WHAT'S NEW AT Q

The Official Newsletter of Q Laboratories, Inc.

November 2013
VOLUME XIV ISSUE 3B

An ISO/IEC 17025 Accredited Laboratory

FROM THE PRESIDENT'S DESK

Q Laboratories, Inc. is beginning the final stage of what has been a 10-year facility upgrade project with the long-awaited renovation/expansion of our Analytical R&D lab, our Analytical Chemistry lab and our Microbiological Media Preparation lab. We recently completed construction of our Mass Spec laboratory which houses our ICP/MS and LC/MS and has space for additional instruments, which we plan to acquire in the near future. This room was designed to provide an optimal environment for sophisticated instrumentation. The main feature of the ten-year plan was the construction of a 9000 sq. ft. addition to our existing building (completed in November 2010). This new addition houses our state-of-the-art Microbiology R&D Laboratory as well as administrative offices, our Quality Assurance Unit (QAU) and conference/meeting rooms. The additional building allowed us to expand our sample receiving area to accommodate the substantial sample volume we receive each day. We were also able to expand the Microbiology lab considerably and partition it into sections depending upon the sample type/matrix. We will now focus on expanding the remaining areas into the space created in the original building when we moved the Microbiological R&D lab and the administrative offices into the new building. Our growth has seen our staff increase from approximately 50 employees in 2008 to nearly 100 today. The additional space has not only allowed for this increase in personnel, but also made all of the laboratory and sample receipt work spaces more efficient. This has enabled us to improve the manner in which we provide services, and mitigate the growing pains of continued expansion.

David G. Goins

David G. Goins, President

NEW EQUIPMENT

Q Laboratories, Inc. has acquired a Fourier Transform Infrared Spectrometer (FTIR) for the Analytical Chemistry and Analytical R&D Laboratories. Among other uses, FTIR is utilized to identify pharmaceutical ingredients and is the preferred methodology in many United States, European, Japanese, etc. Pharmacopoeias. FTIR has also become the method of choice in determining the purity of many traditional, as well as novel, dietary supplement ingredients. As Dietary Supplement GMPs become more enforced and dietary supplement manufacturers face added scrutiny, FTIR has become an invaluable tool in determining and demonstrating the identity and purity of dietary supplement ingredients. FTIR is applicable to both solid and liquid samples and is primarily used to provide qualitative results, however in some applications, quantitative data can be generated. Results are available quickly utilizing FTIR. Contact Q Laboratories, Inc. to discuss how FTIR can be utilized to verify the quality of your products.

For more information about the services provided by Q Laboratories, Inc. go to www.qlaboratories.com.

METALS

As mentioned in previous issues of this newsletter, implementation of USP chapters <232> and <233> regarding elemental impurities has been delayed several times. One reason for the delays, is USP has been awaiting release of ICH Q3D, Guideline for Elemental Impurities. In July, the final draft of ICH Q3D was released for comments. ICH Q3D provides, among other things, the evaluation of the toxicity data for potential elemental impurities; the establishment of a Permitted Daily Exposure (PDE) for each element of toxicological concern; and the development of controls designed to limit the inclusion of elemental impurities in drug products to levels at or below the PDE. ICH Q3D arranges elemental impurities into 4 classifications: Class 1 elemental impurities are significantly toxic across all routes of administration and include Arsenic, Lead, Cadmium and Mercury. Class 2 are toxic to a greater or lesser extent based on route of administration. In addition, some of the elements present in Class 2 are infrequently observed as impurities in materials used to produce drug products and as such, unless intentionally added have a low probability of inclusion in the drug product. Class 2 elemental impurities include Vanadium, Molybdenum, Selenium, Gold, Thallium, Palladium, Platinum, Iridium, Osmium, Rhodium, Silver, Ruthenium and Cobalt. Class 3 includes Antimony, Barium, Lithium, Chromium, Copper, Tin and Nickel and are impurities with relatively low toxicity (high PDEs) by the oral route administration but require consideration in the risk assessment for other routes of administration such as inhalation and parenteral. Class 4 elemental impurities are elemental impurities for which a PDE has not been established due to their low inherent toxicity and/or regional regulations. If these elemental impurities are present or included in the drug product they are addressed following the practices defined by other guidelines and regional regulation. The elements in this class include: Aluminum, Boron, Iron, Zinc, Potassium, Calcium, Sodium, Manganese, Magnesium and Tungsten. The guidance recommends a four-step risk assessment process: Identify, Analyze, Evaluate and Control. *Identify* known and potential sources of elemental impurities that may find their way into the drug product. *Analyze*: Determine the probability of observance of a particular elemental impurity in the drug product. *Evaluate*: Compare the observed or predicted levels of elemental impurities with the established PDE. *Control*: Document and implement a control strategy to limit elemental impurities in the drug product. USP has yet to release a new effective date for <232> and <233>.

MEET THE Q LABORATORIES' STAFF

Michael Goins is the IT/Marketing Coordinator at Q Laboratories, Inc. Mike has been with the company, since 2012. He is responsible for maintaining and optimizing the entire IT Network at Q Laboratories, Inc. including servicing the Data Server and all lab work stations as well as coordinating the current implementation of the Laboratory Information System (LIMS). He also assists with all marketing functions including trade shows, website and strategic planning.

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