Nelson Labs
A Sotera Health company

02 Feb 2022

Regulatory Inspection History, GMP and GLP Compliance, and Debarment Statement

Dear Sponsor,

Nelson Laboratories (NL), LLC located at 6280 South Redwood Road, Salt Lake City, UT 84123, is audited by the U.S. Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), the European Medicines Agency (EMA), and the Australian Government Therapeutic Goods Administration (TGA) according to current good manufacturing practices (GMP), good laboratory practices (GLP), and good tissue practices (GTP), as applicable. We are also currently ISO 17025:2017 accredited by the ANSI-ASQ National Accreditation Board (ANAB) as a testing laboratory.

We certify that the facility, tests, and controls that are used in the analysis of your products are in compliance with the following:

- Current Good Manufacturing Practices, as codified in 21 CFR 210/211 and 820
- Current Good Tissue Practices, as codified in 21 CFR 1270/1271
- Current Good Laboratory Practices, as codified in 21 CFR 58 or 40 CFR 160, when requested
- Current E.U. and TGA Good Manufacturing Practices

5 Year Regulatory Inspection History

FDA:			**EPA:**		
2016	22-26 Feb	CDRH, CVM, CDER, CBER	2016	28 Jun	GLP
2016	04-08 Apr	BIMO	**EMA:**		
2016	12-15 Apr	CBER	2016	27-29 Sep	EU GMP (DMA)
2018	21-23 Feb	CBER	2021	21-24 Sep	EU GMP (DMA)
2018	27-30 Mar	CDER	**TGA:**		
2021	03-09 Nov	CBER	2018	17-18 Dec	Tissue GMP

Pursuant to Section 306(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 D.S.C. 335a (k), as amended by the Generic Drug Enforcement Act of 1992 (GDEA), NL certifies that it did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) of the Generic Drug Enforcement Act of 1992. No person employed by NL has currently or in the past five (5) years been convicted of any crime described in Sections 306 (a) or (b) of the Generic Drug Enforcement Act of 1992. NL has not been debarred by the FDA and is not currently involved in any debarment proceeding with the FDA.

Nelson Laboratories received an FDA warning letter in 2004. Since that time, no warning letters or any other regulatory actions have been issued against Nelson Laboratories.

Sincerely,

DocuSigned by:
Robert Thoreson
Signer Name: Robert Thoreson
Signing Reason: I approve this document
Signing Time: Feb 4, 2022 | 2:46 PM MST
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Rob Thoreson
Director of Quality Assurance
801-290-7618
RThoreson@nelsonlabs.com