

## 2013 PDA India Chapter *Q<sup>U</sup>*ESAP Workshop Schedule

November 11-12, 2013 | Holiday Inn International, Mumbai

### Day 1- 11 November 2013

- ⌘ 0830-0900: Registration & Formalities
- ⌘ 0900-0930: Welcome and Introduction by the PDA India Chapter Board
- ⌘ 0930-1200: Case 1: Investigations- The ABC of expectations
- ⌘ Floating break for refreshments
- ⌘ 1200-1330: Case 2: Environmental Monitoring-Need for preventive controls & verification possibilities
- ⌘ 1330-1415: LUNCH
- ⌘ 1415-1615: Case 3: Understanding Risks for predictive controls
- ⌘ 1615-1630: Tea/Coffee refreshments
- ⌘ 1630-1715: General Open House
- ⌘ 1715-1730: Felicitations

### Day 2-12 November 2013

- ⌘ 0845-0900: Welcome & Recap of Day 1
- ⌘ 0900-1200: Case 4: Uncovering nuances of FDA's draft guidance on 'Circumstances that Constitute Delaying, Denying, Limiting, Or Refusing a Drug Inspection.
- ⌘ Floating break for refreshments
- ⌘ 1200-1330: Case 5: Manual Aseptic Processing- The Crossroads!
- ⌘ 1330-1415: LUNCH
- ⌘ 1415- 1615: Case 6: Sterility Assurance Packages-Essentials & Expectations
- ⌘ 1615-1630: Tea/Coffee refreshments
- ⌘ 1630-1715: General Open House
- ⌘ 1715-1800: Felicitations, Expression of Gratitude & Closure to workshop

**Membership detailing - Enrolment and Volunteering opportunities open throughout the days.**

**PDA INDIA**

**Regd. Office:** 246, 10<sup>th</sup> cross, Telecom Layout, Vijayanagar, Magadi Road PO, Bangalore - 560023

**Office for Communications:** #1661, 15<sup>th</sup> Main, 18<sup>th</sup> Cross, M.C.Layout, Vijayanagar, Bangalore – 560040; [www.pda.org/India](http://www.pda.org/India)

Phone - +91-80-23506562

Email: [pdaindiachapter@gmail.com](mailto:pdaindiachapter@gmail.com)