



Australian Government
Department of Health
Therapeutic Goods Administration

Biologicals application form - a step-by-step guide

Australian Regulatory Guidelines for Biologicals (ARGB)

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TGA Health Safety Regulation

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This application form can only be used to:

- ✓ include a **new biological** on the ARTG
- ✓ **vary** an existing biological entry on the ARTG

This form is **not** used for:

- ✗ cancelling an existing biological ARTG entry. You will need to go to [Request a cancellation to an ARTG entry](#).

Once you have all of the required information, this guide will step you through completion and submission of the application form.

Before you complete this form

You need to read the relevant documents below, otherwise you may not have all of the information you need to complete the form.

- If you want to **include a new biological** on the ARTG, the complete process together with a **checklist** of required information is provided in the following documents:
 - [Applying for inclusion of a Class 2, 3 or 4 biological on the ARTG](#)
 - [Applying for inclusion of a Class 1 biological on the ARTG](#)
- If you want to **vary an existing ARTG entry**, the process is outlined in [Varying biological entries on the ARTG](#).
- To confirm if you need to apply for a **new biological** or to **vary** an existing entry, read [new biologicals based on a parent biological](#).
- If you are applying for a **Class 1 biological**, you will need to have all of the required documentation outlined in [Applying for inclusion of a Class 1 biological on the ARTG](#).

Overview of the submission process

The application form

You need to complete **all** of the information on **each tab** of the form.

Once you have finished, then you will need to **validate** the form, and correct any errors or missing information, before you finally **submit** the form to us.

Accompanying documentation

You cannot submit your documentation **with** the application form.

Class 2, 3 or 4 biologicals

If you are submitting a Class 2, 3 or 4 biological application, or a variation to your ARTG entry, you cannot submit your documentation **with** the application form.

You will need to **send us** the required documentation according to the options provided in the [General dossier requirements](#).

Class 1 biologicals

If you are submitting a Class 1 biological, and you wish to provide documentation to the TGA in relation to your application, it can be emailed to bloodandtissues@health.gov.au with the application number in the Subject header.

Completing the application form

You will need to be a [drafter or submitter](#) in TGA Business Services to fill out the application form.

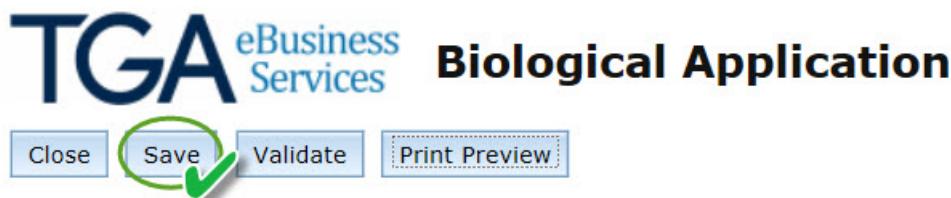
Accessing and saving the form

Opening the biologicals form

1. Log in to [TGA Business Services](#).
2. From the **Application** menu, select the **Biologicals Application Form**.

Saving your form

3. Always save your form **prior to closing** by clicking the **Save** button under the TGA header. The Close button will exit the form without saving.



Applications tab

This tab collects information about the applicant or sponsor.

The application tab is shown below.

Application tab

Sponsor information

4. In the Applications Tab complete all fields marked with a red asterisk.
 - a. **Applicant Name** is filled automatically based on information you have already provided to us.
 - b. Select your **Sponsor name** from the drop-down menu, this allows us to populate the next drop-down menus with your information.
 - c. After selecting the sponsor name, you will be able to use the drop-down menus for the following fields:
 - i. **Sponsor address**
 - ii. **Sponsor preferred billing address**
 - iii. **Sponsor regulatory correspondence address**
 - d. The **contact name** must be a person listed with TGA Business Services, if there is an error message, speak with your Administrator to update your information with us.
 - e. Enter your **contact phone and fax numbers** including the **area code**, or **country code** for overseas applicants.

Type of application

- f. Using the checkboxes provided, select whether you are applying for one of the following:
 - i. **Create a new biological ARTG entry for:**
 - new biologicals
 - new biologicals based on an existing biological
 - ii. **Vary a current biological entry for:**

- variations to biologicals

To vary a current entry, you will need to enter the ARTG number of the entry you want to vary, and then select **Search**. This will populate the form with information held in the ARTG.

ARTG Entry for Variation ***** 123456

The form provides an option to create a new export only biological ARTG entry, but we are currently not accepting such applications.

Application fee

- The **Application Fee** will automatically populate after you have completed and successfully validated the application form.
- The **Exempt from Payment** option defaults to **No** and should **not be changed** without prior confirmation and approval from [Biological Science Section](#).

Registration tab

This tab collects information about your biological. You will need to know:

- the class of your biological

Classification of biologicals

If you have not classified your biological, go to [Classification of biologicals](#). Please [contact us](#) if you seek confirmation of your classification **before** you submit your application. Only correctly classified biologicals will be accepted.

Registration tab showing class and product type entry fields

The screenshot shows the TGA eBusiness Services Biological Application interface. The 'Registration' tab is active. Two dropdown menus are highlighted with green arrows: 'Class of Biological' and 'Product Type'. The 'Class of Biological' dropdown shows 'Select a class...' and the 'Product Type' dropdown shows 'Select a type...'. Below these are fields for 'Label Name' and 'Name'. A note at the bottom states 'This product complies with the following standard(s):' followed by a 'Name' field.

- Once you have selected the **Class of your biological** a list of standards will appear at the bottom of the screen.

