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

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 monitor and coordinate analyst training. Tracy will also assist in assuring all SOPs are adhered to, instrumentation 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 we will continue to do so. Thank you.

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

ICH METALS

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), recently released the, "Guideline for Elemental Impurities Q3D." According to the FDA guidance document on Q3D, "there are three parts of this guidance: 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 application of a risk-based approach to control elemental impurities in drug products… This guidance presents a process to assess and control elemental impurities in the drug product using the principles of risk management as described in ICH Q9. This process provides a platform for developing a risk-based control strategy to limit elemental impurities in the drug product.

The guideline divides metals into three classes based on toxicity: Class 1 metals include mercury, lead, cadmium and arsenic. These metals are significantly toxic across all routes of administration. these four elements should be evaluated during the risk assessment, across all potential sources of elemental impurities and routes of administration; Class 2 metals include gold, nickel, selenium, molybdenum and cobalt — metals considered toxic that are route dependent or based on how they are administered; and Class 3 impurities have relatively low toxicity if taken orally, but require risk assessment for other types of administration, such as inhalation or through injection. Metals in this class include chromium, copper, tin, lithium and barium.

The FDA Guidance reads, "For the purposes of this guidance, the risk assessment process can be described in three steps: Identify known and potential sources of elemental impurities that may find their way into the drug product; Evaluate the presence of a particular elemental impurity in the drug product by determining the observed or predicted level of the impurity and comparing with the established PDE; and Summarize and document the risk assessment. Identify if controls built into the process are sufficient, or identify additional controls to be considered to limit elemental impurities in the drug product."

ENDOTOXINS

USP/NF Chapter 85, *Bacterial Endotoxins Test*, describes the various acceptable tests to detect or quantify endotoxins from Gram-negative bacteria using Limulus amoebocyte lysate (LAL). The FDA recommends that Endotoxin screening may be included in raw material, in-process and finished product release testing for products such as medical devices, parenteral drugs and biological drugs. Q Laboratories, Inc. can perform both the gel-clot method and an automated photometric chromogenic-kinetic method on samples to meet USP and other regulatory guidelines.

GENERAL RESPONSE

The August edition of this newsletter mentioned a letter sent by the State's Attorneys General (AG) of Indiana and New York asking the FDA to increase scrutiny of dietary supplement manufacturers and products. Since that time, the FDA has replied with a letter to the AGs indicating confidence in the Dietary Supplement cGMPs that are already in place and assuring them the FDA is committed to enforcing the current rules and protecting consumers.

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