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Webinar on

Cosmetic Micro Standards, How to Stay in Compliance

Learning Objectives

- *What are cosmetics?*
- *Methods: BAM 23, USP, ISO*
- *Acceptable bioload levels*
- *Objectionable pathogens*
- *Environmental testing*
- *Testing water systems*
- *Testing raw material*
- *Method validation*
- *Testing qualification*
- *Preservative efficacy*
- *Stability testing*

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In this session, we will discuss all of these issues and the best practices for avoiding microbiological contamination of cosmetic products.

PRESENTED BY:

Extensive background in FDA regulated products at the government and industry level. Retired FDA, Cosmetic Industry and State government. Specialist in regulatory compliance, cGMP, process design and control, cleaning and sanitization and, microbiological contamination control.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

What are cosmetics? Paraphrasing the FD&C Act (The Act), Cosmetics are personal care products applied to the human body for the intention of cleansing, beautifying, promoting attractiveness, or altering the appearance. The operative word here is “intent”. If your products go beyond cosmetic intentions they may also be drugs as defined under the Act: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals". If your products are both cosmetics and drugs then you have the added responsibility to assure they meet two different microbiological standards. It is a common misconception that if a cosmetic product meets drug standards it is in compliance with the Act. Drug products are generally held to USP standards. Cosmetics are expected to comply with Bacteriological Analytical Manual Chapter 23, Microbiological Methods for Cosmetics. There is a significant difference between USP 61/62 and BAM 23 in how bioload is determined and how results are interpreted. BAM 23 sets maximum bioload levels, whereas USP levels are not specific to products. BAM 23 also takes a different approach to determining the presence of objectionable microorganisms. It allows for up to 7 days of enrichment prior to identifying species. FDA typically uses 72 hours of enrichment for all cosmetics tested in their laboratories. With extended enrichment times, FDA also finds far more opportunistic pathogens than are found following USP. The presence of objectionable microorganisms will likely illicit a Warning Letter from FDA if they are recovered from your products.

Objectionable microorganisms can come from three sources: raw materials, water, and the environment. Controlling microorganisms that can end up in your products is essential. Because of the high variability of formulations found in cosmetic manufacturing, keeping an eye on “house” organisms is very important. If you are a contract manufacturer, when you bring a new formula into your plant it is not unusual for house microbes to show up in these new products. In order to avoid contamination issues instituting robust environmental, raw material and water testing regimens are highly recommended.

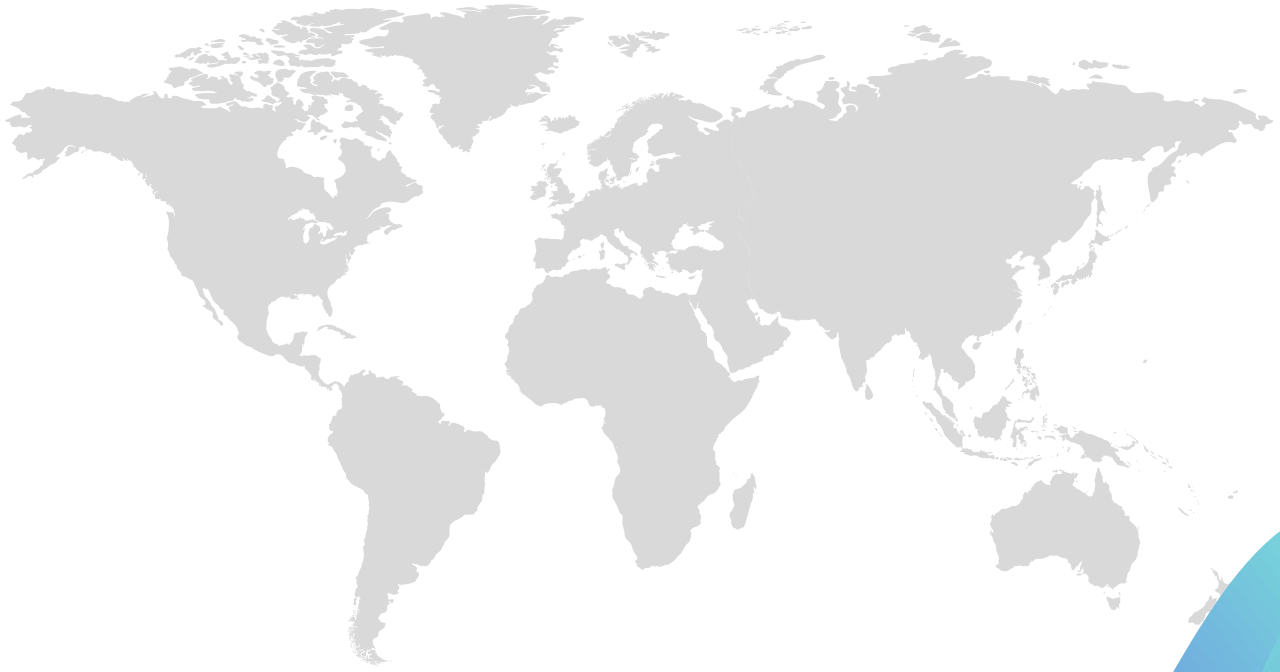
Highly complex formulations common in cosmetic products present a unique challenge to determining the adequacy of preservation. Following standardized testing methods, it is not uncommon to overlook the presence of undesirable microorganisms. This is due to two primary weaknesses, failure to properly qualify each product verses the chosen test and erroneous validation methods. Failure to implement testing procedures capable of identifying objectionable microorganisms can lead to product failures weeks or months after being put on the market. Implementing a stability testing program will also increase the likelihood of avoiding micro failures.