Product type

6. We have provided the following list of **Product types**:

- a. Amnion
- b. Blood components
- c. Cardiovascular tissue
- d. Cellular therapies
- e. Faecal microbiota transplant
- f. Musculoskeletal tissue
- g. Ocular tissue
- h. Skin

You need to select the most appropriate **Product Type** for your biological. If your biological does not fit well within the options provided, please [contact us](#) to discuss. We are able to update this list if needed.

ARTG label name

7. The **Label name** will automatically populate in according to the structure below, after you have completed and successfully validated your form. They must be unique for each entry in the ARTG.

ARTG label names

Class 1 and Class 2 biologicals:

- Product Type + Sponsor Name

Class 3 and Class 4 biologicals:

- Product Type + Product Name + Dosage Form + Container Type
- Product Name for Class 3 & 4 biologicals will include the Sponsor Name (see [Product Name](#) section)

Biological standards

8. Select **all** the **biological standards** applicable to your biological using the check boxes.

Biological standards

To successfully complete and validate the form, you must select **at least one** standard, but you should **select all standards** that apply to your biological.

We require you to **demonstrate compliance** with all of the relevant standards in your product

dossier submitted with your application.

Registration tab list of biological standards

This product complies with the following standard(s):

	Name
<input type="checkbox"/>	TGO 87: General requirements for the labelling of biologicals
<input type="checkbox"/>	TGO 105: Standard for Faecal Microbiota Transplant Products
<input type="checkbox"/>	TGO 84: Standards for human cardiovascular tissue
<input type="checkbox"/>	TGO 83: Standards for human musculoskeletal tissue
<input type="checkbox"/>	TGO 85: Standards for human ocular tissue
<input type="checkbox"/>	TGO 86: Standards for human skin
<input type="checkbox"/>	TGO 88: Standards for donor selection, testing and minimising infectious disease transmission
<input type="checkbox"/>	Code of GMP for blood, blood components, tissues and cellular therapy products
<input type="checkbox"/>	British Pharmacopoeia
<input type="checkbox"/>	European Pharmacopoeia
<input type="checkbox"/>	United States Pharmacopoeia

Manufacturer tab

You need to list **all** manufacturers of your biological. This includes:

- all testing facilities you use for donor infectious disease testing
- all microbiology testing facilities
- sterilisation and/or irradiation facilities
- any packaging facilities.

At a minimum, **you must have** a pending, or approved, manufacturing licence or clearance for all manufacturers in order to select them from the drop-down menus in the form.

Where your manufacturer already has a manufacturing licence or clearance, use the information on their certificate to complete this part of the form.

Sponsor's responsibilities

As a sponsor of a Class 2, 3 or 4 biological **you are responsible** for ensuring **all** of your manufacturers:

- have a pending or approved manufacturing licence or GMP certification
- maintain current manufacturing certifications for the life of your product

Manufacturer tab

The screenshot shows the 'Manufacturers' tab selected in the top navigation bar. Below it, there are buttons for 'Add Manufacturer' and 'Remove Selected'. A callout bubble highlights the 'Apply for a New Manufacturer' button, which is specifically for 'Class 1 biologicals only'. The interface includes tabs for 'Name and Address', 'Manufacturer Steps', 'GMP Ref and Status', and 'GMP Conditions'.

Apply for a new manufacturer

This option is only available for **Class 1 biologicals** since manufacturers of Class 1 biologicals do not require a licence or certification.

Adding a manufacturer for Class 2, 3, 4 biologicals applications

Search for a manufacturer

9. Search for your manufacturer by selecting **Add Manufacturer**, a **Search for manufacturer** pop-up box will appear:

The search window has fields for 'Where?' (Australian Manufacturer selected), 'Context' (Manufacturer's name selected), and a search input field. It also includes a 'Manufacturer Site' section with a dropdown and a 'Manufacturer pending approval' checkbox. The 'Steps performed by this Manufacturer' section shows a table with columns for 'Select to Add a Step', 'Add', and 'Remove'. The 'Steps Performed' table is empty. At the bottom are 'GMP Ref:', 'Status:', and 'Conditions:' fields, and 'Add' and 'Close' buttons.

10. To search for your manufacturer in our database, you need to:

- select where your manufacturer is based, either in Australia or overseas.
- You can then choose whether you want to search by:
 - Manufacturer's name
 - Client ID
 - MIS Licence No – for Australian manufacturers only
 - MIS Clearance No – for overseas manufacturers only

Where? Australian Manufacturer Overseas Manufacturer
Context: Manufacturer's name Client ID MIS Licence No.

OR

Where? Australian Manufacturer Overseas Manufacturer

Context: Manufacturer's name Client ID MIS Clearance No.

Note: You must be the Sponsor that the TGA clearance has been issued to for an overseas manufacturing site.

11. In the text bar **Type part/all of a Manufacturer's Name, then click Search**, enter information that matches the **Context** you selected in **Step 10**, it does not have to be the Manufacturer's Name.

- a. To search by **Manufacturer's name**, you can enter the name or part of the name followed by an asterisk e.g. pro*, then select **Search**.
- b. To search by **MIS Licence No.** or **MIS Clearance No.**, the complete number must be entered for the search to work correctly.
12. The number of matches to your search criteria will appear above the field, you can then **select your manufacturer** from the drop-down list that contains the search results.

13. To start a new search, you can select **New Search** and repeat the process from [search for a manufacturer](#).

If you can't find your manufacturer:

- Try another search term, e.g. **client ID** rather than **Name**.
- Check the search details used are correct against the manufacturer details in TGA Business Services.
- Overseas manufacturer may have multiple TGA Clearances, each specific to a designated

sponsor.

