

# Qalitex Highlights Importance of Real-Time Stability Testing in Post-Market Surveillance

*Qalitex urges brands to use real-time stability data in post-market checks, warning accelerated studies alone may not reflect true shelf-life.*

IRVINE, CA, UNITED STATES, June 20, 2025 /EINPresswire.com/ -- [Qalitex Laboratories](https://www.QalitexLaboratories.com/), a provider of scientific testing and regulatory support services, is advising dietary supplement and cosmetic brands to revisit their post-market quality assurance strategies by incorporating real-time [stability testing](#) programs.

While accelerated stability studies are commonly used for estimating product shelf life prior to launch, Qalitex Labs emphasizes that real-time stability data—collected under actual storage conditions over the full duration of a product’s shelf life—is critical for long-term compliance, consumer safety, and regulatory defensibility.

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Post-launch, your product’s story isn’t over. Real-time data shows whether it truly holds up—on real shelves, in real time, for real people.”

*Nour Abochama, Vice President for Operations at Qalitex*

## Why Real-Time Stability Matters Beyond Initial Shelf-Life Validation

Stability testing is a regulatory requirement in both the dietary supplement and [cosmetics sectors](#), designed to demonstrate that a product maintains its identity, strength, quality, and purity throughout its labeled shelf life. However, in practice, many brands rely heavily on accelerated stability data, particularly when facing tight product launch timelines.

Accelerated studies are designed to simulate long-term effects using elevated temperature and humidity conditions. While valuable for predicting



trends, they do not always reflect how a product behaves under real-world storage scenarios.

Qalitex warns that without a parallel real-time stability program, brands may lack critical data to support shelf-life claims during post-market reviews—especially if complaints, inspections, or regulatory inquiries arise months or years after initial release.

“Real-time stability data isn’t only a technical formality,” said Nour Abochama, Vice President for Operations at Qalitex. “It’s the foundation for verifying that products continue to meet safety and quality expectations throughout their commercial lifecycle.”

#### Growing Regulatory Emphasis on Post-Market Quality Monitoring

Regulators in both the U.S. and international markets have expanded their focus on post-market surveillance. This includes requests for ongoing data to support product safety and efficacy after launch, particularly when consumer complaints, adverse events, or label discrepancies are reported.

For dietary supplements, the U.S. Food and Drug Administration (FDA) may request evidence during inspections or compliance reviews to demonstrate that shelf-life claims remain valid throughout the distribution window. Brands without up-to-date real-time stability data may find themselves unable to support those claims.

Cosmetic products face similar scrutiny, especially when formulated with natural extracts, active botanicals, or preservative systems that degrade over time. Real-time data can help demonstrate microbial stability and preservative effectiveness under ambient conditions across the product’s full shelf life.

Qalitex Labs notes that an absence of real-time data may not trigger immediate enforcement but could pose issues during inspections, litigation, or international regulatory filings where long-term product performance is assessed.

#### Implications for GMP Compliance and Product Recall Risk

Under current Good Manufacturing Practice (cGMP) regulations, firms are required to establish a written testing program that ensures a product meets its specifications throughout its shelf life. This includes maintaining adequate documentation to support expiration dating.

Qalitex points out that reliance on predictive models or accelerated data alone may fall short of these requirements, particularly if product composition, packaging, or supply chain conditions change post-launch.

Without real-time testing, brands may also face increased vulnerability to consumer dissatisfaction, product returns, or recalls if the product deteriorates in ways not predicted by pre-market data. Examples include:

Loss of active ingredient potency in supplements  
Preservative failure in personal care products  
Phase separation in emulsions  
Color, odor, or texture shifts under typical storage

Real-time data provides early detection of such issues and helps companies respond proactively rather than reactively.

### Challenges and Misconceptions Slowing Real-Time Program Adoption

Despite its value, real-time stability testing remains underutilized. One factor, Qalitex notes, is the perception that it is resource-intensive and offers limited immediate return, particularly for fast-moving consumer goods with shorter shelf lives.

Some companies also assume that passing accelerated studies negates the need for real-time monitoring. However, Qalitex cautions that accelerated conditions may not reveal certain degradation pathways, especially for complex or novel formulations.

Another misconception is that real-time studies are only relevant during initial product development. In reality, they are a crucial component of ongoing quality assurance, particularly for high-volume SKUs, regulated exports, or products with frequent formulation updates.

### Integrating Real-Time Stability Into Post-Market Quality Systems

To address these gaps, Qalitex recommends that brands integrate real-time stability testing into their routine post-market surveillance systems. This includes:

- Selecting representative product lots for long-term monitoring
- Storing samples under typical warehouse and retail conditions
- Periodically testing key attributes (potency, microbial load, organoleptics)
- Aligning testing intervals with labeled shelf-life periods (e.g., 0, 3, 6, 12, 24 months)
- Documenting all data for regulatory and internal audit readiness

For smaller or emerging brands, Qalitex notes that even limited real-time programs covering top-selling SKUs can provide meaningful compliance value and help validate broader shelf-life assumptions.

### The Value of Real-Time Data in International Regulatory Submissions

Beyond domestic requirements, real-time stability testing is often a prerequisite for regulatory approval in international markets. Countries in Asia, the Middle East, and Latin America may require detailed long-term stability documentation before approving shelf-life claims or granting import licenses.

This makes real-time data not just a compliance asset but a commercial enabler for companies

seeking global expansion.

Qalitex has observed delays in market access due to insufficient long-term data, even for products already sold in the U.S. In such cases, retroactive real-time testing may take months to complete, delaying entry or forcing brands to revise expiration dates.

#### A Strategic Approach to Ongoing Product Stewardship

Qalitex encourages brands to shift from viewing stability testing as a launch milestone to seeing it as a continuous commitment. In today's regulatory environment, product stewardship does not end at release—it requires ongoing verification that a product continues to meet the same safety and quality standards over time.

This approach also supports better decision-making when considering reformulations, packaging changes, or sourcing updates. Real-time data can help companies determine whether such changes impact product performance under actual market conditions.

“Real-time testing allows brands to spot emerging trends, validate shelf-life accuracy, and avoid surprises in the field,” Abochama added. “It’s a smart investment in product reliability and regulatory resilience.”

#### Qalitex's Commitment to Advancing Scientific Stability Practices

As part of its commitment to scientific integrity and regulatory alignment, Qalitex provides both accelerated and real-time stability testing programs tailored to dietary supplements, functional foods, and cosmetic products.

The company continues to monitor evolving regulatory expectations in the U.S. and abroad and regularly advises clients on designing appropriate testing protocols based on formulation type, market destination, and product risk profile.

With this advisory, Qalitex highlights the growing importance of real-time stability testing as a key element of post-market quality assurance and encourages all brands—regardless of size or product category—to revisit their shelf-life validation strategies in light of long-term performance expectations.

Contact Qalitex here for assistance: <https://qalitex.com/contact-us/>

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