

UPDATES ON ELEMENTAL IMPURITIES ANALYSIS OF PHARMACEUTICAL AND NUTRACEUTICAL PRODUCTS

An informative technology based discussion on the new USP and ICH regulations

COMING TO A CITY NEAR YOU!

Locations:

September 15, 2015

Double Tree by Hilton
Philadelphia-Valley Forge
301 West DeKalb Pike
King of Prussia, PA 19406

September 16, 2015

Bethesda North Marriott
Hotel & Conference Center
5701 Marnelli Road
Bethesda, MD

September 17, 2015

Double Tree by Hilton
Raleigh Research Triangle Park
4810 Page Creek Lane
Durham, NC 27703

Register Here

[www.agilent.com/chem/
USP2015_seminartour](http://www.agilent.com/chem/USP2015_seminartour)

Control of impurities, including elemental (inorganic) contaminants, has always been a concern in the development and production of pharmaceutical and nutraceutical products, and dietary supplements.

ICH Q3D and USP<232> define the target analytes and limits based on toxicological data rather than method capability, and require the quantitative determination of individual metal concentrations, in place of the current sulfide precipitate test in USP<231>. Chapter <2232> of the US Pharmacopoeia build upon chapter <232> for the the “Big Four” analytes and only targets dietary supplements.

The reference analytical methods suggested in USP<233> are ICP-MS and ICP-OES, replacing USP<231>’s colorimetric analysis. The fifteen target analytes in USP<232> include the “Big Four” highly toxic elements: arsenic (As), cadmium (Cd), mercury (Hg) and lead (Pb), which are controlled at the lowest level in pharmaceutical products.

Environmental contaminants and inorganic catalysts should be limited in drug products and must be measured if they may have been introduced during the formulation process, or as a result of the production processes.

Join us for a morning to discuss:

- The latest updates and requirements
- Techniques for measuring tough samples
- Tips to achieve the lowest sensitivity
- Next steps in meeting the upcoming requirements

All in an environment where you can network and collaborate with your peers. We will have application scientists available to answer your specific questions.

See next page for Agenda.



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AGENDA

8:30 a.m.	Registration and Breakfast
9:00 a.m.	Introduction and latest updates on USP and ICH : The latest on USP Chapters <232>, <2232>, and <233>
9:30 a.m.	Innovative ICP-MS and ICP-OES solutions for elemental impurity analysis
10:30 a.m.	Break
10:45 a.m.	Discussion on Software and Compliance
11:15 a.m.	Demystifying ICH Q3D and USP <232>/<233>: Thoughts on sample preparation using microwave digestion – presented by Milestone
12 noon	Lunch and Open Discussion
1 p.m.	Adjourn



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