Qalitex Laboratories Offers GMP Consulting for 21 CFR Part 111 Quality System Development

GMP Consulting Supports FDA Audits, SOPs, Testing, and GMP Readiness for Supplement Manufacturers

IRVINE, CA, UNITED STATES, March 17, 2026 /EINPresswire.com/ -- Qalitex Laboratories, an ISO 17025-accredited testing laboratory with GMP consulting capabilities serving dietary supplement manufacturers across California and North America, today outlined the core components of a 21 CFR Part 111-compliant quality system and common gaps identified during FDA cGMP inspections.

FDA's current Good Manufacturing Practice regulations for dietary supplements, codified in 21 CFR Part 111, set minimum quality standards that all supplement manufacturers must meet. The regulations cover facility design, equipment qualification, raw material testing, in-process controls, finished product testing, batch record documentation, and complaint handling. Compliance applies to all manufacturers, including contract manufacturers, private label brands, and importers.

Inspection data shows recurring cGMP violations in supplement manufacturing facilities. Common observations include:

Incomplete or outdated written procedures for laboratory operations

Failure to conduct identity testing on all incoming ingredients

Inadequate batch production records

Lack of established specifications for raw materials and finished products

“The pattern we see most often is a manufacturer has a quality system on paper that looks complete, but the written procedures don’t reflect what happens on the floor,” said Nour Abochama, Vice President of Operations at Qalitex Laboratories. “FDA investigators identify that gap quickly. A mock audit is valuable because it tests both documentation and practice, giving manufacturers time to address gaps before an actual inspection.”

Qalitex’s GMP Consulting Program begins with a cGMP gap analysis, evaluating the manufacturer’s existing quality system against 21 CFR Part 111, identifying deficiencies, and prioritizing corrective actions by regulatory risk. This is followed by a mock FDA inspection, conducted using FDA protocols, with a written report detailing observations and recommended corrective actions.

A core component of the program is SOP development. Qalitex provides a library of 21 CFR Part 111-compliant SOP templates covering laboratory operations, raw material receiving and testing, in-process controls, finished product testing, batch record documentation, equipment cleaning and maintenance, environmental monitoring, and complaint handling. SOPs are customized to the manufacturer’s operations and aligned with current FDA expectations.

For manufacturers seeking NSF GMP certification — a third-party program recognized by major retailers and Amazon — Qalitex’s GMP Consulting Program includes pre-assessment mock audits and corrective action support. Retailers including Whole Foods Market, Costco, and Target require GMP certification or equivalent documentation from supplement suppliers.

“Brands that invest in their quality systems proactively can respond quickly when retailers or Amazon request compliance documentation,” said Abochama. “Brands that wait until a problem arises spend significantly more time and resources correcting issues. A well-designed quality system is a competitive advantage, enabling brands to meet regulatory and retailer expectations efficiently.”

Resources:
Full article: https://qalitex.com/services/gmp-consulting/

About Qalitex Laboratories
Qalitex Laboratories is an ISO 17025-accredited third-party analytical testing laboratory with facilities in Irvine and San Diego, California. The laboratory provides certificate of analysis (COA) testing, heavy metal analysis by ICP-MS, microbiology testing per USP <61> and <62>, preservative efficacy testing, stability studies under ICH guidelines, and regulatory compliance support for dietary supplement brands, cosmetic companies, and consumer goods manufacturers. Turnaround times start at 48 hours for standard panels. Testing programs meet 21 CFR Part 111, California Proposition 65, Amazon supplement compliance requirements, and Health Canada NHP Directorate standards.

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