

## A workshop on Pharmaceutical Quality Assurance /Quality Control (QC/QA) MODULE - I

**DAY 1: 11<sup>th</sup> OCTOBER 2019**

Time	Title of presentation	Speaker
<b>Inaugural Session</b>		
9:00-09:30 Hrs.	Registration of Participants	
9:30-10:30 Hrs.	Conference inauguration	
	<b>Chief Guest</b> <b>Shri. M. Madan Mohan Reddy,</b> Whole Time Director, Aurobindo Pharma	
	<b>Dr Shashi Bala Singh,</b> Director, NIPER Hyderabad	<b>Shri. Udaya Bhaskar,</b> Director General, Pharmaceuticals Export Promotion Council of India (Pharmexcil)
<b>TEA BREAK (10:30-10:45 Hrs.)</b>		
<b>Session 1</b>		
10:45-11:15Hrs	Pre Training Assessment	Dr. D Roy, NIB Former Deputy Drug Controller Senior Regulatory Consultant National Institute of Biological
11:15-13:00 Hrs	Good Manufacturing Practices and Quality Systems: An Overview	Dr. D Roy, NIB
<b>Lunch Break (13:00-14:00 Hrs.)</b>		
<b>Session 2</b>		
14:00-15:30 Hrs	Current Good Manufacturing Practices (c-GMP)AND Quality Unit	Dr. Ashutosh Dikshit Head-Compliance Almelo Pvt Ltd, Hyderabad
<b>TEA BREAK (16:00-16.15Hrs)</b>		
16:15-17:00 Hrs	Case studies	Dr. D. Roy, NIB

**DAY 2: 12<sup>th</sup> OCTOBER 2019**

Time	Title of presentation	Speaker
<b>Session 3</b>		
9:00-10:30 Hrs.	Pharmaceutical "Quality by Design" (QbD): An Introduction and Applications	Dr. Premnath Shenoy Former Director, Regulatory Affairs Astra Zeneca
<b>TEA BREAK (10:30-11:00 Hrs.)</b>		
11:00-13:00 Hrs.	HVAC, Water System & Compressed Air System	Dr. D. Roy
<b>Lunch Break (13.00-14.000 Hrs)</b>		
<b>Session 4</b>		
14.00-15.30 Hrs	Validations including Process, Analytical, Cleaning & HVAC	Dr. D. Roy
<b>TEA BREAK (15:30-16:00 Hrs)</b>		
15.45 -17.00Hrs	Case Studies	

**DAY 3: 13<sup>th</sup> OCTOBER 2019**

Time	Title of presentation	Speaker
<b>Session 5</b>		
9.00-11.00 Hrs	<b>Introduction to Quality Management System</b> <ul style="list-style-type: none"> <li>• Quality Management System</li> <li>• Annual Product Quality Review (APQR)</li> <li>• Managing Incidents</li> </ul>	Dr Premnath Shenoy
<b>Tea Break (11.00-11.15Hrs)</b>		
<b>Session 6</b>		
11:15-13:00 Hrs	<b>QMS</b> <ul style="list-style-type: none"> <li>• Approach to Categorization of Deviations</li> <li>• Deviation &amp; Change Control</li> <li>• Corrective &amp; Preventive Action (CAPA)</li> <li>• Technical Report Writing – Use of Fishbone diagram and Pareto Charts</li> </ul>	Dr Premnath Shenoy
<b>Lunch Break (13:00-14.00Hrs)</b>		
14:00-15:30 Hrs	Case studies	Dr. Premnath Shenoy
<b>Tea Break (15.30-15.45Hrs)</b>		
15.45- 17.00Hrs	Sum up of Three Days program Post Training Assessment Certificate Distribution	