- Check the format of the Client ID, licence or clearance numbers.
- If an application for a **new manufacturer** has recently been lodged with us, please allow a few days for the details to appear.
- If the manufacturer is still not available, they are likely not in the system with a current TGA licence or clearance and a [new application](#) will need to be submitted.

14. Select the **Manufacturer Site** from the drop down menu provided. This information will be dependent on the manufacturer selected in the previous field.
15. If your manufacturer is pending licence or clearance approval from the TGA, you must select the '**Manufacturer pending approval**' check box. Approval must be granted before the biological can be included on the ARTG.

Changes and corrections to your application form, such as addition of a TGA clearance number for a manufacturer, can be made at any time up until a decision is made on your application.

Manufacturing steps performed

16. In the **Steps performed by this Manufacturer**, select the only the manufacturing steps performed for your biological at the selected Manufacturing Site by either:
 - using the drop-down menu and scrolling through the steps to find those wanted
 - typing text in the field. Any steps containing the text will appear in the drop-down menu, which can then be selected.
17. Once the desired step is selected, click the **Add** button to add it to the **Steps Performed** table. More than one step can be added, by repeating from Step 16.

The selected steps are strictly validated against the manufacturing steps approved by the Manufacturing Quality Branch (MQB). If there are issues validating manufacturing steps please [contact MQB](#).

18. You can remove any **unwanted steps** by selecting the box to the left of the unwanted step(s), and clicking the **Remove** button.

Steps performed by this Manufacturer

Steps Performed	Add	Remove
<input checked="" type="checkbox"/> Anti-HBs Confirmatory		
<input type="checkbox"/> ABO Group and Rh Type		

Saving your manufacturers' details

19. To save your entries and return to the **Manufacturing tab**, click the **Add** button at the **bottom left** of the window.

✓ **Add** button will:

- **save** all information and add your manufacturer's details to the application
- **close** the dialogue box
- **return** you to the **Manufacturers tab** in the Biologicals application, with details of the new manufacturer you have just entered appearing in the Manufacturers tab.

✗ **Do not click Close**, as this will **delete all information** entered and return you to the Manufacturers tab.

Search for a Manufacturer

Where? Australian Manufacturer Overseas Manufacturer

Context: Manufacturer's name Client ID

Type part/all of a Manufacturer's Name, then click Search

Manufacturer Site

Search for and select a manufacturer first...

Manufacturer pending approval

Steps performed by this Manufacturer

Steps Performed	Add	Remove
<input checked="" type="checkbox"/> Anti-HBs Confirmatory		
<input type="checkbox"/> ABO Group and Rh Type		

GMP Ref:
Conditions:

19  

20. **Only** use the **Close** button if you want to **delete all information** and return to the Manufacturers tab on the biological application form.

21. If additional manufacturing sites need to be added then repeat from [Adding a Manufacturer](#).

Modifying manufacturer's details

22. To make any changes to the manufacturer's details, double-click the required manufacturer from the list in the **Manufacturers tab**. Make the changes in the **Search for a Manufacturer** dialogue box as described in [Manufacturing steps performed](#).

23. To save any changes, select the **Update** button, which has the same function as the **Add** button in Step 19. The **Close** button will **delete all changes** and return to the Manufacturers tab.



Removing a manufacturer

24. To remove a manufacturer from your application, open the **Manufacturers tab** and select the check-box of the manufacturer you want to remove, then click the **Remove Selected** button.

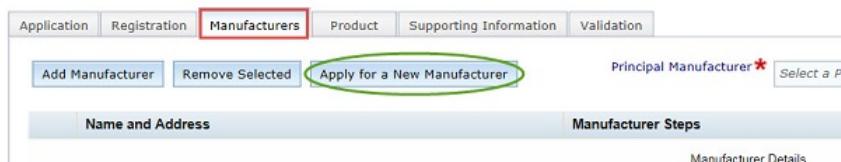
Select principal manufacturer

The final step in the manufacturer tab is selecting your principal manufacturer.

25. Once the details of all manufacturers have been entered, you need to select one as the **Principal Manufacturer** from the drop-down list. The manufacturer must be approved for 'Release for supply'.

Adding a manufacturer: for Class 1 biologicals only

26. If you have a Class 1 biological, the **Apply for a New manufacturer** button in the **Manufacturers tab** is selectable (this is not active for any other class of biological).



The screenshot shows a navigation bar with tabs: Application, Registration, Manufacturers (which is highlighted with a red box and has a green circle around the 'Apply for a New Manufacturer' button), Product, Supporting Information, and Validation. Below the tabs, there are buttons for 'Add Manufacturer', 'Remove Selected', and 'Apply for a New Manufacturer'. To the right, there is a section for 'Principal Manufacturer' with a 'Select a Pi' button. The main area is divided into 'Name and Address' and 'Manufacturer Steps' sections.

27. Click on **Apply for a New Manufacturer** to bring up **Request for entry of a new manufacturer on the TGA Client database** form.

Request for entry of a new manufacturer on the TGA Client database

This email new manufacturer request facility will be sent to the corporate management area of TGA for entry of the manufacturer name and address details into the TGA Client database. The attached or supporting information will be used to help resolve duplicate names or other administrative anomalies. A return email will be used to help resolve any name and address concerns.

The request is for
 Contact person
 Email
 New manufacturer name:
 Manufacturer address:
 Country:

Please attach documentation containing the name and address details to support the administrative request. Up to three separate attachments can be added to this form, but only one is mandatory.

Your application is saved as a draft. Once your new manufacturer has been entered into the TGA Client database, you will receive a return email indicating the manufacturer name is available for inclusion in your application.

28. Complete all of the required fields and attach the requested information.

29. Once completed, select **Send**. Your application will be saved as a draft and processed by us. We will enter the manufacturer into our records, and send you an email indicating your manufacturer is ready to select in your application.

