WHAT'S NEW AT Q

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An ISO/IEC 17025 Accredited, cGMP/GLP Compliant Laboratory

FROM THE PRESIDENT'S DESK

A question we often get from clients or potential clients who manufacture and/or market health and beauty care products is whether their product(s) is regulated as a cosmetic or as a drug. I always defer to the Federal Food, Drug, and Cosmetic Act (FD&C Act) which defines Cosmetics as, "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance." For example, deodorant, make-up, toothpaste, moisturizers and perfumes. A Drug, on the other hand is an article, "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" Examples include, treatments for dandruff or acne, sunscreen products, antiperspirants, and diaper ointments. Some products are both cosmetics and drugs. Examples include anti-dandruff shampoos and antiperspirant-deodorants, as well as moisturizers and makeup with SPF (sun protection factor) functionality. These must meet the requirements for both cosmetics and drugs. The basic difference in the regulations for drugs and cosmetics is drug products require pre-market approval by the FDA before they can be sold, whereas cosmetics generally do not.
Q Laboratories, Inc. can provide a wide range of services on all of these products to help you achieve regulatory approval, regardless of which designation your product(s) receive.

David G. Goins, President

MEET THE Q LABORATORIES' STAFF

Brandi Heiland is the Office Leader at Q Laboratories, Inc. Brandi is tasked with assuring all incoming samples are logged in and processed into the appropriate laboratory in a timely manner. She also manages the process of transferring laboratory results into report format and sending those results to clients.

DIETARY SUPPLEMENT CHAPTER

While focus has been on the pending new chapters in USP/NF on Elemental Impurities Chapters <232> and <233>, the companion Chapter <2232> Elemental Contaminants in Dietary Supplements is also scheduled to be implemented concurrently with <232> & <233>. The Chapter reads, "The objective of this general chapter is to limit the amounts of elemental contaminants in finished dietary supplement dosage forms labeled as conforming to USP or NF standards. This general chapter is not intended to set limits for dietary ingredients. Those limits are set in the corresponding individual monographs." The focus of this general chapter is on the four major elements of toxicological concern: arsenic, cadmium, lead, and mercury. Contact Q Laboratories, Inc. for more information on USP/NF Ch. <2232>.

RAW MATERIALS - COSMETICS

Most manufacturers are familiar with requirements to test their finished products for quality safety, but under FDA cGMP Guidelines for Cosmetics, it is required to test your raw materials in order to assure they meet the required standards. Raw Materials are required to be, "(s)ampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage (animal and vegetable origin materials and those produced by cold processing methods should be reviewed for filth and/or microorganism contamination), as well as properly identified and controlled to prevent the use of materials that fail to meet acceptance specifications." As for water as a raw material in cosmetic products, GMPs require the water, "is being tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality." These specifications may include Total Bacteria Count, Pathogens, Total Coliform Count, Total Organic Carbon, Conductivity and pH.

USP <1227>

USP Chapter <1227>, according to the text of the compendium, "provides guidelines for the validation of methods for the estimation of the number of viable microorganisms, for the detection of indicators or objectionable microorganisms, for the validation of microbiological methods used in antimicrobial effectiveness testing, and for the sterility testing of Pharmacopeial articles. It is generally understood that if a product possesses antimicrobial properties because of the presence of a specific preservative or because of its formulation, this antimicrobial property must be neutralized to recover viable microorganisms. This neutralization may be achieved by the use of a specific neutralizer, by dilution, by a combination of washing and dilution, or by any combination of these methods." Chapter <1227> provides an overview of this process. The tests under Antimicrobial Effectiveness Testing <51>, Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62> require the validation of recovery methods. To ensure that the results of the tests are credible, neutralization of antimicrobial properties of the test solution is required before estimating the number of viable microorganisms. A validated method for neutralizing the antimicrobial properties of a product must meet two criteria: neutralizer efficacy and neutralizer toxicity. The validation study documents that the neutralization method employed is effective in inhibiting the antimicrobial properties of the product (neutralizer efficacy) without impairing the recovery of viable microorganisms (neutralizer toxicity). Validation protocols may meet these two criteria by comparing recovery results for treatment groups. In most cases, if the formulation of the product(s) does not change, the Validation Study is a one-time requirement.
Q Laboratories, Inc. can perform a Validation Study for your product(s) following Chapter <1227> guidelines. Contact us and an analyst can help you design a validation study that meets your particular needs.

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