Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

GMP Clearance questionnaire

Complete this questionnaire **prior** to submitting your GMP clearance application and upload it as part of your evidence package on your TGA ebusiness services portal under 'Other' in the evidence tab where:

- the evidence for a new manufacturing site has either expired, that is more than three (3) years have passed since the last inspection and no more acceptable recent evidence covering the required scope is available, or
- a renewal application is to be submitted and no more acceptable recent inspection has been undertaken of the manufacturing facility.

Section 1 – Sponsor to complete

Sponsor name	
Client ID	
GMP Clearance application tracking number	

1.2 Manufacturing scope

Active Pharmaceutical Ingredient (API): N/A ☐

☐ Sterile/Biotech ☐ Non-Sterile ☐ Sterile/Biotech & Non-Sterile

Finished Product: N/A ☐

☐ Sterile/Biotech ☐ Non-Sterile ☐ Sterile/Biotech & Non-Sterile

Please provide details of the finished product manufacturers / GMP Clearances relevant to the supply chains for the API's nominated in the clearance application scope.

API	Product name	Finished Product Manufacturer	GMP Clearance

1.3 Validation Master Plan

Where clearance application scope is non-sterile, provide the latest Validation Master Plan where new or modified equipment are used for products supplied to the Australian market.

Validation Master Plan attached Yes ☐ No ☐

Declaration

In signing this form, I, as the sponsor/agent acting on behalf of the sponsor, declare that the information contained within Section 1 is true and accurate.

Name			
Signature		Date	

Section 2 – Manufacturer to complete

The following questions are to provide information about the compliance status of the manufacturer and changes to the site **since the last inspection by a recognised regulatory authority**.

Date of last inspection	
Regulatory authority	

1 – Site and Personnel Details

	Site details	Details have changed since last inspection
Manufacturer name		☐ No ☐ Yes – Date of change*
Full address of manufacturing site		☐ No ☐ Yes – Date of change*

*Provide reason for the change

1.2 Have there been any key organisational changes to personnel at the site since the last inspection e.g. change of production manager, change of quality manager, change of site manager (senior person on site)? Please provide details of changes below:

1.3 Has there been any significant change in total personnel numbers (permanent and/or temporary) not outlined within the Site Master File provided and have there been any announced personnel redundancies or termination of long term or embedded contract personnel?

(i.e. indicating downsizing of the operation). Significant addition of staff to meet an upturn in demand should be reported particularly where this equates to around a 10% increase or more and particularly where temporary staff will be used to fill the shortfall.

Company Ownership/ Structure or Status

1.4 Has there been any change of ownership of the site or change of position or role of the site in the wider organisation e.g. site sale or company merger or takeover, organisation restructured and site or QA lead reporting through different group or person?

1.5 Please confirm which buildings manufacture products for the Australian market. Please advise if these buildings are used to manufacture product for other markets, and which markets product is supplied to.

2 – Materials Handled and Non-Therapeutic Product Manufacture

2.1 Does the site currently manufacture or handle medicines containing anti-neoplastics, immunosuppressants, hormones, steroids, penicillins, vaccines, toxic substances, biological agents, gases and/or other hazardous materials?

Where this information is included within the Site Master File, provide page number _____

☐ No

☐ Yes– Please provide details of the materials handled below

2.2 Does the site currently manufacture non-therapeutic products, for example, veterinary products, food, cosmetics, etc.? In particular has the site engaged in the manufacture of insecticides, herbicides or animal poisons?

Where this information is included within the Site Master File, provide page number _____

☐ No

☐ Yes– Please provide details of the non-therapeutic products below

2.3 Does the site operate different Quality systems for different product types manufactured?

Where this information is included within the Site Master File, provide page number _____

☐ No

☐ Yes– Please provide details of the quality systems below

2.4 Has there been an increase in the production of any products, which has resulted in the use of additional lines or reassigning existing lines for the manufacture of this product. If yes, provide details of which products and how significant the increase has been.

2.5 Have there been any outsourcing activities or bringing back in-house previously outsourced activities directly related to production or Quality Control?

3 – Subcontracting

3.1 Have any new sub-contractors been added which are not referenced within the Site Master File or GMP Agreement relevant to product supply into Australia?

☐ No

☐ Yes – Please provide details of the subcontract.

Step Sub-contracted	Dosage form(s)	Sub-contractor

3.2 Please specify if there are any comments for this section:

4 – Deviations

4.1 Please summarise any Critical or Major deviations that have occurred, including out of specification and out of trend results, rejected batches, media fill or sterility failures and the status of each root cause investigation and Corrective and Preventative action since the last inspection:

Deviation	Current status	Comments

4.2 Please summarise the status of each Corrective and Preventative Action agreed with the Inspector following the last inspection by a recognised regulator:

Inspection date	

Deficiency	Corrective and Preventative Action Agreed	Current status	Comments	Has an effectiveness review been completed, if yes provide date

4.3 Other changes, quality or compliance issues to be notified.

Any other changes or issues that the site believe may indicate a step change in the sites risk to product quality or of being non GMP compliant, producing defective batches or affecting patient safety.

Section 5 – Facility Changes

Facilities/Equipment

5.1 Has any construction work been undertaken, or is any construction work currently being carried-out or planned for the manufacturing site?

☐ No

☐ Yes – Please provide the details and dates for this construction.

5.2 Have there been any changes in the following areas? If yes, provide details in Change details table.

Change	Response
Change in building use	☐ No ☐ Yes
Expansion of buildings / manufacturing areas	☐ No ☐ Yes
Major refurbishment of buildings	☐ No ☐ Yes
Major refurbishment of utilities	☐ No ☐ Yes
Major renovations requiring requalification	☐ No ☐ Yes
New equipment	☐ No ☐ Yes
Modified equipment	☐ No ☐ Yes
New technology (equipment)	☐ No ☐ Yes
New IT or computerised systems	☐ No ☐ Yes
Modified IT or computerised systems	☐ No ☐ Yes

5.3 Change details table:

Change description including building or room number	Type of Qualification performed	Status of Qualification	Date commenced	Date completed

6 - Anticipated changes

Please advise any changes that are anticipated to happen within a period up to two years. It is expected that these may not be confirmed changes and that information reported will be the best available at the time.

Declaration

In signing this form, I, as a representative of the manufacturer, declare that the information contained within Section 2 is true and accurate.

Name			
Signature		Date	