WHAT'S NEW AT Q

The Official Newsletter of Q Laboratories, Inc.

November 2016
VOLUME XV ISSUE 3B

An ISO/IEC 17025 Accredited Laboratory

Celebrating 50 Years of Scientific Excellence and Service

FROM THE PRESIDENT'S DESK

You work in a fast-paced industry where time is money. Regulatory and quality considerations are of primary concern and there are several factors at work effecting these concerns on an almost daily basis. Creating your products in an efficient manner while maintaining utmost quality is imperative. Q Laboratories, Inc. tries to eliminate some of this stress by serving as a dependable partner for our clients. By providing worry-free microbiology and analytical chemistry laboratory services, we can offer peace-of-mind by removing one more concern from your list. You have enough issues to worry about, finding a reliable lab to help you in your quality control and regulatory compliance efforts should not be one of them. We pride ourselves on offering a level of service to our clients that enables them to focus on their internal processes and continue to produce safe, high-quality products.

David G. Goins

David G. Goins, President

CLEAN COSMETICS

Cosmetic cGMPs require that manufacturers ensure that the raw materials they use of are of sufficient quality and safety. Raw materials should be sampled 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). Ingredients should also be properly identified and controlled to prevent the use of materials that fail to meet acceptance criteria. While the raw material suppliers should provide Certificates of Analysis (C of A) for their materials it is ultimately the responsibility of the manufacturer to verify the quality of the ingredients.

GMPs also instruct cosmetic manufacturers regarding water when used as an ingredient in a product. The manufacturer must first determine if the water is used as-is (directly from the tap) or has been treated with a process such as, deionization, distillation, or reverse osmosis. Procedures must be in place to determine that the water is of a defined quality, is not affected by materials used in the water treatment equipment, is being tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality; and the entire system for supplying water is set up to avoid stagnation and risks of contamination (this system should be routinely cleaned and sanitized utilizing a process that ensures no biofilm build-up).

IT'S EASY BEING GREEN

If you want to receive this newsletter via email, send an email to mg@qlaboratories.com with "EMAIL ONLY" in the subject line.

ANTIBACTERIAL NOTE

On September 2nd, the FDA issued a final rule indicating a list of 19 active ingredients that can no longer be marketed as antibacterial ingredients in consumer antiseptic wash products because they are not generally recognized as safe and effective (GRAS/GRAE). This final rule applies to consumer antiseptic wash products that are intended for use with water and are rinsed off after use, including hand washes and body washes. The rule does not apply to consumer hand sanitizers or wipes, or antibacterial products used in health care settings. An FDA press release states, "(c)ompanies will no longer be able to market antibacterial washes with these ingredients because manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections." The rule was originally proposed in December 2013 and challenged manufacturers to produce data, clinical and otherwise, proving these 19 ingredients were safe and effective and measurably better than plain soap and water. When no data was forthcoming and other data gathered by the FDA indicated these ingredients were ineffective and in some cases, such as triclosan and triclocarban, potentially harmful, the FDA proceeded to finalize the rule. The rule states, "New data suggests that the systemic exposure to these active ingredients is higher than previously thought, and new information about the potential risks from systemic absorption and long-term exposure is now available. New safety information also suggests that widespread antiseptic use could have an impact on the development of bacterial resistance." Three ingredients, benzalkonium chloride, benzethonium chloride and chloroxylenol (PCMX), will continue to be evaluated for safety and effectiveness for another calendar year and based on data received, the FDA will make a determination on the status of these ingredients. The rule further stipulates, "(m)anufacturers have one year (September 6, 2017) to comply with the rulemaking by removing products from the market or reformulating (removing antibacterial active ingredients) these products." Many manufacturers have already phased out certain ingredients based on the release of the 2013 proposed rule.

NEW APPOINTMENTS

Bryan Wirthwine,. has been named Chemistry Laboratory Supervisor at Q Laboratories, Inc. Bryan will oversee the everyday operation of the Chemistry Lab including analyst training and workflow. Bryan previously served as Analytical R&D Lab Supervisor for Q Laboratories, Inc.

Sarah Stolze has been appointed Customer Relations Director at Q Laboratories, Inc. She will be responsible for coordinating all incoming phone calls and requests for information and providing pricing and sampling supplies to clients.

David Isfort. has been promoted to Microbiology Group Leader-Food at Q Laboratories, Inc. David will assist the Lab Supervisor in maintaining adequate analyst training and keeping clients apprised of sample status, as well as monitoring sample flow-through.

Q Laboratories, Inc. • 1400 Harrison Avenue • Cincinnati, Ohio 45214-1606
Phone: (513) 471-1300 • Fax: (513) 471-5600 • E-mail: office@qlaboratories.com