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. is proud to announce that we have been Certified as Proficient in the isolation of Legionella from water samples by the Centers for Disease Control and Prevention's (CDC) Environmental Legionella Isolation Techniques Evaluation (ELITE). The three-month long process qualifies labs in the testing of Legionella in potable and non-potable water. According to the CDC website, "the certification indicates that the lab's procedures are consistent with federal recommendations and that they meet or exceed typical industry standards for recovery of Legionella." This certification is only offered using culture methods to isolate the bacteria and does not allow for rapid methods such as Molecular or lateral flow. As of the printing of this newsletter, Q Laboratories, Inc. is the only privately-owned, commercial lab in the State of Ohio to have this ELITE Certification.

David G. Goins, President

AOAC RECOGNITION

Erin Crowley has been elected as Vice-Chair of the AOAC Official Methods Board (OMB). Erin will subsequently become Chair of the OMB in 2016 and serve a three-year term. The OMB is established, "to serve the AOAC in a scientific and advisory capacity on methods and the methods validation process. To provide ethical, timely, open and independent scientific oversight for the processes, policies and procedures of AOAC International. To approve Final Action status for new and revised First Action Methods following a proactive review. This applies to all method validation protocols. To address requests for action and resolve disputes in the methods approval process in accordance with established policies and procedures. To establish and maintain communications with method-related committees through appointment of liaisons, active participation, or invitation of committee representatives to attend OMB meetings."

ANALYTICAL METHOD VALIDATION

ICH Q7, *Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients*, provides guidance for validating analytical methods. "Analytical methods should be validated unless the method employed is included in the relevant pharmacopoeia or other recognized standard reference. The suitability of all testing methods used should nonetheless be verified under actual conditions of use and documented." *ICH Harmonized Tripartite Guideline Q2 (R1), Validation Of Analytical Procedures: Text And Methodology* is the standard used when validating analytical methods. ICH Q2 identifies the four most common types of analytical procedures requiring validation,: Limit tests for the control of impurities; Quantitative tests for impurities' content; Identification tests; and, Quantitative tests of the active moiety in samples of drug substance or drug product or other selected component(s) in the drug product.

COSMETIC STABILITY

A few years ago, COLIPA and CTFA (now the Personal Care Products Council) collaborated on a document entitled, "Guidelines On Stability Testing of Cosmetic Products," providing some excellent guidance on designing and executing stability studies for cosmetic products. There is valuable insight in this document for developing stability studies for pharmaceutical, OTC and dietary supplement products as well. The document defines the purpose of stability testing to be, "to ensure that a new or modified product meets the intended physical, chemical and microbiological quality standards as well as functionality and aesthetics when stored under appropriate conditions," adding, "this document aims to set out guidelines in order to predict and assure the stability of products in the market place. Its purpose is to aid manufacturers of cosmetic products in the selection and the refinement of the appropriate stability tests."

FDA PRIORITIES

In July, the FDA published a draft document for public comment entitled, "Food and Drug Administration Strategic Priorities 2014-2018." In the document, the FDA defines and explains five "Cross-Cutting Strategic Priorities": Regulatory Science, Globalization, Safety and Quality, Smart Regulation and Stewardship. These priorities pertain to all of the diverse products the FDA regulates, such as pharmaceuticals, health and beauty care products, OTCs, dietary supplements, tobacco products and certain food and beverage products. Regarding "Safety and Quality" the document reads, "Safety and quality are integral to FDA's mission of promoting and protecting public health. Safety and quality include 1) the practices used to make products, 2) the integrity of the supply chain that delivers these products to their users, and 3) methods for protecting the public, including laboratory sample analyses for select product categories and product safety reporting systems." The document also presents the FDA's core mission goals and objectives: Enhance Oversight of FDA-Regulated Products; Improve and Safeguard Access to FDA-Regulated Products to Benefit Health; Promote Better Informed Decisions about the Use of FDA-Regulated Products; and Strengthen Organizational Excellence and Accountability.

TRADE SHOWS

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

- **Supply Side West,** October 8-9, Las Vegas**; (Booth# 16125)**
- **ContractPharma Contracting and Outsourcing Expo,** September 18th, New Brunswick, NJ**. (Booth# 47)**
- **AAPS Annual Meeting and Expo,** November 2-5, San Diego**; (Booth# 750)**

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