Product tab

Before completing this tab, you need to have selected the **Class of Biological** in the [Registration tab](#). The class of your application will appear automatically on this tab.

This tab is for entering information about your biological, such as:

- formulation
- container
- other vital information

Single or multiple products

If you have a Class 3 or Class 4 biological, you can only have a **single product** entry on the ARTG.

If you have a Class 1 or Class 2 biological, your ARTG entry may contain **multiple products** but only if **all** of the following conditions apply:

- ✓ All the products are regulated under the **same standards**.
- ✓ All products have the **same** intended use.
- ✓ All products are manufactured by the **same principal manufacturer**.
- ✗ Products must not meet the definition of [separate and distinct goods](#).

Each product will need to be added separately following the procedure below.

Product details

30. Select **Add Product** to open the **Product Details** dialogue box and complete all fields.

Product name

31. Enter the proposed name of your biological that you believe is appropriate to appear on the ARTG, applying the principles outlined below.

The structure of the Product name(s) will depend on whether your biological is a tissue or cell therapy. In general, the name will be constructed from applicable product descriptors, reference to whether it is autologous or allogeneic, and then the trade name and/or Sponsor name.

Each product name must be unique.

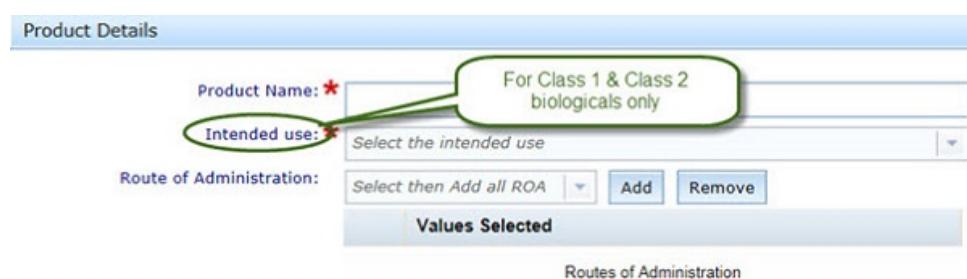
For Class 2 entries, the product name does not appear in the ARTG label name.

For Class 3 and 4 entries, the product name does form part of the ARTG label name.

Guidance on naming of biologicals or the active ingredient and construction of 'product names', is yet to be published. Prior to approval we will work with you to agree on the appropriate product name.

Intended use or indication

32. If you have a Class 1 or Class 2 product, select the most suitable **intended use** from a drop-down list.



Product Details

Product Name: *

Intended use: *

Route of Administration:

For Class 1 & Class 2 biologicals only

Select the intended use

Select then Add all ROA Add Remove

Values Selected

Routes of Administration

What we mean by intended use

For Class 1 and 2 biologicals the term **intended use** is used to reflect the broad clinical use of the product. More information is available in the [dossier requirements](#).

Selecting the intended use for your biological

You should select the **most appropriate** use for your biological. We will discuss this with you during the review process and if required we can make changes and update the list of intended uses to suit your biological.

33. If you have a Class 3 or Class 4 biological, you will be required to complete a free text box titled **Proposed Therapeutic Indication**. We suggest you provide a description of how you intend to use the biological. We will finalise the wording of the indication with you during the review process.



Product Details

Product Name: *

Proposed Therapeutic Indication: *

Route of Administration: *

Alternate field for Class 3 and Class 4 biologicals only

Select then Add all ROA Add Remove

Route of administration

34. Select a **route of administration** from the drop-down list then click the **Add** button, your selection will appear in the **Values Selected** list.

Route of Administration: Intraarterial

Add Remove

Values Selected

Routes of Administration

35. You can enter multiple routes of administration by repeating the above step.

36. You can **delete** a selected **route of administration** by selecting an entry from the **Values Selected** list and clicking the **Remove** button.

Route of Administration: Intraarterial

Add Remove

Values Selected

Intraarterial

Dosage form

37. Select **Dosage Form** from the drop-down menu. If you can't find a suitable option, you may need to select **Not elsewhere classified**.

Formulation details

38. You will need to enter each active ingredient and excipient separately using the **Add Formulations** button.

Formulations: *

Type	Role	Ingredient Name	Qty	Qty Units	Ingredient Info
Formulation Details					
<input type="button" value="Add Formulation"/> <input type="button" value="Remove Selected"/>					

Multiple formulation entries

If you have multiple components in your biological, you will need to use the **Add Formulation** button to enter the details of each ingredient separately in the Formulation Details box (next step). For storage media each ingredient within the solution may not need to be entered.

Combination products

If you have a combination product, such as a regenerative medicine product combined with a matrix, both components should be listed as separate formulation entries. Use the **Add Formulation** button and complete the Formulation Details for each component (next step).

39. The **Add Formulation** button will cause the **Formulation Details** dialogue box to open. Enter all details outlined below, then select **Add to List** to save the information to the **Product Details** section of the form. **Do not** click **Cancel** unless you want to return to the Product Details section without saving any information entered.

Formulation Details

Formulation Type* Active Excipient

Ingredient Role* Standard

Ingredient Name*

Select Quantity Options* Ingredient Quantity Ingredient Quantity Range

Ingredient Quantity* Select the Unit of Proportion

Ingredient Quantity From Ingredient Quantity To

Additional Ingredient Information*

Is this ingredient of animal or* Yes No

Add to List **Cancel**

40. **Formulation Type:** Choose if your entry is for the [active ingredient](#) or for the [excipient](#).

