Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Mr Rob Thoreson
Director of Quality Assurance
Nelson Laboratories LLC
6280 South Redwood Road
Salt Lake City UT
United States Of America

TGA Reference: 2014/047975

Subject: Issue of GMP certificate MI-2019-CE-11409-1

Dear Mr Thoreson,

Please find enclosed the GMP certificate for your manufacturing premises.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely,

Signed and authorised by

Frances Harding
Senior GMP Inspector
Manufacturing Quality Branch

03 June 2025

Contact: GMP@health.gov.au, Phone: 1800 020 653

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-CE-11409-1

Issued to:

Nelson Laboratories LLC

Manufacturing Site Address:

6280 South Redwood Road
Salt Lake City Utah
United States Of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following Section 32EA(1) of the *Therapeutic Goods Act 1989* in connection with manufacturers of Biologicals (items made from or containing human cells or human tissues) located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 05 to 07 March 2024, it is considered that the manufacturer complies with the Good Manufacturing Practice (GMP) requirements of the Australian Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products (2013).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

Issue Date: **03 June 2025** **Expiry Date:** **07 September 2026**

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2019-CE-11409-1

MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Manufacturing Step
Testing Laboratory – Blood Tissue Cellular	Product Microbial Contamination Testing Identity of Organism

The following limitations are applicable to these manufacturing operations:

The certificate is restricted to sterility testing, including bacteriostasis and fungastasis testing.

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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TGA Health Safety Regulation