Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
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>.

Inspection feedback form – Interpretation of requirements

Please note

The terms 'inspection' and 'inspector' are synonymous with the terms 'audit' and 'auditor' used by the Medical Devices Branch.

Important notice

This form is intended to provide the TGA with comments about the interpretation of the Manufacturing Principles, Code of GMP, ISO 13485, conformity with the Essential Principles, and the legislative framework. Feedback received will be used to assess the consistency of inspectors' interpretations and assist in our training programs.

Feedback received in this form will not be treated as a complaint. If you wish to lodge a complaint, please follow the Inspection & inspectors complaint process

It is necessary for the purposes of continuous improvement to identify both the manufacturer and the inspector(s) involved. These details will be kept strictly confidential and will be de-identified for training purposes and/or any corrective action.

For information about how your personal information is protected under the *Privacy Act 1988* please go to <https://www.tga.gov.au/privacy>.

Part 1: Manufacturer and inspection details

Manufacturer			
Address of manufacturing premises			
Date of inspection(s)		**Inspector(s) names**	

☐ Please provide me with a reply.

☐ No reply is required.

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TGA Health Safety Regulation

Name		Position	
Signature		Date	

The TGA thanks you for your comments.

Part 2: Interpretation of GMP/QMS requirements

Describe the situation(s) where you believe the inspector(s) did not correctly interpret the requirements of the Manufacturing Principles, Code of GMP or ISO standard, Essential Principles and/or the regulatory framework. You should provide as much detail as possible and explain why you believe the practice or process (leading to a deficiency or nonconformity) should have been interpreted differently. Add additional pages if required.

Comments:

	Yes	No
Did the interpretation lead to a critical or major deficiency/nonconformity?	☐	☐
Was the deficiency/nonconformity included in the items for discussion provided to you at the conclusion of the inspection?	☐	☐
Did the inspector clearly explain the rationale for the deficiency/nonconformity?	☐	☐
Did you have the opportunity to discuss your views?	☐	☐