WHAT'S NEW AT Q

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FROM THE PRESIDENT'S DESK

Things are taking on a gilded shine around here as we prepare to celebrate the 50th Anniversary of Q Laboratories in 2016. Beginning as a one-person operation in 1966 and growing into our current 110-employee organization, the past 50 years have seen a fascinating evolution of our company. From humming "Cherish" by the Association and "Last Train to Clarksville" by the Monkees, to rocking out to Mark Ronson and Bruno Mars' "Uptown Funk" and Omi's "Cheerleader" (full disclosure – I had to look that up), Q Laboratories, Inc. has remained up with the times as far as the latest trends, methods and technologies that have developed over the last half-century. Anniversaries are times to reminisce on the past and remember the good times as well as the bad. Fortunately for Q Labs, the good times far outnumber the bad. When I reflect on how Q Laboratories has been able to sustain and grow over 50 years, I keep coming back to the excellent people who have worked here, and continue to work here. Q Labs' story has many chapters and hundreds of authors, but I sincerely believe the staff we have now is the finest we have ever assembled, and I would stack them up against any group around. One thing I am certain of is I will not be around in another 50 years (at least not at Q Laboratories), but I am honored to have been a part of the first 50 and part of this incredible organization and look forward to celebrating our Golden Anniversary in 2016.

David G. Goins, President

MEET THE Q LABORATORIES' STAFF

Tracy Williams has been named Chemistry Group Leader at Q Laboratories, Inc. Tracy will help monitor and control sample flow-through in the Chemistry lab in order to optimize turn-around times, as well as help facilitate and coordinate analyst training. Tracy will also assist in assuring all SOPs are adhered to, instrumentation is fully operational and client requests are responded to in a timely manner.

IT'S EASY BEING GREEN

Q Laboratories, Inc. remains committed to doing our part for the environment. As part of this commitment we are trying to limit our use of paper by offering you the opportunity to receive the quarterly Q Laboratories, Inc. newsletter electronically via email, instead of through the postal service. In the future, i**f 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**. If you prefer to continue to receive the newsletter via postal mail you can continue to do so. Thank you.

For a complete list of the services offered by Q Laboratories, Inc. please visit www.qlaboratories.com

FSMA ACTION

A major component of the Food Safety Modernization Act (FSMA) was enacted on September 17, 2015 when the FDA released the final rule, "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food." The rule accomplishes two things, modernizing the long-standing current good manufacturing practice requirements (which have not been updated since 1986), and adding requirements for domestic and foreign facilities that are subject to FDA regulation for Registration of Food Facilities to establish and implement hazard analysis and risk-based preventive controls for human food. According to the official Federal Register version of the regulation, "the rule is intended to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system."

According to the FDA website, the rule mandates that, "Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:" Hazard analysis – identifying biological, chemical, and physical hazards; Preventive controls – ensuring that the hazards identified are minimized or prevented, including process, food allergen, and sanitation controls, as well as supply-chain controls. Covered facilities must also have a recall plan in place; Oversight and management of preventive controls – including monitoring to assure that preventive controls are consistently performed, corrective actions and corrections to both resolve a problem, but also take action to lessen the probability the problem will occur again, and verification, to ensure that preventive controls are consistently implemented and effective.

The FDA indicates, "The preventive controls final rules require that a facility verify that hazards are being controlled and take corrective actio 15323-7A n to prevent contamination; and product testing and environmental monitoring are examples of steps a firm may take. A facility's decision to conduct product testing, and to establish the frequency of such testing, will reflect a risk-based approach consistent with its hazard analysis. Consequently, the FDA expects that facilities that produce foods that have frequently been associated with outbreaks of foodborne illness or pathogen contamination, or produce ready-to-eat foods for which an effective preventive control cannot be implemented, would establish product testing programs more often than facilities that do not produce such foods. Similarly, a facility that identifies an environmental pathogen as a hazard requiring a preventive control, for example, sanitation controls, would conduct environmental monitoring. Such a facility would decide what, if any, role product testing would play as a verification activity or as part of a corrective action as a result of positive findings from environmental monitoring, based on the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system."

Other provisions of the rule include explicit instructions on precautions taken for prevention of allergen cross-contact. The new cGMPs dictates that certain previously nonbinding provisions, such as education and training, are now binding. The Rule is official on November 16, 2015, but compliance dates vary from one to three years depending on the size of the business and whether the organization is subject to the FDA's Pasteurized Milk Ordinance.

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