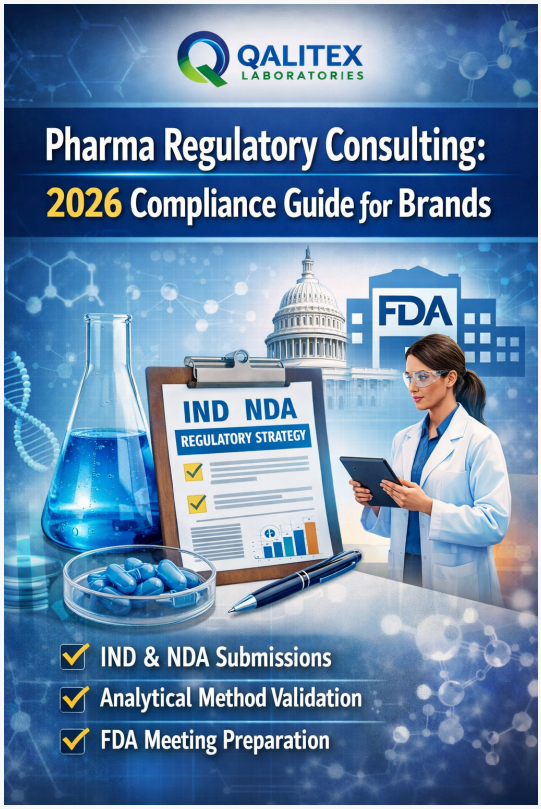
Pharma Regulatory Consulting: 2026 Compliance Guide for Brands

Pharmaceutical regulatory consulting for drug developers and CROs: IND CMC, method validation, NDA strategy, and FDA Type B support.



IRVINE, CA, UNITED STATES, April 1, 2026 /EINPresswire.com/ -- Qalitex Laboratories, an ISO 17025-accredited testing laboratory with pharmaceutical regulatory consulting expertise, today highlighted its suite of services for drug developers and biotech companies navigating IND applications, NDA submissions, and FDA meeting strategy. By combining integrated laboratory testing with regulatory consulting, Qalitex helps accelerate regulatory timelines and reduce the risk of delays.

“Pharmaceutical development involves multiple regulatory touchpoints, from IND application to NDA submission,” said Nour Abochama, Vice President of Operations at Qalitex Laboratories. “Our integrated approach ensures drug developers have both the testing data and regulatory guidance needed to meet FDA expectations efficiently.”

Key Pharmaceutical Regulatory Consulting Services

IND Application Support: Qalitex provides guidance and testing support for the CMC section of IND submissions, including stability studies, analytical method validation, and manufacturing process documentation—critical elements for avoiding FDA clinical holds.
FDA Type B Meeting Preparation: Pre-IND, end-of-Phase 2, and pre-NDA meetings are pivotal milestones. Qalitex helps prepare briefing documents, frame questions for FDA, and anticipate regulatory feedback.
NDA Regulatory Pathway Analysis: The team evaluates the optimal pathway for each drug candidate—covering 505(b)(1), 505(b)(2), and 505(j) submissions, clinical data needs, CMC documentation, and projected timelines.
CMC Strategy for Contract Manufacturing: For developers working with third-party

manufacturers, Qalitex advises on manufacturing process development, analytical method strategy, stability program design, and regulatory documentation review.

“Time-sensitive regulatory milestones—IND filings, pre-NDA meetings, or responding to a Complete Response Letter—require immediate, expert guidance,” Abochama added. “Our practice ensures developers can meet FDA deadlines with confidence.”

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

Resources:
Full article: Pharmaceutical Regulatory Consulting Services

Nour Abochama
Qalitex Laboratories
+ +1 949) 881-6661
email us here
Visit us on social media:
LinkedIn
Instagram
Facebook
