



Seminar On
‘Impurity Profile: Drug Substance, Excipients and Drug Product’

HOTEL RADISSON, MIDC CENTRAL ROAD, ANDHERI (EAST), MUMBAI
9.30 AM TO 5.00 PM TUESDAY, 23RD OCTOBER 2018

| SCHEDULE | TOPICS | SPEAKERS |
|--|---|---|
| 9.00 am – 9.30am | Registration – Tea/Coffee | |
| | Inaugural Session | |
| 9.30 am -9.40am | Welcome Address (Facilitator) – Mr. Daara B. Patel <i>Secretary-General, IDMA</i> | |
| 9.40 am – 9.50 am | Setting the Tone | Mr. J. L. Sipahimalani, <i>Quality Management & Technical Committee, IDMA & APA</i> |
| 9.50 am – 10.05 am | Keynote Speaker | Mr. P B N Prasad, <i>Deputy Drugs Controller, West Zone, CDSCO</i> |
| 10.05 am – 10.20 am | Guest of Honour | Mr. O. S. Sadhwani, <i>Ex Joint Commissioner, FDA Maharashtra</i> |
| 10.20 am – 10.40 am | Chief Guest | To Be Confirmed |
| 10.40 am – 10.50 am | Vote of Thanks | Mr. B R S Rao, <i>Chromochemie Laboratory Pvt. Ltd</i> |
| 10.50 am – 11.05 am | Tea/ Coffee Break | |
| Technical Session – Facilitator Dr. Milind Joshi, President, Global Regulatory Management, J. B. Chemicals & Pharmaceuticals Ltd. | | |
| 11.05 am – 11.45 am | Forced Degradation and Impurity Profiling | Dr. P L Sahu, <i>Scientific Director, National Dope Testing Laboratory (NDTL)</i> |
| 11.45 am – 12.20 pm | TBD | Dr. Srinivas Malladi, <i>Chromochemie Laboratory Pvt Ltd.</i> |
| 12.20 pm – 1.00 pm | USP Initiatives on Impurities | Technical Speaker From <i>USP India (P) Ltd</i> |
| 1.00 pm - 2.00 pm | Networking Lunch | |
| 2.00 pm - 2.40 pm | TBD | Dr. Antony Gomas, <i>Head of Quality Operations, Mylan Pharmaceuticals Pvt. Ltd.</i> |
| 2.40 pm - 3.20 pm | Approaches and understanding of Genotoxic impurities in Drug substance, Excipients and Drug Product | Mr. Rahul Gupta, <i>Vice President-Regulatory Affairs, USV Pvt. Ltd.</i> |
| 3.20 pm – 3.35 pm | Tea/ Coffee Break | |
| 3.35 pm – 4.15 pm | TBD | Dr Anita Soman, <i>Sun Pharma Advance Research Company</i> |
| 4.15 pm – 4.50 pm | Panel Discussion Moderator : Ms. Meena Shah, <i>Consultant, Regulatory Affairs</i> | |
| 4.50 pm – 5.00 pm | Summing up & Vote of Thanks | Dr. Milind Joshi, <i>President, Global Regulatory Management, J. B. Chemicals & Pharmaceuticals Ltd.</i> |