

WHAT'S NEW AT Q

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FROM THE PRESIDENT'S DESK



Changes have been coming fast and furious here at Q Laboratories over the past few months. The construction of our 9000 sq.ft. building addition is coming along nicely and we expect to be able to move in sometime in late Summer early Autumn 2010. We recently officially opened our Chemistry R&D Laboratory under the direction of Sara Goetz (see profile below). The Chemistry R&D Lab will complement the Microbiology R&D laboratory already in existence and enable us to handle method development and validation projects with more expertise and specification. To properly equip the Chemistry R&D Lab to handle the type of projects it is designed for, we have acquired a new LC/MS/MS instrument. This acquisition allows us to take on analytical projects and methods we previously have not been able to perform. It allows us to provide an even more comprehensive, "one-stop-shopping" experience for our clients. These changes and our ability to maintain our steady and substantial growth are primarily due to the excellence of our staff. We are fortunate to have an extremely dedicated, intelligent and hard-working staff whose talent and integrity have fueled our continued success over the years.

David G. Goins

David G. Goins, President

DIETARY SUPPLEMENTS

In September 2009, the USP's Council of the Convention Section on the Quality of Food Ingredients and Dietary Supplements, released a whitepaper entitled, *Access To Good Quality Dietary Supplements*. The paper offers six suggestions for possible USP Convention action and improvement in the regulation of dietary supplements: 1) Public Monographs And Reference Materials - To the extent feasible, documentary standards and reference materials offered by USP should expand to cover all the products in the dietary supplements market; 2) Adherence To Public Standards - Public quality standards conserve both regulatory and manufacturer resources. They work to achieve consistency in the quality of a dietary supplement both within and between manufacturers, and allow updating; 3) International Harmonization - Global harmonization of public standards would ensure quality, identity, and label uniformity in international commerce, and could facilitate international commerce of good quality dietary supplements; 4) Education - Practitioners should receive training on proper counseling of consumers on the use of dietary supplements and consumers should be educated about the importance of disclosing such usage to healthcare providers; 5) Verification - USP Verification Programs could also be used to increase confidence that ingredients and products moving in the international market comply with the quality specifications including absence of known/identified adulterants and contaminants; and 6) Regulatory Oversight - Dietary supplement product registration or pre-market notification might be considered as a means of monitoring the number and type of dietary supplements moving in commerce in the U.S. and helping to assure the safety of dietary supplements.

HEAVY METALS

As mentioned in a previous issue of this newsletter, the USP has proposed changes to the current analysis for Heavy Metals, replacing the current Chapter <231> with three new chapters, Elemental Impurities-Limits <232>, Elemental Impurities-Procedures <233> and Elemental Contaminants in Dietary Supplements <2232>. The proposed changes appear in the Jan-Feb issue of *Pharmacopeial Forum* and are available on the USP website. Chapter <232>, Elemental Impurities-Limits, categorizes elemental impurities into Class 1 and Class 2 impurities. Class 1 impurities are classified as: elements that should be essentially absent from products, are known or strongly suspected human toxicants and are considered environmental hazards. The allowable level for Class 1 impurities ranges from 0.5 ppm to 1.5 ppm. Class 1 impurities are arsenic, cadmium, lead and mercury. Class 2 elemental impurities include: Chromium, Copper, Nickel, Palladium and many others. They are assessed as elements that should be limited in products, but are less toxic than Class 1 impurities. Acceptable limits of Class 2 elements range from 10 ppm to 250 ppm. In many cases acceptable limits of Class 1 and Class 2 impurities are different for oral dose products versus parenteral dosage products.

USP, Chapter <233>, Elemental Impurities-Procedures, "describes the validation of two types of procedures, limit and quantitative, for the measurement of elemental impurities and provides criteria for the approval of alternative procedures. The chapter also describes two referee procedures, inductively coupled plasma-atomic (optical) emission spectroscopy (ICP-OES) and inductively coupled plasma-mass spectrometry (ICP-MS), both using closed vessel microwave digestion. The choice of procedure, including the sample preparation and the instrument parameters, is the responsibility of the user...." The two referee procedures are described. Criteria for the approval of alternative procedures are also described. An alternative procedure will require complete validation for each element of interest. In addition, a system suitability evaluation using a USP Reference Standard or its equivalent should be demonstrated on the day of analysis. Alternative procedures that meet the validation requirements described herein are considered to be equivalent to Procedures 1 and 2."

MEET THE Q LABORATORIES' STAFF

Sara Goetz has been promoted to Chemistry R&D Laboratory Supervisor at Q Laboratories, Inc. Ms. Goetz has worked as a Chemist at Q Laboratories, Inc. since 2001 and previously served as Group Leader (2007-2008) and Supervisor (2008-2010) of the Analytical Chemistry Department. As Chemistry R&D Laboratory Supervisor, Ms. Goetz will be responsible for overseeing all method development and validation projects as well as method verification/qualification, (including AOAC-RI and OMA projects) method transfer and new technology implementation and utilization.



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