Qalitex Discusses Stability Testing Needs for Products Marketed Under Multiple Climate Zones

Qalitex Laboratories highlights the need for stability testing across multiple climate zones to ensure shelf-life accuracy in international markets.

IRVINE, CA, UNITED STATES, July 4, 2025 /EINPresswire.com/ -- As manufacturers expand into international markets, Qalitex Laboratories is emphasizing the importance of climate zone-specific stability testing. The California-based scientific testing firm notes that standard stability protocols—while broadly accepted—may not fully reflect the environmental conditions products face once distributed across regions with high heat, humidity, or seasonal variability.

Stability data generated under temperate conditions may not provide adequate assurance of shelf-life accuracy in countries located within tropical or arid zones. Qalitex advises that testing strategies be evaluated to account for these regional differences, particularly for products with extended distribution chains or long shelf-life claims.

ICH Guidelines: A Global Benchmark With Regional Gaps

The International Council for Harmonisation (ICH) provides widely adopted stability testing standards for pharmaceuticals and related products. The most common conditions used are 25°C/60% relative humidity (RH) for long-term storage and 40°C/75% RH for accelerated studies. These conditions generally align with temperate regions in Europe, North America, and parts of Asia.

However, Qalitex cautions that these conditions may not accurately reflect the real-world exposure experienced by products marketed in warmer or more humid regions. Areas such as

> Stability claims are not just scientific—they're environmental. And if the environment changes, the science has to follow."
>
> *Nour Abochama, Vice President for Operations at Qalitex*

Southeast Asia, Central Africa, the Middle East, and parts of Latin America present distinct climatic conditions that fall outside the original ICH reference range.

"ICH conditions provide a solid foundation, but regional climates can vary significantly from these parameters," said Nour Abochama, Vice President of Operations at Qalitex. "Brands selling into global markets should evaluate whether their current protocols account for the environmental stressors found in those regions."

WHO and National Authorities Define Climatic Zones

In addition to ICH guidance, the World Health Organization (WHO) and several national regulatory bodies use a four-zone classification system to represent different global climates. These include:

Zone I: Temperate
Zone II: Subtropical and Mediterranean
Zone III: Hot and dry
Zone IVa/IVb: Hot and humid

Each zone has associated testing conditions, ranging from 30°C/35% RH to 30°C/75% RH. In certain jurisdictions, national authorities require that stability studies reflect these specific conditions before a product is approved for distribution or import.
Mismatch Between Testing Conditions and Distribution Zones
Qalitex has reviewed multiple stability programs where products were exposed to environmental conditions not covered by original testing. In such cases, degradation not observed under standard ICH conditions later emerged in the form of:
Changes in color, odor, or consistency

Separation or clumping in semi-solid formats

Decline in formulation integrity

Increased microbial activity in ambient storage

Environmental stress may also be amplified by shipping delays, warehouse conditions, and local

retail storage practices that deviate from controlled environments.

Packaging Performance May Vary Across Climate Zones

The stability of packaging materials can also be affected by temperature and humidity fluctuations. Materials such as plastics, foil laminates, and adhesives may behave differently when exposed to regional extremes.

Qalitex has documented cases where packaging that performed adequately under Zone II conditions showed signs of warping, seal degradation, or compromised barrier protection under Zone III and IV conditions. These changes may not immediately affect safety, but they can reduce shelf-life accuracy and increase the likelihood of quality complaints.

Increasing Regulatory and Retail Scrutiny

Several national authorities now request that stability data reflect the climate of the destination market. For example, regulators in India, Brazil, and the Gulf Cooperation Council (GCC) countries have published requirements for Zone III or IV testing as part of registration and labeling approval.

Some retailers are also beginning to ask for regionally aligned documentation as a condition of onboarding or continued listing, especially in markets where heat and humidity are known to challenge product stability.

Recommendations for International Market Compliance

To address these regulatory and environmental challenges, Qalitex recommends that manufacturers:

Determine the climate zones of all intended distribution regions

Review existing stability data for alignment with those zones

Conduct additional studies under Zone III or IV conditions when necessary

Validate packaging materials against local environmental extremes

Monitor long-term performance in-market through real-time studies

Maintain complete documentation of all zone-specific studies for audit readiness

Qalitex further advises that any contract testing or manufacturing partners be briefed on zone-appropriate protocols, particularly for export-bound product batches.

Stability Testing Must Align With Environmental Exposure

While ICH conditions remain the industry baseline, Qalitex encourages manufacturers and quality teams to consider whether that baseline aligns with actual product journeys and usage

environments.
“Temperature and humidity have a direct impact on product integrity,” Abochama said. “When conditions shift, testing parameters should shift with them.”
Qalitex’s Role in Climatic Zone Stability Testing
Qalitex provides stability testing services that align with international climate zone classifications. These include real-time and accelerated protocols conducted under conditions appropriate to Zones I through IV. The laboratory also supports packaging assessments, distribution simulation, and regulatory documentation to meet the expectations of health authorities and commercial partners worldwide.
For more information on Qalitex’s climate zone-specific stability testing services, visit www.qalitex.com.

Nour Abochama
Qalitex Laboratories
email us here
