USP Elemental Impurities Implementation Advisory Group
Meeting # 2
Wednesday, August 7, 2013
1:00–3:00 p.m. Eastern Time
Teleconference

Meeting Summary

Advisory Group Members

1. John Kauffman, FDA and ICH Q3D Rapporteur (current)
2. Robert Osterberg, USP Toxicology Expert Committee
3. John Punzi, CHPA
4. David Klug, IPEC
5. John Leighton, FDA
6. Mark Schweitzer, ICH Q3D Rapporteur (through Step 2)
7. Phyllis Walsh, NJPQCA

Unable to Attend
Jon Clark, FDA; David Gaugh, GPhA; Gordon Johnston, GPhA

Invited Guest Unable to Attend
Paul Seo, FDA

USP Staff
Roger Williams, V. Srini Srinivasan, Todd Cecil, Angela Long, Catherine Sheehan, Mario Sindaco, Marie Temple, Matthew Van Hook, Kahkashan Zaidi

After Dr. Roger Williams called the meeting to order, Mr. Mario Sindaco described the activities of the two Working Groups formed by the Advisory Group.

1. **Special Impact on Manufacturers Working Group**
   This Working Group's goals were to consider issues experienced by manufacturers of products especially impacted by the elemental impurities standards, and identify potential solutions. The Working Group discussed that while USP drug product monographs provide solutions for drug product manufacturers, USP cannot provide a solution for ingredient manufacturers. FDA representatives confirmed that ingredient manufacturers should work with FDA to find solutions to their unique issues. With these conclusions, the Working Group completed its work.

2. **Implementation Working Group Report**
   This Working Group met twice to consider common challenges manufacturers may experience when implementing the elemental impurities standards, and the impact of the standards on regulatory filings. The Working Group noted the positive effect of the availability of the ICH Q3D Step 2 document on industry's ability to prepare for implementation of elemental impurities standards. The Working Group also identified potential issues such as requirements for products with longer shelf lives, testing capacity, staff training needs, regulatory filing requirements, and limits for topical products. The Working Group noted their preference that implementation occur through the General Notices (*GNs*) because it would enable manufacturers to use a risk-based approach. Industry representatives noted their increasing familiarity with ICP-MS.

3. **Advisory Group Discussion**

The Advisory Group discussed several implementation timing proposals received in comments to the proposed implementation provision in *GNs*. USP proposed full implementation of the *GN* provision by December 1, 2015. The Advisory Group also discussed a staged or tiered implementation by dosage form. The Advisory Group reviewed the various revision vehicles by which USP could implement the *GN* proposal, including regular revision, accelerated revision, or direct approval of the deferred provision. The Council of Experts Executive Committee, which is responsible for *GNs*, will consider these approaches at its September 2013 meeting.

The USP Elemental Impurities Expert Panel will meet in late September 2013 and will make recommendations to the General Chapters–Chemical Analysis Expert Committee regarding alignment with the limits specified in ICH Q3D and limits for topical products. The Expert Committee will meet in October 2013 to consider the Expert Panel's recommendations.

Dr. Williams thanked the Advisory Group members for their time and insights and concluded the work of the Advisory Group. He suggested, however, that they might be called upon as necessary for further input.