

Guidance on Accounts, Contacts, Users and Record Visibility within the ePQS Portal

Accounts

Salesforce, the software running ePQS, uses the term account to describe an organization, or private individual.

An account can have zero, one or more related contact records. Meaning an account does not need to have a child contact.

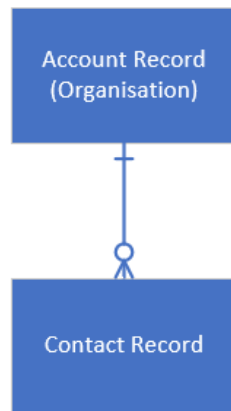
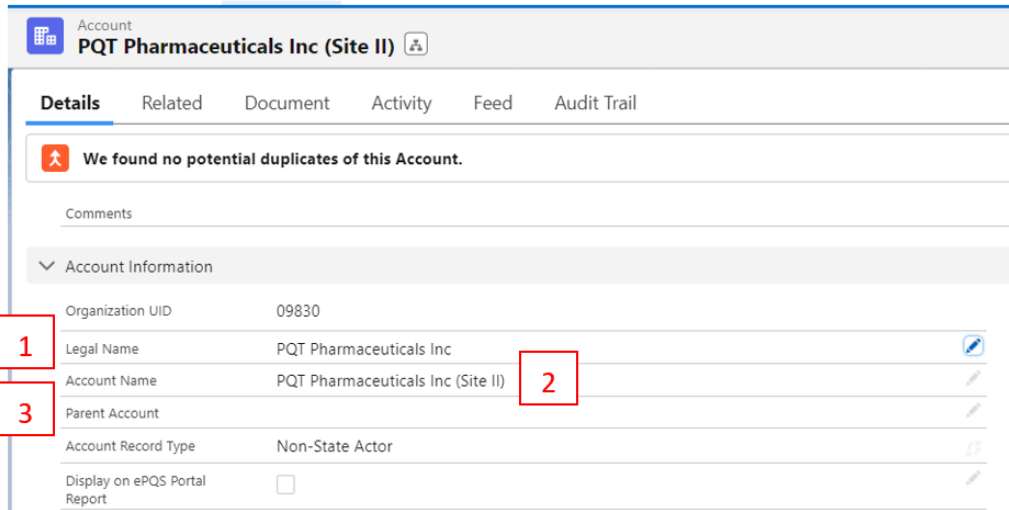


Figure 1: Relationship between account and contact records.

Accounts have several means of identification: Account UID (1); Legal Name (2), Account Name (3) (see figure 2).



Account	
PQT Pharmaceuticals Inc (Site II)	
Details Related Document Activity Feed Audit Trail	
We found no potential duplicates of this Account.	
Comments	
Account Information	
Organization UID	09830
1 Legal Name	PQT Pharmaceuticals Inc
3 Account Name	PQT Pharmaceuticals Inc (Site II) 2
Parent Account	
Account Record Type	Non-State Actor
Display on ePQS Portal Report	<input type="checkbox"/>

Figure 2: Account record identification fields.

Account UID is an automatically generated number. . Account Name is an internal name assigned by PQT to more easily differentiate entities with the same Legal name.

Account Hierarchy

Within ePQS it is possible to organize accounts into a hierarchy if requested by companies. This has no systemic effect on record visibility, but is for information only.

Nonetheless, grouping accounts into a hierarchy can be very helpful for PQT to understand company oversight and responsibilities, as illustrated in figure 3.

Contacts can be arranged freely among the hierarchy using direct and indirect relationships (covered in following sections).

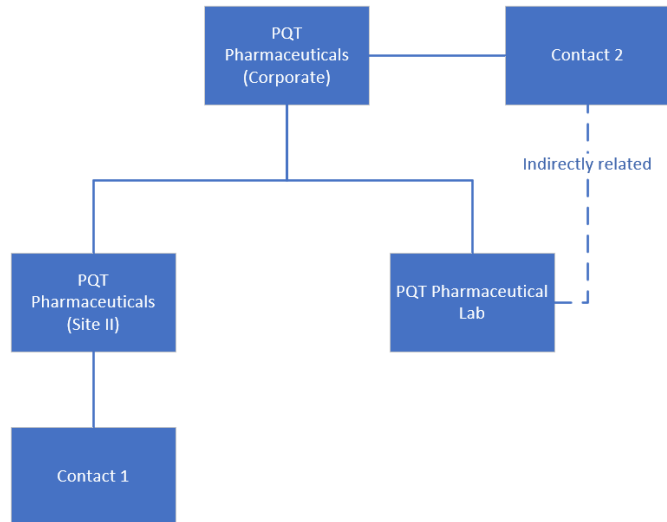


Figure 3: Example of accounts arranged in a hierarchy

Contacts

A contact record, is a record describing a person.

A contact must be related to at least one account.

A single contact record can be related directly to only one account.

A single contact record can be indirectly related to multiple accounts

An example of where a single contact might have an indirect relationship might arise when a contact belongs directly to the corporate account of the company, but has responsibilities at one of the company's manufacturing sites. Since Account "membership" dictates record visibility, a contact of a corporate regulatory account may also wish to be an indirect contact of Accounts listed on manufacturing sites in order to have visibility of related records.