Formulation Type* Active Excipient

41. **Ingredient Role:**

Formulation Type* Active Excipient

Ingredient Role* Standard

Formulation Type* Active Excipient

Ingredient Role* Standard Proprietary Ingredient

- If you are entering an **Active** ingredient, the **Ingredient Role** will default to **Standard**, as there are currently no active ingredients that are proprietary ingredients.
- If you are entering an **Excipient** ingredient, you need to select whether it is a **Proprietary** or **Standard** ingredient. If your ingredient is not a proprietary ingredient, then you should select Standard.

Biologicals with proprietary ingredients

If your biological contains proprietary ingredients, you must supply us with the formulation details before it can be included on the ARTG.

To enter your proprietary ingredient on the ARTG, use the [Notification of a new proprietary ingredient form](#).

Ingredient name

42. To complete the **Ingredient Name**, enter part or the full ingredient name, then click **Search**. Once complete (this should not take more than a few minutes), the number of matches will be shown and you can then **select** the ingredient from the **drop-down** list.

Ingredient Role Standard Proprietary Ingredient

Ingredient Name sodium chloride

Select Quantity Options Ingredient Quantity Ingredient Quantity Range

Ingredient Quantity sodium chloride

New Search

2 matches

a. While the search is in progress, you may stop by clicking **Cancel** and enter a different term.

Ingredient Name sodium chloride

Please wait... loading search results...

Cancel

b. To start a new search, simply click **New Search**.

Ingredient Name sodium chloride

New Search

The [database containing ingredient names](#) can be searched through our website. Only ingredients marked as ACN Category are available in the application form. If you cannot find an ingredient you need, you will need to contact [TGA Names](#) about requesting a new ingredient to be added to our tables.

Quantity options

43. You can choose either **Ingredient Quantity** or **Ingredient Quantity Range**, depending on your ingredient. If your ingredient has a quantity that is 'greater than' or similar units, please enter this information in the **Additional Ingredients Information** text box shown in the next step.

a. Use **Ingredient Quantity** if your product is a single unit or a fixed quantity. Enter the value in the box provided and select the units from the drop-down menu.

Select Quantity Options Ingredient Quantity Ingredient Quantity Range

Ingredient Quantity 1

Select the Unit of Proportion

OR

b. Use **Ingredient Quantity Range** if your product ingredient covers a range. Enter the minimum and maximum values in the boxes provided and select the units from the drop-down menu.

Select Quantity Options Ingredient Quantity Ingredient Quantity Range

Ingredient Quantity From 1

Ingredient Quantity To 20

Select the Unit of Proportion

44. **Additional Ingredients Information:** You can enter any information in this text box that may facilitate our review of your application. For example, you should mention if an ingredient is sourced from more than one supplier and whether the purity varies significantly.

Animal or human origin ingredients

45. Select if your ingredient is of animal or human origin.

Is this ingredient of animal or **human** origin? Yes No

Animal or Human Origin	Species	Tissue	Preparation	Country

Add Animal Origin

Remove Selected

Animal Origin Details

- a. If you select **Yes**, an additional table will appear, as shown below, and you will be required to complete further information.
- b. If your ingredient is of **either animal or human** origin, you need to select **Add Animal Origin** to open the **Animal or Human Origin** box.

Animal or Human Origin

Required Data	
Species: *	<input type="text"/>
Tissue: *	<input type="text"/> Select the Tissue
Preparation: *	<input type="text"/> Select the Preparation
Country: *	<input type="text"/> Select/Add a Country
<input type="button" value="Add"/> <input type="button" value="Remove"/>	
Values Selected	
Animal Origin Country Details	
<input type="button" value="Add to List"/> <input type="button" value="Cancel"/>	

- c. Select the **Species**, **Tissue**, **Preparation** and **Country** from the drop-down menus.
- i. You can enter multiple countries by clicking the **Add** button. This will add the selected country to the **Values Selected** table and you can then select another country by repeating this process.

Country: *

Australia

Values Selected

Animal Origin Country Details

- ii. You can **Remove** a selected country by checking the box for the unwanted entry in the **Values Selected** list and clicking **Remove**.

Country: *

Australia

Values Selected

<input checked="" type="checkbox"/> Australia

d. Use the **Add to List** button to **save** your information and **return** you to the **Formulation Details** box. Cancel will return you to the Formulation details box without saving the information.

Animal or Human Origin

Required Data

Species: *	<input type="text"/>
Tissue: *	<input type="text"/> Select the Tissue
Preparation: *	<input type="text"/> Select the Preparation
Country: *	<input type="text"/> Select/Add a Country

Add to List will close this box and **save** the information to the **Formulation Details**

Add **Remove** **Values Selected**

Animal Origin Country Details

Add to List **Cancel** **Cancel** will exit this box without saving

e. The information you have entered in this section will be added to a table in the **Formulation Details** box as shown below.

Formulation Details

Formulation Type *	<input type="radio"/> Active <input type="radio"/> Excipient																	
Ingredient Role *	<input type="radio"/> Standard																	
Ingredient Name *	<input type="text"/> Skin																	
Select Quantity Options *	<input type="radio"/> Ingredient Quantity <input type="radio"/> Ingredient Quantity Range																	
Ingredient Quantity *	<input type="text"/> 1 <input type="text"/> Unit																	
Additional Ingredient Information *																		
Any other information about this ingredient																		
Is this ingredient of animal or human origin?	<input type="radio"/> Yes <input type="radio"/> No																	
<table border="1"> <thead> <tr> <th>Animal or Human Origin</th> <th>Species</th> <th>Tissue</th> <th>Preparation</th> <th>Country</th> </tr> </thead> <tbody> <tr> <td>Add Animal Origin</td> <td><input type="checkbox"/></td> <td>Human</td> <td>Epithelium</td> <td>Live</td> <td>Australia;</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Animal or Human Origin	Species	Tissue	Preparation	Country	Add Animal Origin	<input type="checkbox"/>	Human	Epithelium	Live	Australia;						
Animal or Human Origin	Species	Tissue	Preparation	Country														
Add Animal Origin	<input type="checkbox"/>	Human	Epithelium	Live	Australia;													
<input type="button" value="Add to List"/> <input type="button" value="Cancel"/>																		

Your **saved** information from the **Animal or Human Origin** box

f. If you want to **remove** an entry from the **Animal or Human Origin** table, use the checkbox to select the unwanted entry and click **Remove Selected**.

