



**USP Elemental Impurities Implementation Advisory Group  
Meeting # 1  
Thursday, June 6, 2013  
Teleconference**

**Meeting Summary**

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**Advisory Group Members**

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| 1. Jon Clark, FDA (unable to attend)              | 6. John Kauffman, FDA, Current ICH Q3D Rapporteur     |
| 2. David Gaugh, GPhA (unable to attend)           | 7. David Klug, IPEC                                   |
| 3. Gordon Johnston (for David Gaugh), GPhA        | 8. John Leighton, FDA (unable to attend)              |
| 4. Bob Osterberg, USP Toxicology Expert Committee | 9. Mark Schweitzer, ICH Q3D Rapporteur through Step 2 |
| 5. John Punzi, ChPA                               | 10. Phyllis Walsh, NJPQCA                             |

**USP Staff**

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| 11. Roger L. Williams, M.D., CEO   | 16. Catherine Sheehan, M.S., Senior Director, Excipients (unable to attend) |
| 12. V. Srinivasan, Ph.D. Executive Vice President and CSO  | 17. Mario Sindaco, M.S., MBA, Director, Compendial Affairs                  |
| 13. Angela G. Long, M.S., Senior Vice President, Global Alliances and Organizational Affairs and Executive Secretariat | 18. Matthew Van Hook, J.D., Vice President and Senior Counsel               |
| 14. Todd L. Cecil, Ph.D., Vice President, Monograph Modernization  | 19. Kahkashan Zaidi, Ph.D., Principal Scientific Liaison                    |
| 15. Scott Kuzner, Ph.D., Manager, Council of Experts Support   |   |

After calling the meeting to order, Dr. Roger Williams explained that that Advisory Group is appointed under the USP Bylaws to advance the work of the Council of Experts and the Convention and provide advice to staff. Advisory Group members were chosen to represent key stakeholder organizations that bring a particular perspective needed for advising USP on matters related to the implementation of Elemental Impurities General Chapters.

The purpose of the Advisory Group is to provide advice to USP on how to advance a timely implementation of USP's Elemental Impurities General Chapters <232> *Elemental Impurities—Limits* and <233> *Elemental Impurities—Procedures*.

Two working groups were established to address key areas of the implementation:

- **Implementation Requirements Related to <232> and <233>:** This working group will consider common challenges manufacturers will face in implementing the standards.
- **Special Impact on Manufacturers:** This working group will evaluate issues for manufacturers whose products are especially impacted by the elemental impurities standards and consider regulatory and other solutions.

The Working Groups will provide reports at the next meeting of the Advisory Group, which is scheduled for August. Concurrent with the work of these subgroups, USP staff will work with the USP Elemental Impurities Expert Panel to consider potential revisions to General Chapter <232> in response to the ICH Q3D Step 2 document. The entire Advisory Group will participate in discussions related to next steps and timing of the standard.