

December 3, 2018

Dear Valued Customer,

We recognize that our customers are facing increased competition and ever-growing demands to get their products to market quickly and cost effectively. As these demands on you continue to change and grow, we at Nelson Labs are determined to grow and improve to help you meet these demands. As part of our strategy to meet our customers' needs, we have expanded our laboratory presence globally. We are excited to say that Nelson Labs now has a network of 13 lab locations in eight countries that are working together to meet the needs of our customers worldwide. Eight of these locations are conveniently collocated with a sterilization facility. Five of these laboratories are standalone facilities that are ready to perform expanded mission-critical testing to meet all of your needs.

As an added benefit to our customers, we have initiated a program to assess and qualify each of the Nelson Labs facilities for our customers. Each location will be assessed to our quality standards following strict ISO 17025 requirements and applicable GMP regulatory expectations for a testing laboratory. This means that you can rely on each qualified location and know that the same strict quality and regulatory standards apply to each of our labs—without the need to audit each location. The advantages of this process to you are:

- Nelson Labs maintains a high level standard of quality throughout its entire laboratory network which provides customers with increased flexibility.
- Customers will have access to the same trusted contacts, experts and quality oversight while using any of our locations.
- Utilizing multiple Nelson Labs locations will help provide testing backup locations, redundancy and increased capacity. In the case of maintenance shutdowns, natural disasters, increased demands on capacity, customers will have options.
- The ability to shift testing from one lab to another during times of full capacity will help to improve testing turnaround times.
- Utilizing a laboratory that has closer proximity may help to reduce costs and turnaround times.

As part of the qualification process, we have compiled a packet of information and documents for your use and internal qualification process. This qualification packet includes the following:

- **Scope of Site Qualification.** Documents the requirements met during the evaluation by the Nelson Labs Quality team.
- **Site Qualification Assessment Summary.** Stating when the on-site assessment was performed by the Nelson Labs Quality and Regulatory team, to what standards the assessment was performed, and if the lab meets these standards and quality requirements.

6280 S. Redwood Road

Salt Lake City, UT 84123

801-290-7500 | nelsonlabs.com



- **Site Certificate of Qualification.** Certifying that the quality system of the lab meets Nelson Labs standards as defined in our Quality Manual—MAN0001 Rev. 16.
- **Site Quality Information Matrix.** Quality, business, and location-specific information to help answer your questions concerning each location is available [HERE](#) on the Nelson Labs website.

We constantly strive to maintain the scientific, quality, and regulatory expertise internally to support your global laboratory testing needs. Our experts can assist with advising on test setup and coordinating the required testing within our global network of labs. We welcome the opportunity to speak with you about how our global network of labs will be able help you meet your testing needs.

Please reach out to your sales representative for more information, or contact me directly if you have questions about Nelson Labs quality. We appreciate your business and continued partnership to help safeguard global health.

Sincerely,

A handwritten signature in black ink that reads "Matt Cushing". The signature is written in a cursive style.

Matthew D. Cushing
Senior Director Global Quality
MCushing@nelsonlabs.com
801-290-7692

CERTIFICATE

OF QUALIFICATION

Nelson Laboratories, LLC
1500 West Thorndale Avenue
Itasca, IL 60143

An evaluation was performed on the above site according to Nelson Labs procedures for On-site Supplier/Subcontractor Audit Process - SOP0159 Rev 4. Nelson Labs (NL) certifies that the quality system meets company standards as defined in the NL Quality Manual – MAN0001 Rev 16.

Please refer to the accompanying Scope of Evaluation for information detailing the evaluation criteria and methods for continuous monitoring of the site to assure continued compliance.



Matt Cushing, Senior Director Global Quality

SCOPE OF SITE QUALIFICATION

Nelson Laboratories, LLC
1500 West Thorndale Avenue
Itasca IL 60143

Has been evaluated by the Nelson Labs quality team and found to meet the requirements of the following:

| | |
|--|---|
| <p>cGMP - FDA FEI #3000717698</p> | <ul style="list-style-type: none"> • Evaluated to general requirements of CFR 210, 211, 820 and 1271 Subpart D (Drug/Device/Tissue) for a testing laboratory. • Most recent FDA inspection was reviewed – corrections were verified to be complete and satisfactory. |
| <p>ISO 17025 – ANAB Certificate # AT-2490</p> | <ul style="list-style-type: none"> • Evaluated through ANSI-ASQ National Accreditation Board. • Evaluated through NL internal audits procedure – SOP0103 which is performed annually to all applicable causes of ISO 17025. • Evaluated during the assessment according to SOP0106 requirements according to FRM0205 |
| <p>NL Quality Manual MAN0001 Rev 16</p> | <ul style="list-style-type: none"> • Evaluated through assessment performed Aug 2018 • Site complies with and is trained to MAN0001 which details the quality policy and quality requirements of NL. Also continually monitored through NL Management Review – SOP0099. |
| <p>Continuous Monitoring Activities</p> | <ul style="list-style-type: none"> • Monitored through NL internal audits procedure – SOP0103 which is performed annually to all applicable clauses of ISO 17025. • Monitored through NL Management Review procedure – SOP0099 which provides periodic trend and metric review including quality performance to set goals. |

Valid to: 31 Dec 2020

Site Qualification Assessment Summary

Assessment Summary: An on-site assessment was performed on 29-30 Aug 2018 to evaluate compliance with the following:

- CFR 210, 211, 820 and 1271
- ISO 17025:2005
- Nelson Labs (NL) Quality Manual – MAN0001 and quality policy

Purpose: The assessment was performed to determine the qualification status of the site based on the industry regulations and the high quality standards that Nelson Laboratories expects from qualified suppliers, subcontractors and its own testing labs.

This assessment was also performed on your behalf to determine if the site meets the high quality standards and regulatory requirements to perform testing as a qualified supplier for you and to assure you that Nelson Labs quality standards are maintained at this site.

Conclusion: APPROVED

As a result of this assessment the NL facility located at 1500 W. Thorndale Ave in Itasca, IL is considered **APPROVED** for full use of services. The Itasca location meets and/or exceeds the requirements of the NL quality manual (MAN0001), the NL supplier management program (SOP0106), as well as the applicable CFRs and ISO standards for a quality management system.

This documented approval is intended to be used as qualification documentation for your files in order for you to fulfill internal requirements for qualification of facility as a laboratory testing provider.

Ongoing Monitoring: In addition to meeting the requirements for qualification the Itasca location is continuously monitored for quality performance through regular reporting/oversight, internal audits and management review.

Evaluation date: 29-30 Aug 2018

Site evaluation performed by: Matt Cushing, Senior Director Global Quality



Matt Cushing, Senior Director Global Quality