

**USP Workshop on
Quality of Chemical Medicines - Impact of Impurities & Strategies for control
June 11-12, 2015
Hotel Hyatt Regency, Mumbai, India
Agenda (As on 18th May 2015)**

Thursday, June 11th 2015 (DAY 1)

8:00 a.m. Registration

8:45 a.m. USP Welcome
K.V.Surendra Nath, Ph.D, USP-India

General Session

9:00 a.m. Control strategy for impurities from development stage to market release
K.V.Surendra Nath, Ph.D, USP-India

9:20 a.m. Monograph Modernization
Jon Clark, MS, USP-US

9:40 a.m. Pending Monographs
Jon Clark, MS, USP-US

10:00 a.m. Morning Tea Break

10:20 a.m. **Session 1: Approaches on Organic Impurities**
Chair: Milind Joshi, Ph.D, J.B.Chemicals&Pharmaceuticals Ltd

Topics Covered:

- Impurities in DS & DP <1086>
- Transition of Ordinary impurities <466> to <476>
- Chromatography <621>-
- Liquid Chromatography, Spectrometry & Light scattering <851>

USP-Perspective – General Chapters on Organic Impurities

Leonel Santos, Ph.D, USP-US
Horacio Pappa, Ph.D, USP-US

Industry Perspective – Challenges and Case Studies

Saul Gylys, Perrigo Consumer Health Care, US
Fabian D'souza, TEVA India Pvt Ltd

12:15 p.m. Panel Discussion and Q&A Session
(*Milind Joshi, Ph.D, Leonel Santos Ph.D, Horacio Pappa, Ph.D, Mr. Saul Gylys, Mr. Fabian D'Souza, Mr. Rahul Gupta, Piramal Enterprises*)

1.30 p.m. Lunch

2.15 p.m.

Session 2: Approaches on Inorganic Impurities

Chair: Rajiv Desai, Ph.D, Alembic Pharmaceuticals Limited

Topics Covered:

- Heavy Metals <231>, Elemental Impurities Limits <232>,
- Elemental Impurities Procedures <233>
- Plasma Spectrochemistry <730>

USP-Perspective– General Chapters on Inorganic Impurities

Horacio Pappa Ph.D, USP-US

Industry Perspective – Challenges and Case Studies

Ramesh Vishwanathan Ph.D, Syngene International

Joachim Weiss, Ph.D, Thermo Fisher Scientific GmbH

3.30 p.m.

Panel Discussion and Q&A Session

(Rajiv Desai, Ph.D ,Horacio Pappa, Ph.D, Ramesh Vishwanathan, Ph.D, Joachim Weiss, Ph.D, Leonel Santos, Ph.D)

5:00 p.m.

End of Day 1, Networking Hi-Tea

Friday, June 12th 2015 (DAY 2)

General Session

- 9:00 a.m. Product Quality & Patient Safety
Ajaz S. Hussain, Ph.D, Insight Advice & Solutions, LLC, (Ex Deputy Director USFDA, Quality Group)
- 9:20 a.m. Revision process, Accelerated processes PF to USP-NF, Impurity limits
Leonel Santos, Ph.D, USP-U.S
- 9:40 a.m. Flexible Monographs
Jon Clark, MS, USP-U.S
- 10:00 a.m. Morning Tea Break
- 10:20 a.m. **Session 1: Approaches on Residual Solvents and Specific Tests**
Chair: Antony Raj Gomas, Ph.D, Mylan Pharmaceuticals
- Topics Covered:**
- Residual solvents <467>
 - Chromatography <621> GC component only
 - Identification and Quantification of solvents by NMR
 - Water content <921>
 - Loss on Drying <731>
 - Residue on ignition <281>
 - Approaches on Ionic Impurities in Quality of chemical Medicines.
- USP Perspective**
Horacio Pappa, Ph.D, USP-US
Sanath Goud, Ph.D, USP India
Sharad Mankumare, Ph.D, USP India
- Industry Perspective- Challenges and Case Studies**
AVSS Prasad, Ph.D, Hetero Drugs
Sukumar Sinha, Ph.D Glenmark Research Centre
V R Sankar Babu, Metrohm India Ltd
- 12:30 p.m. Panel Discussion and Q&A
(Antony Raj Gomas, Ph.D, Horacio Pappa, Ph.D, Sanath Goud, Ph.D, Sharad Mankumare, Ph.D, AVSS Prasad, Ph.D, Sukumar Sinha, Ph.D, Leonel Santos, Ph.D.)
- 1.30 p.m. Lunch
- 2.15 p.m. **Session 2: Approaches on Non-drug related impurities**
Chair: Ajaz S. Hussain, Ph.D, Insight Advice & Solutions, LLC, (Ex Deputy Director ,USFDA, Quality Group)

Co Chair: Vijay Kshirsagar, TRAC Pharma Consulting

Topics Covered:

- Extractable & Leachables
- Adulterants

USP Perspective

Horacio Pappa, Ph.D, USP-US

Industry Perspective – Challenges and Case Studies

Anirudha Vaidya Ph.D, Analytical Solutions

KK Bhagchandani, ACD Labs

- 3:15 p.m. General Session on Data Integrity
Deepti Mehra, Ph.D, Hospira
- 3:40 p.m. Afternoon Tea Break
- 4:00 p.m. Panel Discussion and Q&A
(Ajaz S. Hussain, Ph.D, Mr Vijay Kshirsagar, Horacio Pappa, Ph.D, Mr. KK Bhagchandani, Anirudha Vaidya Ph.D, Deepti Mehra, Ph.D, Jon Clark, MS)
- 5:00 p.m. Closing Remarks & Adjourn
Milind Joshi, Ph.D, J.B. Chemicals & Pharmaceuticals Ltd