



## Tentative Agenda

### 9<sup>th</sup> Regional Workshop

On

### “Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries– A Way Forward”

**Date:** May 9, 2019

**Venue:** Yashoda Hospital, Near H-1, Kaushambi, Ghaziabad, Uttar Pradesh 201001

**Time:** 09:30 AM- 04:00 PM

<b>I. Registration (9.30 AM- 10.00 AM)</b>		
<b>II. Inaugural Session (10.00 AM- 10.30 AM)</b>		
Welcome Address & Opening Remarks		
PvPI Audiovisual		
Introduction of Participants		
<b>Tea (10:30 AM- 11:00AM)</b>		
<b>III. Technical Session</b>		
<b>Time</b>	<b>Topic</b>	<b>Speaker</b>
<b>11:00 AM- 11:45 AM</b>	Pharmacovigilance: Basics, Methods, Practices & A Brief Overview of PvPI	AMC Representative
<b>11:45 AM- 12:30 PM</b>	Pharmacovigilance regulations in Drugs & Cosmetics rules 1945: Schedule Y and M guidelines	CDSCO Representative
<b>12:30 PM- 01:15 PM</b>	Materiovigilance Programme of India (MvPI)-An overview, Role of NHSRC in medical device procurement& progress of MvPI	MvPI Representative
<b>Lunch (01:15 PM- 02:00 PM)</b>		
<b>02:00 PM- 03:00 PM</b>	Introduction to E2B XML format, Other Forms & Formats (e.g. CIOMS) for ADRs/ AEs reporting to PvPI	Industry Representative
<b>03:00 PM- 03:30 PM</b>	Engagement of MAHs in PvPI: Current Scenario & Way Forward	NCC-PvPI, IPC Representative
<b>03:30 PM- 04:00 PM</b>	<b>Panel Discussion &amp; Concluding Remarks</b>	