the application until it is submitted. This means only that creating-user can recommence the application.

If there is a need for someone else in your company to recommence the wizard please contact PQT. The ownership can be quickly changed.

5. When I tried adding a product site in the application wizard, I could not locate the company I needed to refer to? (*11 April 2025*)

At various times in the application wizards, the user is requested to input the company (Account) that will be responsible for a particular task. For instance, the company undertaking a step in the product's manufacture. Based on the key letters entered, the system will next offer any matching Account records in the system for selection.

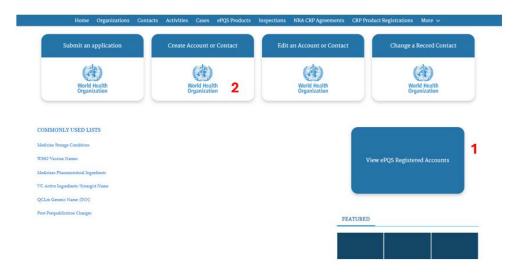
Necessarily, the account must already exist in the system before the application is started. To determine if the Account is present, please download the spreadsheet from the tile indicated as "1" in the figure below. If the account is not present, please download the Create Account form indicated as tile "2", and send this to the relevant assessment team.



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6. When I log into the portal for my company, I can not open the account details for Accounts used as Product Sites (*11 April 2025*)

The accounts that a user can see in detail – that is being able to open the record – is based on whether the user is related as a contact to that account.

Users that are registered in the system are often initially related to the corporate address only, rather than the various subsidiaries. If users need greater visibility a request can be made to associate the contact record of the user to further related Accounts.