In this session, we will discuss all of these issues and the best practices for avoiding microbiological contamination of cosmetic products.

FDA expects cosmetic products to meet specific microbiological standards. Your products may be subject to recall because you are not testing them to standards used by the FDA. Because of the ever-changing preservative pallet, it is increasingly important to assure the microbiological integrity of the products you send to the market.

Who Should Attend ?

Senior leadership and Directors,
Managers and Supervisors



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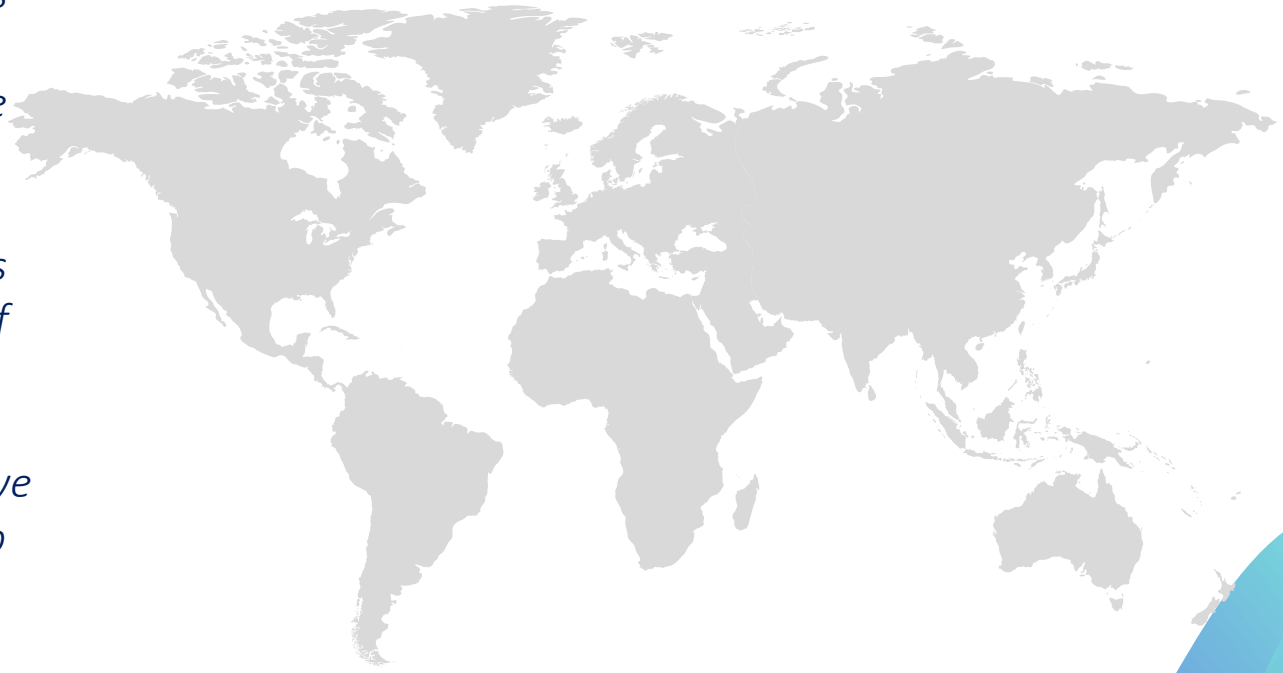
Why Should You Attend ?

FDA policy and guidance on testing cosmetic products require firms that manufacture and distribute cosmetics to incorporate testing of products to assure their safety. If you do not have sampling and testing procedures in place that meet FDA's Bacterial Analytical Manual Chapter 23 (BAM 23) requirements you are operating out of compliance. If, for any one of a multitude of reasons, FDA determines a need to evaluate your micro methods you will not be in compliance. The problem is that the FDA does not have specific rules regarding how to stay compliant. It is up to each firm to determine how to implement the FDA standards and be able to demonstrate that their products are in compliance. Determining how to implement sampling and testing is not as easy as just running tests and documenting the results. Sampling and testing protocols must fit into a sound quality system. What happens when you have an OOS result? Are you doing what FDA and your customers expect?



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