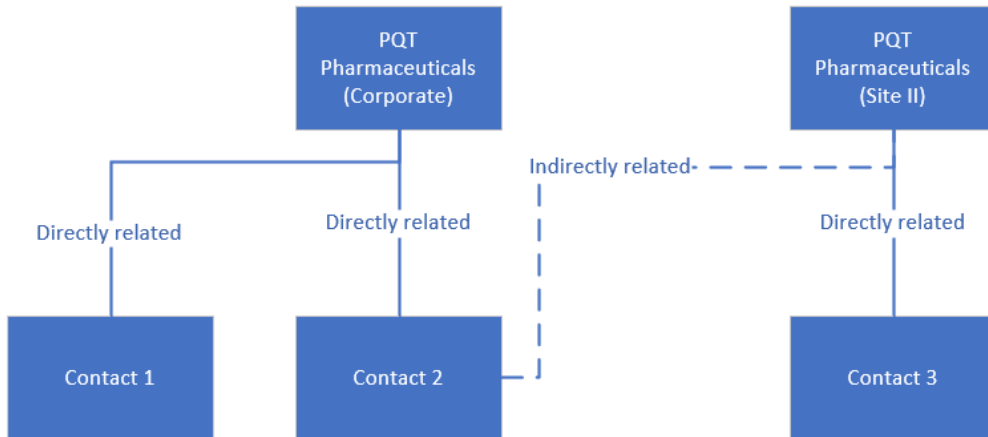


Figure 4: An example of Contact 2 having direct and indirect Account relationships.

Another example might arise, on rare occasions, if the person acts as an agent for more than one company

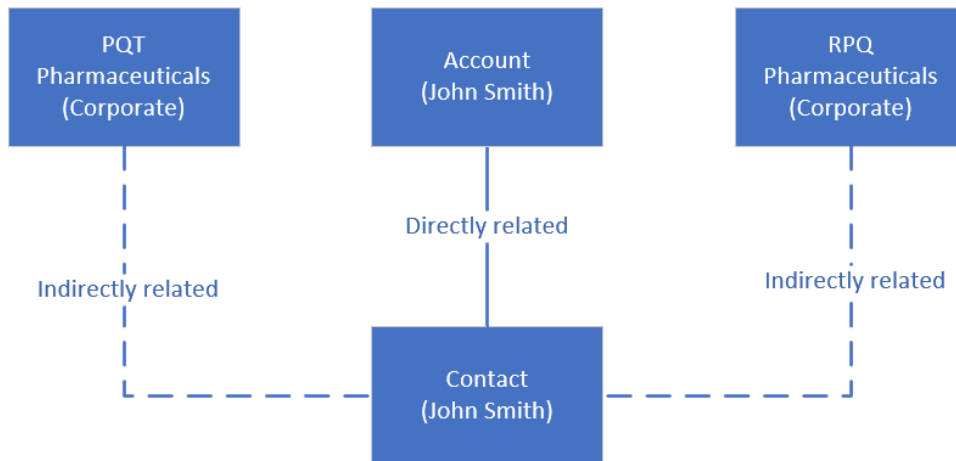


Figure 5: An example of a Contact having indirect Account relationships with several Accounts.

Primary Account Contact

An account can have many related contacts, but it is possible to nominate a primary contact for an account.

The primary contact has no additional system-related abilities. However, account or contact requests from the primary contact will be assumed to be authorized by the company without covering the need for covering letters of supporting documentation.

Users

Practically speaking a user is a contact who can access the ePQS portal.

There are three types of external users and typically a user must choose only one. These are:

1. An Applicant, Manufacturer or Laboratory
2. A National Regulatory Authority user
3. An PQT external expert

The User type dictates the types of records a user will be able to see in the portal, and what they can do within the portal.

Equally important, the relationship of the user's contact record to other account records has an impact on which records a user can see in the portal (See Record Visibility).

Record visibility

An applicant, manufacturer or Laboratory user will typically see the following record types in the ePQS Portal:

- Any accounts record to which they are directly or indirectly related.
- The contacts records of any accounts they are directly or indirectly related to.
- Product records where directly or indirectly related accounts are listed as the Application Organization.
- Application records where directly or indirectly related accounts are listed as the Application Organization.
- Activity records assigned to themselves or any user of an account they are directly or indirectly related to.
- Inspections records, once completed, where directly or indirectly related accounts are listed as the Site Organization.
- All NRA CRP Agreement records.

It is important to understand that if a user (contact record) is related to more than one account (see indirect relationship) the user will see relevant records related to all of these accounts. Therefore attention should be given to account-contact relationship.

A National Regulatory Agency user will typically see the following record types in the ePQS Portal:

- Any accounts records to which they are directly or indirectly related.
- The contacts records of any accounts they are directly or indirectly related to.
- Collaborative Registration Procedure Agreement records, where their NRA Organization is listed.
- Any product records involved in an active CRP procedure, provided the NRA user is specifically recorded as the Agency's Collaborative Registration Procedure (CRP) Contact.

An External experts will see:

- Their account record
- Their contact record
- Related Activity records
- Any records specifically shared with them in the course of their duties

Field visibility

External users do not have full visibility of the fields present on records, even if they have access to the record.