Animal or Human Origin	Species	Tissue	Preparation	Country	
Add Animal Origin	<input checked="" type="checkbox"/>	Human	Epithelium	Live	Australia;
Remove Selected					

Save formulation details

46. To save your **Formulation Details**, use the **Add to List** button at the bottom of the dialogue box. This will return you to the **Product Details** box with your formulation details added. If you select **Cancel**, you will return you to the Product Details box **without saving** any information.



Product starting material

If you have used **starting materials of human or animal origin**, even though it is not present in the final product, you **must** tell us.

Examples may include:

- porcine trypsin used to remove adherent cells from cell culture plates
- bovine serum albumen used in buffers
- fetal calf serum used in cell culture media
- feeder cell layers used to support growth of stem cells

47. If you have used material of human or animal origin **during production** that is not present in the final product, you must select **Yes** to the question **Has material of human or animal origin been used that is not present in the final product?**

a. You will then need to complete details by selecting the **Add Starting Material** button.

Has material of human or animal origin been used that is not present in final product? Yes No

Add Starting Material Ingredient Name Ingredient Information

Remove Selected Starting Material Details

Ingredient names - starting material

48. In the **Product Starting Material** box, enter the **Ingredient name** and select **Search**, following the same procedure as described in [Formulation details – Ingredient Name](#).

Product Starting Material

Ingredient Name: *

Additional Ingredient Information: *

Animal or Human Origin: *

Species Tissue Preparation Country

Add Animal Origin Remove Selected Animal Origin Details

49. **Additional Ingredients Information:** You can enter any information in this text box that may facilitate our review of your application, such as, name or description of feeder cells used.

Animal or human origin - starting material

- Enter information on the Animal or Human Origin material, as previously described for the [Formulation Details – Animal or Human Origin Ingredients](#).
- Be sure to **save** entered information by selecting **Add to List**. **Cancel** will return you to the Product Details box **without saving** any information.



Product container details and shelf life

- To enter product container details and shelf life information, select the **Add Product Container** button to open the **Product Container** box.

Product Container Details

Container Type:

Container Material:

Product Shelf Life

Shelf Life Time:

Shelf Life Temperature:

Shelf Life Conditions:

Add **Remove**

Values Selected

Shelf Life Condition Details

Add to List **Cancel**

Product container details

- In the **Product Container** box, select the **Container Type** and **Container Material** from the drop-down menus provided. If you have more than one type of material, select the material that is **primarily** in contact with the product.

Product shelf life

- Enter the **Shelf Life Time** in the text box and select the appropriate **Units** from the drop-down menu. This should be the time the biological product remains fit for use.
- Select the **Shelf Life Temperature** from the drop-down list.
- Shelf Life Conditions** is a mandatory field for Classes 2, 3 and 4 biologicals.

a. Select the **Shelf Life Conditions** from the drop-down menu, then click the **Add** button. This will add the selected condition to the **Values Selected** list. You can select more than one condition by repeating this process.

Shelf Life Conditions: * Protect from X rays

Add Remove

Values Selected

Do not Refrigerate

b. You can remove a selected **Shelf Life Condition** by checking the box for the unwanted entry in the **Values Selected** list and clicking **Remove**.

Shelf Life Conditions: * Protect from X rays

Add Remove

Values Selected

Do not Refrigerate

Protect from X rays

57. **Save** your information by selecting **Add to List**, this will return you to the **Product Details** box. Only select **Cancel** if you want to return to the Product Details box **without saving** any information.



58. **Additional Shelf Life Information** is a free text field you can use to provide any additional information regarded as necessary, such as 'once at room temperature, do not re-freeze and use within 24 hours'.

Bioburden and sterility treatments

In the final section of the **Products Tab** we collect information related to bioburden and sterility treatments.

Has this product been subject to* bioburden reduction? Yes No

Has this product been terminally* sterilised? Yes No

Has this product been aseptically* processed? Yes No

59. **Has this product been subject to bioburden reduction?** You are required to indicate if bioburden reduction processes are applied to your biological.

a. Selecting **Yes** will provide a drop down menu for you to select a burden reduction method.

Has this product been subject to* bioburden reduction? Yes No

Has this product been terminally* sterilised? Yes No

Has this product been aseptically* processed? Yes No

Add to List Cancel

NO
Antimicrobial treatment
Aseptic Handling
Beta Irradiation
Chemical
Dry Heat
Electron Beam Sterilisation
Ethylene Oxide
Filtration
Gamma Irradiation
Gas Plasma Sterilisation
Glutaraldehyde
Heat Killed
NO
Propylene Oxide
Steam
Sterilisation - super critical carbon dioxide

b. Select **No** if this does not apply.

60. **Has this product been terminally sterilised?** You are required to indicate if terminal sterilization is applied to your biological.

a. Selecting **Yes** will provide the same drop down menu as shown in the previous step: select the terminal sterilisation process used for your biological.

b. Select **No** if this does not apply.

61. **Has this product been aseptically processed?** If aseptic processing has occurred during the manufacturing process, subsequent to the initial collection of the biological starting material, select **Yes**; otherwise, select **No**.

