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MICROBIAL SOLUTIONS

Charles River Microbial Solutions for Cosmetics

Your quality system may be putting your brand at risk.

In today's challenging regulatory environment, the pressure to release products faster while eliminating the risk of contamination continues to increase. Scrutiny from regulatory agencies surrounding cosmetic product safety is becoming magnified, and the need to ensure quality testing systems are up to par without impeding production is essential. With these increasingly complex consumer, regulatory, and production demands, many small to midsize manufacturers of ingredients and products are failing to adapt and adopt better methods for assessing product quality and safety, especially in the eyes of regulatory agencies. Are you keeping pace with regulatory expectations?

Releasing safer, cleaner products to market.

Releasing contaminated product poses a greater risk to consumer safety and your brand than ever before. Since cosmetics are FDA-regulated, agencies are beginning to hold manufacturers accountable for the safety and quality of their products, just as they do in the pharmaceutical industry. With legislative changes proposed that would increase regulatory oversight, cosmetic manufacturers must be concerned about the safety of personal care product ingredients, inspection of facilities and records, and developing good manufacturing practices.

To adopt cGMP (current good manufacturing practices) in a production environment, most manufacturers must undertake a series of upgrades to improve their quality system, production process, and product release testing. In the past these improvements were frequently dismissed as too expensive and resource-dependent to carry out while only providing benefits for efficiency. Though the cost of implementation may be considered relatively high, the risks and long-term costs of outdated quality testing methods is higher.

Today, contamination introduced during manufacturing can no longer be remedied by the addition of antibacterial, bacteriostatic, or bactericidal preservatives. Without the ability to effectively "clean up" the product later, it must be cleaner through every step of the production process. While these products may still be subject to the same acceptable level of contamination allowed by regulators, they've realized the potential costs, risks, and production impacts of not operating as clean as possible.

EVERY STEP OF THE WAY

The old methods of "dirty" manufacturing are no longer acceptable in today's competitive market.

In order to move away from a manufacturing philosophy that inherently carries a certain level of risk, quality must be preserved from start to finish. Raw materials, in-process samples, and final product testing should be implemented as part of a good manufacturing process, addressing contamination earlier and faster.

For years, the world's leading consumer care and cosmetic manufacturers have been using a "clean-by-design" process, meeting the demands of consumer trends, ultra-short production cycles, and brand protection. When production schedules are so tight that products are manufactured and delivered to a store shelf within the same day there is no room for error. And while conventional microbial limits testing is a tried and trusted method, it has its limitations.

Advances in science have allowed for improvements in technology to quickly and accurately determine whether a product is contaminated, identify the exact organism, and confirm the quality of the product.

- One of the most trusted methods for achieving this operational state is our rapid microbial detection using Celsis® ATP-bioluminescence.
- By using the same gold standard detection methods as the largest manufacturers, growing companies can reduce traditional growth confirmation assays from 3-5 days down to 24 hours, minimizing hold time costs and confirming product quality sooner.
- The inherent subjectivity of manual enumeration or visual turbidity confirmation is removed with a confident "Yes/No" answer, providing critical information whether to release or hold a product.

The real question is: Why risk your company's product and reputation by continuing to manufacture at risk, when there are options that help ensure product quality while still allowing you to decrease assay run time by 80%?

Along with improved test methods, records management and data integrity play a powerful role in meeting regulatory requirements. However, companies often view records management through the lens of merely capturing results in any convenient manner, incorrectly assuming this is sufficient. What they fail to realize is that regulators are increasingly concerned about the data's security and what measures have been taken to ensure that it is attributable, legible, contemporaneously recorded, original, and accurate (ALCOA).

To meet these requirements, companies must learn how to modernize the recording, reporting, and storing of their data.

- Celsis® instrument software provides a powerful suite of tools to manage data archiving, results analysis, and reporting.
- Both local and remote users alike can quickly query results to find specific data based on multiple criteria, design and generate graphs for easy data trending analysis (including on-screen preview), and export reports to information management systems.
- An unlimited system log records events by each user and maintains records for the lifetime of the installation, in compliance with 21 CFR Part 11 and EC Annex 11 regulatory requirements for data integrity.

Proactive quality systems that reduce risk.

The cosmetic products industry has a known history of recall notices issued that name the following organisms as microbial contaminants: *B. cepacia, P. aeruginosa, S. aureus, E. coli. K. pneumonieae*, and *S. marcescens*.

The presence of these opportunistic microorganisms in products that are applied directly to the body, near the eyes and mucous membranes, or on potentially abraded skin is hazardous to consumer health and has potential for severe consequences. Aside from the obvious concern for consumer safety, a microbial contamination is also costly in terms of immediate financial impact and longer-term damage to the brand's reputation. So how can you reduce the risk of a product recall associated with these and other known harmful organisms?

The first step in most risk-reduction approaches is identification and characterization of the objectionable organism. Accurate identification can only occur if the organism is present in the microbial library that is referenced.

For maximal regulatory compliance, the standards and principles applied to cosmetic products can be based on those applied in the pharmaceutical industry for non-sterile products. In addition to known objectionable organisms for a particular product, the significance of any microorganism that is recovered from microbial testing should be evaluated to determine whether or not they are objectionable (per US Pharmacopeia – USP <1111>). Similarly, the Parenteral Drug Association (PDA), in its Technical Report No. 67, recommends a systematic framework to structure available data, information, and knowledge into a cohesive and transparent tool to enable decision-making and inform risk management.

In other words, regulators recommend routine environmental monitoring and data trending as a best practice.

Environmental monitoring is a fundamental aspect of cGMP compliance and is a proven strategy for contamination risk mitigation for cosmetic manufacturers. Accurate identification of environmental isolates plays an important role in this strategy because it helps record the routine flora of the facility and allows the quality system managers to detect and analyze any deviations from the norm.

The key to accurate identification is a relevant and validated microbial reference library and consistent use of reliable methods.

Charles River offers cGMP-compliant microbial ID technologies, with turnaround times as fast as the same day.

Microbial ID services:

- AccuGENX-ID®: The DNA sequence of each sample submitted for identification is compared to the validated Accugenix® library – the industry's most up-to-date database for environmental isolates, encompassing over 10,000 relevant species. Our expertise includes the ability to distinguish between very closely related microorganism groups to the species level, such as *Burkholderia cepacia* complex and many others.
- AccuPRO-ID®: The MALDI-TOF assay yields a unique protein spectral fingerprint that is then compared to the Accugenix® validated database for bacterial and yeast identification. This solution provides higher accuracy rates and faster results, and is a less expensive option for routine monitoring programs.

When you have confidence in your ID results, you can gain a better understanding of the big picture and the ability to aggregate and trend EM data. But collecting and managing this data can be difficult and time consuming, which is why having the right tool to automate these processes can lead to significant time (and cost) savings.

Complementary EM data management tools:

- Our Customer Web Portal includes a robust tracking and trending solution for all environmental isolates identified with Accugenix®. It offers customization features for data entry fields and reports while meeting the requirements of both 21 CFR Part 11 and GAMP5. Through this platform, customers the have the ability to sort and filter specific organisms, analyze frequency of occurrence, review Gram reaction, and more.