WHAT'S NEW AT Q

The Official Newsletter of Q Laboratories, Inc.

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An ISO/IEC 17025 Accredited Laboratory

FROM THE PRESIDENT'S DESK

Q Laboratories, Inc. has been named one of the 55 fastest growing companies in Greater Cincinnati by the Cincinnati Business Courier. We also have a chance to be named the fastest growing company in our revenue group at the "Fast 55" Luncheon in June. Whenever the topic of our continued growth comes up, people often ask to what do I attribute this growth and success. My immediate response is always our success is a reflection of our outstanding staff. We are fortunate to have outstanding people in our management group as well as many very talented microbiologists and chemists working in our laboratories. But when people inquire what it is about our business plan that makes us successful, I always have to reply that it is our emphasis on service that separates us from some of our competitors. We believe that delivering test results is only a portion of our responsibility to our clients. Helping them understand and interpret the results and apply it to their particular situation is also a task we take very seriously. A result is only usable if you know what to do with it, and we try to make every effort to assure the results we provide present a clear picture for the client. But at the end of the day, I am certain what has spurred our success is a combination of factors. We only know one way to do business and thus far that has worked. That being said, we will never stop trying to improve the service and the science we provide to our clients.

David G. Goins

David G. Goins, President

GMPs

Cosmetic product GMPs, as indicated by the FDA, provide specific guidance as it pertains to water quality: "The water used as a cosmetic ingredient is used as-is (i.e., directly from the tap) or if it has been treated before being used (i.e., has it been treated by such means as deionization,distillation, or reverse osmosis) – 1) There are established procedures for ensuring that the water used as a cosmetic ingredient; 2) Is of a defined quality; 3) Is not affected by materials used in the water treatment equipment; 4) Is being tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality; and 5) The entire system for supplying water used as a cosmetic ingredient is set up to avoid stagnation and risks of contamination (This system should be routinely cleaned and sanitized according to an appropriate SOP that ensures no biofilm build-up)." Q Laboratories, Inc. can help you determine if your water is of sufficient quality. Contact an analyst (513-471-1300 or office@qlaboratories.com) who can help you set up a testing program for your facilities' water.

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OTCs

On March 25th and 26th, the FDA held a Public Hearing entitled, "Over-The-Counter Drug Monograph System -Past, Present And Future," to bring together experts to discuss potential changes/ updates/ upgrades to the OTC Drug Review process. The OTC Monograph system has not been changed on over 40 years and the FDA has deemed it time to at least broach the subject of what changes could be made to improve and modernize the system. According to the Federal Register notice, the purpose of the hearing was, "to obtain input on the Over-The-Counter (OTC) Drug Review (sometimes referred to as the OTC Monograph Process, OTC Monograph, or OTC Drug Review). The Agency would like input on how to improve or alter the current OTC Monograph Process for reviewing nonprescription drugs (sometimes referred to as OTC drugs) marketed under the OTC Drug Review. This public hearing is being held to obtain information and comments from the public on the strengths and weaknesses of the current OTC Monograph Process, and to obtain and discuss ideas about modifications or alternatives to this process." Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER), welcomed the attendees at the opening of the meeting and expressed her ideas on the OTC Drug Review process and potential alterations to the system, "this 48 year old system has bogged down in recent decades, and really is not meeting the needs of either the public, the consumers, industry, or the FDA. And that's what we want to talk to you about, or hear from you about, more appropriately, in this type of meeting," stated Dr. Woodcock. The three biggest challenges of the current system, according to the Federal Register Notice, are, the large number of products marketed under the OTC Drug Review for which there are not yet final monographs; limitations on FDA's ability to require, for example, new warnings or other labeling changes to address emerging safety or effectiveness issues for products marketed under the OTC Drug Review in a timely and effective manner; and the inability of the OTC Drug Review to easily accommodate innovative changes to regulated products.

MEET THE Q LABORATORIES STAFF

August Smithmeyer has been named Microbiology Group Leader-Pharma for Q Laboratories, Inc. August is responsible for monitoring and optimizing sample flow through for all pharma, cosmetic, OTC and health and beauty care industry samples processed by the Microbiology Lab. He also administers analyst training and scheduling and serves as a point of contact for pharma industry clients. August has worked as a Microbiology Analyst at Q Laboratories since 2010.

TRADE SHOWS

Q Laboratories, Inc. will have representatives at the following industry events in the upcoming months:

- **Ingredient Marketplace,** June 2-3**,** New York, NY; (**Booth# 332**)
- **HBA Global Expo,** June 10-12**,** New York, NY (**Booth# 635**); (**Booth# 1803)**

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