Remove selected product

62. To remove a product entered in the **Product Tab**, check the unwanted product and select **Remove Selected Product**. **WARNING** – this will delete all information **without prompting for confirmation**.

Application Registration Manufacturers **Product** Supporting Information Validation

Class 2 Application
This biological application is for: * a single product multiple products

Add Product **Remove Selected Product**

Name
 skin transplant

This will delete all information on the selected item without prompting for confirmation

Supporting information tab

The Supporting Information tab is not currently functional.

All supporting information for **Class 2, 3 or 4 biological** must be submitted separately from this form, according to the:

- [General dossier requirements](#)
- [Dossier requirements for Class 2, 3 and 4 biologicals](#)

There are no additional documentation requirements for **Class 1 biologicals**. If you wish to provide documentation to the TGA in relation to your Class 1 biological application, it can be emailed to bloodandtissues@health.gov.au with the application number in the Subject header.

Validate your application prior to submitting

When you have finished, you need to **validate the form** before you can submit it to us. This will check that all of the information has been included in your application and entered in the correct format.

If there are any issues, you will be provided with a list of them, and each item must be addressed otherwise the form cannot be submitted.

Run validation check

63. **Immediately before** validating your application form, press the **Save** button under the TGA logo, above the tab banner. This will make sure all entries have been saved before validation.



64. To validate your application, select the **Validate** button.

Review errors after validation

65. You will automatically be taken to the **Validation Tab**, where any errors are listed.

Application	Registration	Manufacturers	Product	Supporting Information	Validation
List of validation messages as of last submission for validation.					
Error Message (Contact Name) is mandatory in Application: [REDACTED] Product information is mandatory in Application : [REDACTED] (Product Complies with the following Standard(s)) is mandatory in Application: [REDACTED] (Contact Fax Number) is mandatory in Application: [REDACTED] (Contact Phone Number) is mandatory in Application: [REDACTED] (Contact Email) is mandatory in Application: [REDACTED] (Principal Manufacturer) is mandatory in Application: [REDACTED] Please select Release for Supply on at least one manufacturer.					

66. The error messages in the Validation Tab are hyperlinked to the section of the application form where the error(s) occurred. You can **double-click** on each message to go to the section of the form that requires your attention.
67. You will need to correct each error and re-validate the form before you can successfully submit your application.

68. Re-validate your application by saving it again and using the **Validate** button until you have no errors in the Validate Tab. After the form has validated immediately **Close** the application form; **do not select Save** or it will remove the validation data.

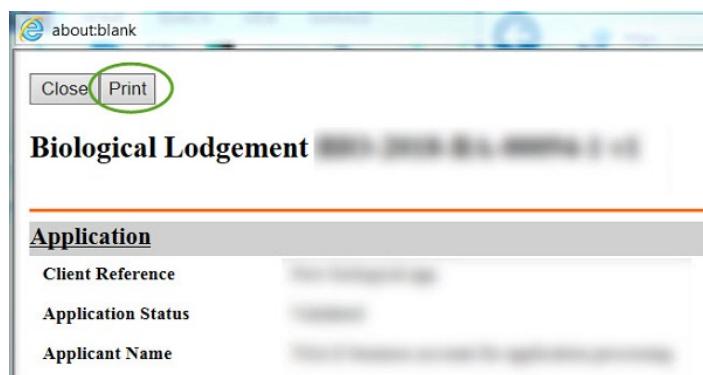
The screenshot shows the TGA eBusiness Services Biological Application interface. At the top, the application ID is BIO-2018-BA-00094-1, and the status is Validated. Below the header, there are buttons for Close, Save, Validate, and Print Preview. The Validate button is circled in green with a checkmark. A callout bubble points to the validation message area, which contains the text: "If no error messages appear, your application has been successfully validated".

After validating – do not save

69. **Do not** use the save button **after** successfully validating your form as this will **delete** all the validation data. Only use the Print Preview or Close buttons if you want to print or exit the form.

Print the form

70. You can print a copy of your application by selecting the **Print Preview** button, next to the Validate button; this will open a new window from which you will be able to select **Print**.



Close the form

71. If you do not want to print your form, you can exit using the **Close** button.

The screenshot shows the TGA eBusiness Services Biological Application interface. At the top, the application ID is BIO-2018-BA-00094-1, and the status is Validated. Below the header, there are buttons for Close, Save, Validate, and Print Preview. The Close button is circled in green.

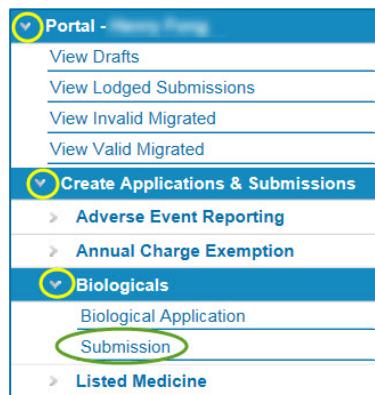
Submitting your application

If you are a submitter, you can submit your application once it has been successfully [validated](#).

You need to **Close** the Biological Application form to submit it, as shown in Step 71.

72. In the menu of TGA Business Services, expand the following menus and then select **Submission**:

- Portal**
- Create Applications & Submissions**
- Biologics - select Submission**



73. This will open the **Biological Submissions** window as shown below.

The screenshot shows the 'Biological Submissions' window. At the top left is the TGA eBusiness Services logo with 'Close' and 'Submit' buttons. The main area has fields for 'Client Name' (with a placeholder 'Select the list...'), 'Applicant Billing Address' (with a placeholder 'Select an address...'), 'Sponsor Name' (with a placeholder 'Select a Sponsor...'), 'Class of Biological' (with a dropdown menu showing 'Class 2'), and 'Invoice Selected Sponsor?' (with radio buttons for 'Yes' and 'No', where 'Yes' is selected). Below this is a table with columns for 'Eligible Applications' (marked with an asterisk), 'Application ID (ver)', 'Prod', 'Spon', 'Spon', 'Class', 'Princ', 'Fee', and 'Appl'. The 'Eligible Applications' column has a dropdown arrow.

