

Southern California Section Addresses Analytical Challenges Faced by Dietary Supplements Industry in Meeting GMPs; Issues Specific to Testing Labs

The dietary supplement industry must meet stricter and more rigorous requirements than in the past. To help the industry prepare for these new requirements, the AOAC Southern California Section held a one-day event on November 7, 2008, in Irvine, California, USA, to bring members of the industry together to discuss how testing laboratories that support the dietary supplement industry can meet these new requirements.

These testing laboratories face many challenges. For example, there is the lack of well-defined refer-

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ence standards. Published analytical methods and proficiency testing programs do not include enough matrixes or analytes. There is a real

need to create uniformity/consistency/clarity of data analysis and results among testing laboratories. These challenges affect not only the individual testing laboratories, but also the industry in general. Without adequate control in testing laboratories, the industry is open to criticism from its customers; this also contributes to increased costs from additional testing, as well as slowing down the production process.

The goals of the meeting were to define current analytical challenges; draft common and practical approaches to meeting challenges; and open communication routes among testing laboratories in order to improve the quality and clarity of analytical data. Achieving these goals would boost customer confidence

in and satisfaction with the analytical data provided.

Sumit Sen, U.S. Food and Drug Administration (Irvine, California, USA), president of the Southern California Section, got the meeting underway as he welcomed participants, introduced members of the Section's Executive Committee, and thanked speakers and sponsors (Dionex, Waters, Cerilliant, and ChromaDex).

Kicking off presentations were William Martin and Alonza Cruse, both from the FDA (Irvine), who defined challenges and stressed the importance of the role played by testing laboratories. They described the problems the FDA encounters, such as dietary supplements that contain active pharmaceutical ingredients.

Jane Weitzel, Watson Pharmaceuticals (Corona,



Jane Weitzel and Sumit Sen



California, USA), chair of the AOAC Analytical Laboratory Accreditation Criteria Committee (ALACC), described how ISO 17025 laboratory management system addresses some of the critical issues faced by the dietary supplement industry. For example, measurement uncertainty, setting specifications, and compliance assessment are all addressed in the ALACC or Eurachem guides.

William Mindak, Center for Food Safety and Applied Nutrition (College Park, Maryland, USA), described some of the challenges faced in the analyses of toxic heavy metals in dietary supplements. He gave practical examples of sample preparation using new microwave dissolution procedures and discussed issues related to improving ICP-MS analysis used to identify and quantify the presence of toxic heavy metals in various matrixes of dietary supplement products—a relevant topic as laboratories prepare to meet the proposed new USP requirements for heavy metals.

Wesley Johnson, Quality Analysis Consultants (Victoria, British Columbia, Canada), described how

other industries have faced—and successfully addressed—similar challenges. The dietary supplement industry can learn from other industries, so it does not have to “reinvent the wheel.” For example, how have other industries implemented proficiency testing when there is no material with which to make test samples?

Sidney Sudberg (Alkemists Pharmaceuticals, Costa Mesa, California, USA) and Celine Ventre described the challenges of a laboratory supporting the dietary supplement industry and the actions they are taking

to address these issues. This included a statistical analysis of Vitamin C data to determine the sample size needed to give adequate test results. They also defined the confusion as to the meaning of “purity” on certificates of analysis (COA) of some reference materials and described how they educate their clients on how to use and interpret the information on the COAs.

Joy Joseph, Joys Quality Management Systems, chair of the USP Expert Committee, Dietary Supplements, Nonbotanical, highlighted “Industry Concerns and Challenges to cGMP Compliance.” Joseph

discussed who establishes specifications and how they can do so; what to do about supporting data for expiration dating; and what is subset testing.

The meeting also included sponsor presentations and was capped off by a lively panel discussion, moderated by Weitzel, on how to tackle the analytical challenges facing the dietary supplement industry. A small group was formed to develop strategies to deal with the lack of reference materials and to initiate some proficiency testing programs.

If you are interested in participating in the Southern California Section, contact Jane Weitzel at mljweitzel@msn.com or Sumit Sen at sumit.sen@fda.hhs.gov. Not a member of your local Section? Contact Liz Cribbin, program manager, Sections Program, at lcribbin@aoac.org and join now. For more information, be sure to check out “Sections” on the AOAC Web site at www.aoac.org or see the Sections calendar on page 56 of this issue. ■

—Jane Weitzel and Sumit Sen
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