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Nelson Labs
A Sotera Health company

TGA GMP Clearance Extension and Inspection Process

Dear Sponsor,

Nelson Labs remains committed to supporting our sponsors' continued access to the Australian market and maintaining compliance with applicable regulatory requirements. As part of this commitment, Nelson Labs operates in accordance with Good Manufacturing Practices (GMP) principles, including those within the TGA GMP framework.

Please be advised that the Therapeutic Goods Administration (TGA) requires Australian sponsors to initiate requests related to GMP Clearance extensions and inspection scheduling and coordinate with the TGA regarding inspection requirements. As a contract testing laboratory, Nelson Labs cannot directly request or initiate a TGA re-inspection on behalf of sponsors.

For sponsors seeking to maintain an active GMP Clearance while awaiting inspection, the TGA advises extension requests to be submitted through the TGA Business Services portal when eligibility requirements are met and using the reason "Awaiting TGA Inspection".

Sponsors seeking advice regarding their specific GMP Clearance, including eligibility for an extension application, or inspection-related requirements should contact the TGA GMP Clearance Team for guidance.

Additional TGA resources may be found at the following links:

- GMP Clearance: Extension processing times
- Sponsor responsibilities related to GMP clearance and certification

Nelson Labs fully supports the TGA inspection process and welcomes the opportunity to host a TGA inspection when scheduled by the agency. We are committed to working collaboratively with customers and TGA representatives to facilitate inspection activities and support regulatory compliance needs.

For further questions, please contact QualityAudits@nelsonlabs.com.

Sincerely,

Signed by:
Kevyn House
Signer Name: Kevyn House
Signing Reason: I approve this document
Signing Time: Nov 9, 2026 | 11:02 AM MST
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