74. Your name should automatically populate in the **Client Name** field. Complete the following fields in the **Biological Submissions** window by selecting from the drop-down menus provided for:

- Applicant Billing Address
- Sponsor Name
- Class of Biological

75. **Invoice Selected Sponsor?** If the **Applicant Billing Address** is the same as that of the Sponsor, select **Yes**. If the billing address is different from that of the Sponsor, select **No**.

Select applications to submit

76. A list of your **Eligible Applications** will be visible. Select the application(s) that is ready to submit using the check box. You may need to use the scroll bar to see the check box on your applications list. Only applications that correspond to the **Class of Biological**, selected above, will appear in the list of **Eligible Applications**.

TGA eBusiness Services **Biological Submissions**

Client Name:

Applicant Billing Address: *

Sponsor Name: *

Class of Biological: *

Invoice Selected Sponsor? Yes No

Eligible Applications: *

	Application ID (ver)	Product Name	Sponsor Name	Sponsor Billing	Class Data	Principal Manu	Fee	Application
<input checked="" type="checkbox"/>	1234567890	Product A	Sponsor A	Address A	Class 2	Manufacturer A	Fee A	Application A
<input type="checkbox"/>	9876543210	Product B	Sponsor B	Address B	Class 1	Manufacturer B	Fee B	Application B
<input type="checkbox"/>	5432109876	Product C	Sponsor C	Address C	Class 3	Manufacturer C	Fee C	Application C

Application Re-Validation Errors:

Please Note: Applications selected for submission must:

1. be of the same Class of Biological
2. have the same Sponsor Billing Address
3. have the same Principal Manufacturer undertaking the Release for Supply step
4. Class 1 or Class 2 selections must conform to the same Product Standards
5. Class 3 or Class 4 selections must have the same Active Ingredient

77. You may choose more than one application to be submitted as a single 'submission' where all of the applications selected have the **same**:

- class of biological
- sponsor billing address
- principal manufacturer undertaking the release for supply step
- product standards, for Class 1 or Class 2
- active ingredient, for Class 3 or Class 4.

My application is not visible?

If your application did not validate successfully, or after the validation you saved the application prior to closing it, then it will not appear in the eligible applications.

Declaration

78. To submit your application(s) click the **Submit** button. A **declaration** window will appear, this will differ depending on the class of biological being submitted.

Before submitting your application(s) please read the declaration below and click the **Accept** button to proceed with this Submission; or click on the Decline button to return to the beginning of the Submission process.

I apply to include in the Australian Register of Therapeutic Goods (the ARTG), the biological(s) described in the application(s) in this form and declare that the information provided in this form and in any accompanying documents is, to the best of my knowledge, current and correct.

I declare that I am a person authorised to complete this application form on behalf of the applicant.

I declare that each biological that is the subject of an application in this form is a Class 2 biological in accordance with the definition of "Class 2 biological" set out in regulation 2 of the Therapeutic Goods Regulations 1990.

I acknowledge that criminal and civil penalties may apply under the Therapeutic Goods Act 1989 (the Act) in relation to the making of statements that are false or misleading in or in connection with an application for inclusion of a biological in the ARTG.

I declare that in addition to this form, supporting documents setting out sufficient information to enable the Secretary to fully evaluate the biologicals described in the application(s) in this form in relation to each of the matters listed in section 32(2) of the Act will be submitted in hard copy (set out in a dossier) along with an identical electronic copy of the dossier on CD/DVD. I acknowledge that my application will not be considered to be complete for the purposes of paragraph 32(2)(b) of the Act until the dossier and CD/DVD are received by the Secretary.

PLEASE NOTE: If a biological is included in the ARTG but the Secretary is later satisfied that a statement made in, or in connection with, the application for including the biological in the ARTG was false or misleading in a material particular, the entry of the biological in the ARTG may be cancelled or suspended.

79. After reading through the **Declaration** you can select one of the following options:

- Accept** – if you agree with the declaration.
- Decline** – to return to the **Biologicals Submission** window **without saving** any of the information entered.
- Close** – to return to the **TGA Business Services** portal **without saving** any of the information entered.

Confirmation of application successfully submitted

80. If you choose to accept the declaration and proceed with the submission, the following notice will appear confirming your application has been submitted, together with the details of the submitted application.

Thank You. The Submission of your application(s) has been successful.

Thank you for the submission of your application. Should this application incur a fee, a copy of the invoice will be emailed to you and to the billing contact for the client.

Submitted Application(s):

Please double click on a row to preview and print a Submission document for the data package. This action may also be performed from the Portal in the lodged submissions view.

Application ID	Sponsor Name	Sponsor Billing Address
0000-2010-000-0000-0000-1	Healthier Lives for All of Australia Pty Ltd	Lindfield Plaza 2000 North Ryde NSW 2113

81. Selecting **Close** will return you to the **TGA Business Services**, where you can continue with other work, or exit.

Version history

Version	Description of change	Authors	Effective date
V1.0	Original publication updated with information reformatted for web publishing.	Biological Science Section Regulatory Guidance Team	July 2018
V1.1	Minor edits to integrate Class 1 applications and FMT products	Biological Science Section	June 2021

Therapeutic Goods Administration

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