

AusUDID Roles

All users submitting, drafting or managing UDI records must have an active TBS account.

Organisation type

TBS system role

Sponsor



Administrator



Manufacturer



Drafter



Sponsor and manufacturer



Submitter



Financial



Your organisation type impacts your organisation's abilities in the AusUDID.

Sponsors are responsible for submitting and maintaining UDI records. Manufacturers may do so on behalf of the sponsor, but the legal responsibility for compliance remains with the sponsor.

The AusUDID supports both manufacturers and sponsors creating and maintaining the UDI records. However, your abilities differ depending on your organisation type.

Actions that can be completed by all user types, including un-authenticated users include:

- Searching and viewing public UDI records
- Downloading public UDI records
- Exporting public UDI records
- Downloading the full database.

*Manufacturers can complete many of the same actions as a sponsor, including drafting and publishing UDI records. However, as manufacturers are not the legal owner of ARTG entries, they are unable to link an ARTG to a UDI record. This responsibility remains with the sponsor.

UDI records published by manufacturers are visible to sponsors, allowing the sponsor to link their ARTG to the UDI record. However, the UDI record remains in a 'published but not publicly available' state until an ARTG is linked. This means that public non-authenticated users cannot view the UDI record.

For more information, see UDI record states.

It is important to note that to be compliant with UDI requirements, the UDI record must be linked to an ARTG and be publicly available.

	Manufacturer	Sponsor	Sponsor and manufacturer
Draft UDI record	✓	✓	✓
Edit draft UDI record	✓	✓	✓
Delete draft UDI record	✓	✓	✓
Publish UDI record*	✓	✓	✓
Edit published UDI record	✓	✓	✓
Link ARTG details to a UDI record	✗	✓	✓
Attach supporting documents to UDI record	✗	✓	✓
Replace supporting documents on UDI record	✗	✓	✓
Remove supporting documents from UDI record	✗	✓	✓
Submit UDI records using Bulk Upload template	✓*	✓	✓
Link ARTG details using Bulk Upload ARTG ID mappings template	✗	✓	✓

*Manufacturers cannot submit ARTG IDs

Your TBS system role impacts your individual ability in the AusUDID.

If your organisation has a TBS account but you are not associated with the account, your administrator must add you as a contact.

If your organisation does not have a TBS Account, please contact TBS support at ebs@health.gov.au.

Information on TBS and TBS Accounts is provided on the TGA website at [TGA Business Services \(TBS\) | Therapeutic Goods Administration \(TGA\)](#).

TBS system roles

The administrator of your TBS account is responsible for adding members of your organisation to your organisation's TBS account for UDI submission purposes. It is your administrator's responsibility to select the appropriate system role for this user.

	Administrator	Drafter	Submitter	Financial
Add contacts to TBS	✓	✗	✗	✗
Access UDI management centre	✗	✓	✓	✗
Draft UDI record	✗	✓	✓	✗
Edit draft UDI record	✗	✓	✓	✗
Publish UDI record	✗	✓	✓	✗
Link ARTG details to a UDI record	✗	✓*	✓	✗
Attach supporting documents to UDI record	✗	✓*	✓	✗
Replace supporting documents on UDI record	✗	✓*	✓	✗
Remove supporting documents from UDI record	✗	✓*	✓	✗
Submit UDI records using Bulk Upload template	✗	✗	✓	✗
Link ARTG details using Bulk Upload ARTG ID mappings template	✗	✗	✓	✗

*Draft records only



TBS Organisation contact roles

We recommend that if the member of your organisation is being added for UDI submission purposes only, that the administrator do not assign an 'Organisation contact role' to this member's contact.

Organisation contact roles, such as Medical Device Regulatory Affairs Contact, are used by the TGA to determine who is best suited in your organisation to contact in scenarios such as post market reviews. Adding organisation contact roles may unintentionally involve members of your organisation in actions or distributions other than UDI.

If you do not wish the member of your organisation being added for UDI submission purposes to be contacted by the TGA, we recommend you also select 'FirstName is not authorised to speak with the TGA'. By selecting this option, the member of your organisation will not be contacted for non-UDI related purposes.