Qalitex Labs Examines Risks of Cross-Contamination Affecting Microbial Stability in Shared Facilities

Qalitex highlights how shared manufacturing facilities may increase microbial instability risks that impact shelf-life claims and delay product launches.

IRVINE, CA, UNITED STATES, July 2, 2025 /EINPresswire.com/ -- As contract manufacturing and shared production lines become more common across the personal care and consumer goods industries, Qalitex Laboratories is warning of increasing risks linked to microbial cross-contamination during production and packaging.

The California-based testing laboratory reports a growing number of stability testing submissions that require retesting after microbial excursions were traced back to shared environments.

> Cross-contamination doesn't always show up at launch—but if it happens during production, your product may not survive the shelf."
>
> *Nour Abochama, Vice President for Operations at Qalitex*

While shared manufacturing arrangements offer logistical and economic advantages, they can introduce significant quality control complexities—particularly for preservative-free formulations or products positioned for long shelf lives. In many of these cases, Qalitex notes that microbial growth observed during stability testing originated from low-level environmental contamination during production, not from inherent formulation flaws.

"Microbial excursions are not always detectable at release," said Nour Abochama, Vice President of Operations at Qalitex.

"We've seen products pass all initial microbial specifications, only to show elevated counts during

mid- to long-term stability intervals. In shared facilities, these patterns often point to process-related contamination from inadequately sanitized equipment or uncontrolled production environments."

Why Microbial Stability Testing Requires Extended Observation

Microbial stability refers to the product's ability to resist the proliferation of bacteria, yeast, or mold during its intended shelf life. Even trace contamination can multiply under favorable conditions, such as elevated humidity or temperature.

Over time, this may result in changes to odor, color, texture, or—more critically—microbial levels that exceed established specifications.

Qalitex has observed that early testing alone often fails to capture delayed microbial growth, particularly in high-water activity products or those stored at ambient conditions. Products processed in shared facilities may harbor low levels of bioburden that remain dormant at initial testing points, but expand during storage.

To address this, Qalitex recommends conducting microbial assessments at multiple stability intervals—typically at T=0, 1 month, 3 months, 6 months, and 12 months—to reflect shelf-life performance under varied storage conditions.

Contamination Risks in Shared Equipment and Packaging Lines

Cross-contamination in shared manufacturing spaces can result from incomplete sanitation of tanks, blenders, transfer lines, or filling equipment between production runs.

Qalitex notes that this risk increases when different product types—such as those with high sugar content, plant-based extracts, or probiotic materials—are processed in the same space without validated cleaning protocols.

In particular, moisture-prone formats such as syrups, soft chews, or emulsions may be more susceptible to microbial contamination if produced on lines that previously handled powders, botanical concentrates, or bulk materials with known microbial activity.

"Shared equipment introduces a traceability challenge," Abochama said. "Unless cleaning verification is performed for microbial presence—not just visual residue or allergens—there may be residual contaminants that affect the next batch."

Limited Environmental Monitoring Poses Documentation Risks

Qalitex has also identified documentation gaps in environmental monitoring practices among some contract manufacturers. During regulatory reviews or third-party platform audits, the

absence of air, surface, or water quality data from the production site may make it difficult for brands to demonstrate product safety over time.

Under FDA's current regulations for cosmetics and related personal care products, manufacturers are expected to control microbial contamination risks during production and to ensure that products meet microbial specifications throughout their life cycle.

While there is no federal mandate requiring third-party environmental data, the agency's inspection records often cite inadequate sanitation controls as a recurring observation.

In outsourced manufacturing contexts, Qalitex recommends that brands review their partners' microbial control programs and ensure that cleaning validation reports, swab data, and environmental monitoring logs are accessible if requested.

Microbial Instability Often Traced to Initial Low-Level Exposure

Products that appear compliant at initial testing may develop microbial issues later in storage due to undetected low-level contamination. These issues can manifest gradually, especially under ambient conditions or in products distributed in warmer climates.

Qalitex advises that full-term microbial stability testing protocols include both microbial load tracking and data on environmental risk factors. This approach helps distinguish between packaging failures, ingredient degradation, and cross-contamination introduced during manufacturing.

To improve reliability, Qalitex recommends including:
Initial microbial baseline (T=0)
Stability checkpoints at 1, 3, 6, and 12 months
Real-world or worst-case storage conditions
Environmental swab data from shared production spaces when available

Clarifying Quality Expectations in Co-Manufacturing Agreements

To mitigate microbial stability risks, Qalitex encourages brands to establish clear quality and testing requirements in contracts with third-party manufacturers. Specific provisions may include:

Documentation of sanitation protocols and cleaning validation for shared equipment
Microbial swab testing pre- and post-batch for shared lines
Routine environmental monitoring of air, surfaces, and water
Disclosure of overlapping production involving materials with elevated microbial profiles

“Shared manufacturing environments are not inherently unsafe,” said Abochama. “But when brand owners do not control the facility, they need to control the data—and that begins with clear contractual expectations and documented testing.”

Microbial Failures Often Lead to Costly Reformulations

Once contamination is detected during stability testing, brands may be required to reformulate with adjusted water activity levels, updated preservative systems, or new packaging formats. In more severe cases, the only resolution may involve shifting to a different manufacturing partner with stronger microbial controls.

According to Qalitex’s internal reviews, timelines for reformulation and retesting following microbial failure can range from several weeks to multiple months, depending on the complexity of the product and the responsiveness of the supply chain.

“These delays can disrupt marketing campaigns, certification schedules, and retail onboarding,” Abochama said. “Preventive testing and facility verification are far more efficient than reactive fixes.”

Laboratory Support for Microbial Stability in Shared Facilities

Qalitex provides microbial stability testing and contamination trace-back analysis tailored to products manufactured in shared environments. These services include:

Full-term microbial stability testing following ICH-aligned conditions
Analysis of microbial risk factors in packaging and formulation
Environmental monitoring programs for shared production facilities
Contamination source identification and documentation support for audits

For manufacturers navigating production through co-packing or multi-client environments, Qalitex recommends incorporating microbial endpoints into stability testing plans from the outset.

Early dialogue with contract partners regarding sanitation, monitoring, and documentation protocols can significantly reduce product risk.

For more information about microbial stability services and cross-contamination trace-back support, visit www.qalitex.com.

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