WHAT'S NEW AT Q

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An ISO/IEC 17025 Accredited Laboratory

Celebrating 50 Years of Scientific Excellence and Service

FROM THE PRESIDENT'S DESK

At Q Laboratories, Inc. we believe being a responsible corporate citizen is a very important part of our mission. For that reason, we have a group of employees who meets regularly to determine ways we can support local charities and groups in need. Recently we have, among other activities, held a book drive for the Literacy Network, a food drive for a local food bank, held a hot dog eating contest to raise money for a local Animal Shelter and collected school supplies to be donated to a local school. We realize our primary focus is to serve our clients and provide a welcoming work environment for our employees. But we also realize we have a responsibility to share our success with the local community and instill in our employees a sense of community awareness. I feel this makes us stronger as individuals as well as a group. Utilizing the resources we have to serve others is one way which we can be a positive force in the community in which we do business.

David G. Goins

David G. Goins, President

NEW APPOINTMENTS

Michael Baim, PhD. has been named Analytical Lab Director at Q Laboratories, Inc. Michael will oversee the everyday operation of the Chemistry and Analytical Research and Development laboratories. Michael previously served as Chemistry Lab Supervisor for Q Laboratories, Inc.

Patrick Bird, M.S. has been promoted to Microbiology Research and Development Laboratory Supervisor. Patrick's previous role at Q Laboratories was Microbiology R&D Lab Project Leader. Patrick will coordinate the various projects and functions of the Microbiology R&D Laboratory.

Erin Crowley, M.A. has been appointed Chief Scientific Officer at Q Laboratories, Inc. Erin's takes over as CSO after ten years as Microbiology R&D Lab Supervisor. Erin will be responsible for the acquisition and development of new technology for Q Laboratories as well as discovering new areas of business and determining the facility requirements of integrating new technologies at Q Laboratories.

Daniel Barket has been named Microbiology Technology Leader at Q Laboratories. Dan will be responsible for transitioning new Microbiology technologies into Q Laboratories' Microbiology Lab, as well as investigating cost-efficient and work-flow expedient methodologies to implement into the Microbiology laboratory.

IT'S EASY BEING GREEN

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

SUPPLEMENT GUIDANCE

The FDA recently released a Guidance Document entitled, "Dietary Supplements: New Dietary Ingredient (NDI) Notifications and Related Issues: Guidance for Industry." An initial draft of this guidance was released in 2011, but after accepting and considering comments and other input, the FDA made revisions and released this latest draft. A dietary ingredient is defined as a vitamin, mineral, herb or other botanical, amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient of those listed. A NDI is a dietary ingredient that was not sold or offered for sale in the U.S. before October 15, 1994. An NDI notification is not required for a dietary supplement containing an NDI if the supplement contains only dietary ingredients that have been present in the food supply as articles used for food in a form in which the food has not been chemically altered. The Guidance indicates, "Manufacturers and distributors of dietary supplements must establish specifications for the components of their products The required types of component specifications include: An identity specification for each component; Component specifications necessary to ensure that specifications for the purity, strength, and composition of dietary supplements manufactured using the components are met; and Limits on the types of contamination that may adulterate or may lead to adulteration of the finished product." Examples of contamination include microbiological contamination, presence of heavy metals and unsafe levels of residual solvents.

COMPOUNDING

Another Guidance released by the FDA addresses sanitary conditions at human drug compounding facilities. The purpose of the guidance is, "to assist compounding facilities in identifying insanitary conditions so that they can implement appropriate corrective actions." The document determines, "Certain procedures are critical to ensuring that compounding facilities do not have insanitary conditions that could compromise drug sterility, including, "Conduct routine environmental monitoring, including a) nonviable airborne particulate sampling; b) viable airborne particulate sampling; c) personnel sampling (including glove fingertip sampling); and d) surface sampling, including but not limited to equipment, work surfaces, and room surfaces. Environmental monitoring provides information on the quality of the aseptic processing environment and, if problematic, the compounding facility should promptly identify potential routes of contamination."

TRADE SHOWS

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

- **AOAC International Annual Meeting and Expo**
  September 18-20**,** Dallas, TX; **Booth# 202)**
- **ContractPharma Contracting and Outsourcing Expo,**
  September 22nd, New Brunswick, NJ. **(Booth# 89)**
- **Supply Side West** October 4-8, Las Vegas; **(Booth #P177)**

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