Qalitex Warns of Compliance Risks from Undocumented Temperature Excursions During Distribution

Qalitex urges brands to document temperature excursions in transit, warning of rising regulatory demands for real-world stability validation.

IRVINE, CA, UNITED STATES, June 27, 2025 /EINPresswire.com/ -- As regulatory scrutiny increases over product quality throughout the entire supply chain, Qalitex Laboratories is drawing attention to a growing compliance concern: insufficient documentation of temperature excursions during transportation and storage.

The California-based laboratory, known for its stability testing services, reports a steady rise in inquiries from personal care and cosmetics brands aiming to strengthen their stability programs in light of transit-related thermal fluctuations.

> “Regulators want proof your product survives the journey. If you’re not tracking temperature shifts in transit, you’re gambling with shelf life and compliance.”
>
> *Nour Abochama, Vice President for Operations at Qalitex*

Temperature excursions—defined as instances when a product is exposed to conditions outside its validated storage range—are being noted more frequently in regulatory audits, including those conducted by the U.S. Food and Drug Administration (FDA).

International submissions, particularly in warmer regions, are also placing greater emphasis on how distribution environments are managed and verified. Undocumented temperature deviations during transit may raise concerns about product quality, especially when physical or chemical stability is affected.

“Waiting for an audit to highlight this issue can expose brands to unnecessary risk,” said Nour Abochama, Vice President of Operations at Qalitex.

“A comprehensive stability program includes visibility beyond the lab. If a product is not evaluated under real-world conditions, regulators may question the reliability of its shelf-life claims.”

Distribution Conditions Are Now Part of the Stability Profile
Standard stability testing protocols typically include ambient and accelerated studies under controlled laboratory settings. However, regulatory expectations are evolving to include consideration of transportation environments—particularly for products sensitive to heat, humidity, or light.

Abochama notes that some manufacturers mistakenly assume packaging validation alone is sufficient. In reality, the product’s entire journey—from the warehouse to the final point of sale—is now regarded as a critical phase in the stability lifecycle. Delays in delivery, exposure to warehouse heat, or multi-zone climate shipping can all contribute to temperature deviations that affect product consistency.

Documentation Gaps May Delay Registrations or Trigger Re-Testing
Qalitex’s internal review of over 70 stability programs conducted over the past year showed that fewer than one-third included documentation related to transit simulation or actual thermal data during distribution. In several cases, regulators requested additional information or raised questions about shelf-life verification due to the absence of temperature handling data.

Such documentation gaps can also pose challenges on e-commerce platforms, where quality complaints—such as changes in texture or product separation—can lead to compliance flags, removal from listings, or requests for further data on distribution stability.

“When platforms or retailers ask for additional shelf-life justification, they may not use the word ‘stability,’” Abochama explained. “But the concern is clear: they want to understand how your product holds up once it leaves the lab.”

Global Guidance Emphasizes Transit Verification
International regulatory frameworks are reinforcing this shift. ICH Q1A(R2) offers guidance on stability testing for new drug substances and products, including storage conditions and data requirements. Meanwhile, distribution-specific regulations such as Good Distribution Practice (GDP) in the European Union emphasize the importance of maintaining quality throughout transit.

In regions like Southeast Asia, the Middle East, and India, local authorities increasingly require evidence that products remain stable under region-specific conditions. Brands expanding into these markets may need to provide data that aligns with local climate realities, and in some cases, conduct additional studies.

Qalitex Services Designed for Real-World Distribution Scenarios
To support compliance in this evolving regulatory environment, Qalitex offers custom protocols that replicate common thermal excursion scenarios. These protocols may include:

Thermal mapping of the supply chain from production to final delivery
Data logging using real-time temperature monitoring devices
Excursion stress testing in controlled environmental chambers
Documentation packages tailored to FDA, ICH, and local regulatory standards
Packaging resilience assessments to evaluate thermal mitigation

“Our testing reflects what actually happens during transit,” Abochama said. “We help brands prepare scientific documentation that can withstand audits, retailer reviews, and registration requirements.”

These services are increasingly sought after by both established companies and smaller enterprises, particularly those outsourcing warehousing or shipping. Limited visibility across the supply chain can make it harder for such organizations to detect temperature-related issues early.

Poor Thermal Planning Can Interrupt Market Access
Qalitex has supported multiple companies facing delays in product registrations abroad due to incomplete distribution documentation. In several cases, temperature excursion data helped prevent the need for revalidation or relabeling of product shelf life.

“Even a single excursion during a trial shipment can highlight gaps in your quality program,” Abochama said. “Without clear records, regulatory authorities may require you to repeat studies or rework your documentation.”

For more information about Qalitex’s services or for regulatory support, visit www.qalitex.com.

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