

ePQS Portal - Creating or editing a Contact or Account

Forms to request to register a new contact or account; edit an existing contact or account; or change and a contact on a specific record can be made via the portal.

Note, that in many situations a change to an account record's details, for example the address of a product site account, must be made via a suitable PQ process since this has regulatory implications.

For a new portal user it is likely the creation of the contact record will occur as part of the registration process. It is also possible that the account creation process may also occur as part of the registration purpose if this is a new organization using the portal

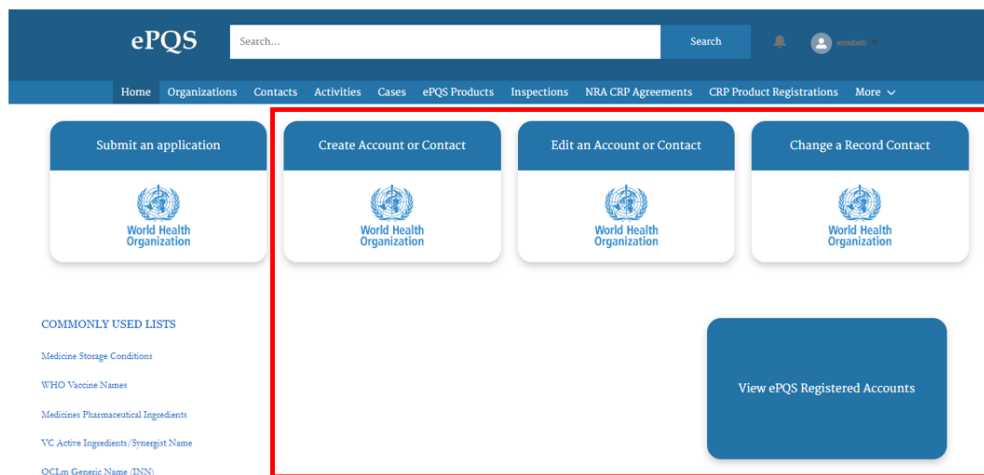


Figure 1: Account-Contact related tile on the Portal home page.

Requests to create an account

The user should check the list of ePQS Registered accounts first before requesting the creation of an account. If there is any doubt over the applicability of a currently registered account, then the user should contact their relevant assessment team.

A user may wish to request the creation of an account for several reasons, but most commonly because they wish to register a site of manufacture.

The requested new account does not necessarily have to be part of the user's legal organization provided the new account has no presence in ePQS (e.g. registered users).

A request for a new account should come from a registered ePQS portal user and be supported by suitable evidence supporting the request.

Create Contact

Not all contact records need to be a user of the ePQS portal, so there are several reasons for which an organization may wish to add a contact to an account.

An organization may wish to add the contact as a direct contact or indirect contact of one or more accounts (see External Guidance - Accounts, Contacts, Users and Record Visibility)

It is possible for an organization to add a contact record for an account for which they do not have legal oversight, provided the account has no presence in ePQS (no registered users). However, if the Account does have active users, any requests relating to contacts for this account should naturally come from the Account holder itself.

A request for a new contact for an account can be made by any contact belonging to that account, together with an appropriate cover letter.

A request for a new contact for an account can be made by the Account's Primary contact without a cover letter.

A request for a new contact for an account that the user does not belong to, should be supported by suitable evidence supporting the request.

Editing an Account

Special consideration needs to be given to editing an account. Depending on the nature of the change and how the account is being used in ePQS, the request may not simply be administrative and may need to follow some PQT process. For instance, a change to the physical address of an account referred to on a product site record, would require a post-Prequalification change to verify the change is acceptable.

Advice from the individual assessment teams should be given priority when considering a change in account details.

A portal user can request changes to an account outside of their Organization, provided this company is not active within the ePQS Portal (has no users). An example might be an account to permit of a 3rd party Product Site. If the company already is registered in the Portal the request should come from the company itself directly.

Otherwise a request for a change in Account details is expected to come from one of the users of that Account.

Editing a contact record's details

Changes to contact details is not uncommon, including indicating a contact is no longer working for a company (see below). A form can be submitted for this purpose.

A portal user can request the alteration of their own contact record.

A portal user from an Account can request the alteration of a contact related to that Account with a supportive cover letter.

A portal user, if the Primary Contact of the Account may request the alteration of a contact related to the Account.

A request to edit the details of a contact from another account will need to be accompanied by evidence of permission from the overseeing account.

Removing a contact

Over time contacts will leave organizations. It is important that PQT is informed of such changes.

Removal of contacts should be requested using the edit Contact form.

When a contact is no longer relevant to a company, the record is typically not deleted in ePQS, since this contact may be present on a historical record.

Rather the contact-account relationships will be marked as inactive and the prefix “zzz” will be added to the first and last name of the contact so that it is readily apparent to any viewer of a record that the contact is no longer active.

This can be seen on the related tab of the account via the portal as shown in figure 2

| | Contact Name | Direct | Active | Start ... | End ... | Account Name | |
|---|---------------------------------|-------------------------------------|-------------------------------------|-----------|---------|-----------------------------------|---|
| 1 | ePQS External Applicant 1 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | PQT Pharmaceuticals Inc (Site II) | € |
| 2 | ePQS External Applicant 2 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | PQT Pharmaceuticals Inc (Site II) | € |
| 3 | ePQS External Applicant 3 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | PQT Pharmaceuticals Inc (Site II) | € |
| 4 | ePQS External Applicant 4 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | PQT Pharmaceuticals Inc (Site II) | € |
| 5 | ePQS NRA User 2 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | PQT Pharmaceuticals Inc (Site II) | € |
| 6 | ePQS NRA User 4 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | | PQT Pharmaceuticals Inc (Site II) | € |
| 7 | zzzePQS External zzzApplicant 5 | <input checked="" type="checkbox"/> | <input type="checkbox"/> | | | PQT Pharmaceuticals Inc (Site II) | € |

Figure 2: Account record, related contacts list, indicating an obsolete contact record.

Editing a contact – account relationship

Besides changing the details of the contact record itself, requests can be made to alter the relationship a contact has to other accounts. A contact must always have a direct relationship to one account, but may have zero, one or more indirect relationships to other accounts (see guidance on accounts and contacts).

Change contact on a product, application record

A final type of change regarding contacts may be to replace the contact who is cited on an application, product record.

Such changes must be requested by a user of the relevant account, almost always the account listed as the Application Organization on the product or application record.

As mentioned elsewhere, ideally such requests come from the user indicated as the Primary Contact on the associated

Removing a Contact or Account

Both account and contact records can be inactivated. Rarely would a record be deleted.

One of the reasons a contact record is not deleted is to preserve the history of contacts and their presence on historical, now closed records (older applications for instance).

For the same reason, to readily identify inactive contacts the prefix “zzz” will be placed in front of the contact names.

If the contact is a user of the ePQS system then inactivation of the contact will necessarily result in inactivation of the user’ access.

Should the Primary Contact change unexpectedly or is not available, as indicated earlier the company may still make a request with appropriate evidence from the respective company for these changes.