

## Pharmaceutical Continuous Manufacturing

Technology Development and Implementation Conference

Workshop organized by United States Pharmacopeia (USP) in collaboration with  
Indian Pharmaceutical Alliance (IPA)

### AGENDA

April 20 & 21 2022 (Virtual Conference)

#### DAY 1: April 20, 2022

<b>Session 1</b> 17:00–17:15 hrs IST	<b>Welcome address</b> <ul style="list-style-type: none"> <li>Jaap Venema, Ph.D., Chief Science Officer, USP</li> <li>Sudarshan Jain, Ph.D., Secretary General - Indian Pharmaceutical Alliance India</li> </ul> <b>Essence of the workshop</b> <ul style="list-style-type: none"> <li>Atul Dubey, Ph.D., Director - PCM, Manufacturing Services</li> </ul>				
<b>Session 2</b> 17:15–17:45 hrs IST	<b>Topic:</b> Importance of PCM for Pharma manufactures in India <b>Keynote speakers:</b> <ul style="list-style-type: none"> <li>Ms. S. Aparna, Secretary, Dept of Pharmaceuticals Government of India</li> <li>S. Chandrasekhar, Ph.D., Secretary, Department of Science &amp; Technology, Government of India</li> </ul>				
<b>Session 3</b> 17:45 – 18:05 hrs IST	<b>Topic:</b> Embracing the Future: Regulatory Considerations and Opportunities in Advanced Manufacturing <b>Special address:</b> <ul style="list-style-type: none"> <li>Sarah McMullen, Ph.D., Director, USFDA India office</li> </ul>				
<b>Session 4</b> 18:05–18:45 hrs IST	<b>Topic:</b> Experiences on PCM from formulation manufacturing perspective <b>Speaker:</b> <ul style="list-style-type: none"> <li>Mr. Sanjay Gorana, Sr. Vice President, Cluster Head Manufacturing, Cipla Ltd.</li> </ul> <b>Topic:</b> Scientific approaches & RTTR/PAT <b>Speaker:</b> <ul style="list-style-type: none"> <li>Abhijit Deshmukh, Ph.D., Global Head - OSD and API Scientific Affairs, Viatris India</li> </ul>				
18:45–18:50 hrs IST	<b>Break</b>				
<b>Session 5</b> 18:50–19:20 hrs IST	<b>Topic:</b> Continuous Pharmaceutical Manufacturing: Quality and Reliability from Process Understanding <b>Speakers:</b> <ul style="list-style-type: none"> <li>Sudhir Nambiar, Ph.D., Chief Scientific Officer, Solara Active Pharma Sciences Limited</li> <li>Lawrence de Belder, Ph.D., Pharmatech Associates (USP company)</li> </ul>				
<b>Session 6</b> 19:20–20:00 hrs IST	<b>Panel Discussions - Challenges in Pharmaceutical industry for introducing the Flow Chemistry/Continuous Manufacturing.</b>				
	<table> <tr> <td><b>Moderator</b></td><td>Rajendra Kumar Potlapally, Ph.D., Sr. Director, Synthetics, USP India</td></tr> <tr> <td><b>Panellists</b></td><td> <ul style="list-style-type: none"> <li>Sudhir Nambiar, Ph.D., Chief Scientific Officer, Solara Active Pharma Sciences Limited</li> <li>Lawrence de Belder, Ph.D., Pharmatech Associates (USP company)</li> <li>DB Sridhar, Ph.D., Sr.Vice President, MS&amp;T, Zydus Cadila</li> <li>Fernando Muzzio, Ph.D., Drug Product development &amp; manufacturing, process development, Distinguished Professor Rutgers University</li> <li>Abhijit Deshmukh, Ph.D., Global Head - OSD and API Scientific Affairs, Viatris India</li> <li>Srinivas Oruganti, Ph.D, Director, Dr. Reddy's Institute of Life Sciences</li> </ul> </td></tr> </table>	<b>Moderator</b>	Rajendra Kumar Potlapally, Ph.D., Sr. Director, Synthetics, USP India	<b>Panellists</b>	<ul style="list-style-type: none"> <li>Sudhir Nambiar, Ph.D., Chief Scientific Officer, Solara Active Pharma Sciences Limited</li> <li>Lawrence de Belder, Ph.D., Pharmatech Associates (USP company)</li> <li>DB Sridhar, Ph.D., Sr.Vice President, MS&amp;T, Zydus Cadila</li> <li>Fernando Muzzio, Ph.D., Drug Product development &amp; manufacturing, process development, Distinguished Professor Rutgers University</li> <li>Abhijit Deshmukh, Ph.D., Global Head - OSD and API Scientific Affairs, Viatris India</li> <li>Srinivas Oruganti, Ph.D, Director, Dr. Reddy's Institute of Life Sciences</li> </ul>
<b>Moderator</b>	Rajendra Kumar Potlapally, Ph.D., Sr. Director, Synthetics, USP India				
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20:00–20:05 hrs IST	<b>Wrap up, End of Day 1</b>				



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#### DAY 2: April 21, 2022

Session 1 16:30–16:35 hrs IST	<b>Recap of Day 1:</b> <b>Speaker:</b> <ul style="list-style-type: none"> <li>Mohamed Takhi, Ph.D., Associate Director, Synthetics, USP India</li> </ul>	
Session 2 16:35–16:55 hrs IST	<b>Topic:</b> PCM in Bio Pharma <b>Speaker:</b> <ul style="list-style-type: none"> <li>Himanshu Gadgil, Ph.D., CEO, Enzene Biosciences Ltd.</li> </ul>	
Session 3 16:55–17:15 hrs IST	<b>Topic:</b> Effective PCM practices using the case study of a protein rich maltodextrin powder manufacture <b>Speaker:</b> <ul style="list-style-type: none"> <li>Babu Padmanabhan, Ph.D., Managing Director &amp; Chief Knowledge Officer, Steer Group</li> </ul>	
17:15–17:35 hrs IST	<b>Topic:</b> Recent Trends in Continuous API Manufacturing <b>Speaker:</b> <ul style="list-style-type: none"> <li>C. Oliver Kappe, Ph.D., Professor, Flow Chemistry R &amp; D, Univ. of Graz, Austria</li> </ul>	
17:35–17:45 hrs IST	<b>Q &amp; A session:</b> Moderated by Mr. Pradeep. O, Sr. Director, RSL, USP Rockville	
Session 4 17:45–18:15 hrs IST	<b>Topic:</b> As continuous chemical reactions are generally well controlled by reaction parameters; what role does PAT have to play in routine manufacturing? <b>Speaker:</b> <ul style="list-style-type: none"> <li>Malcolm Berry, Ph.D., MB Chemistry Consulting Ltd</li> </ul>	
18:15–18:20 hrs IST	<b>Break</b>	
Session 5 18:20–19:10 hrs IST	<b>Topic:</b> Experience and Opportunity in Pharmaceutical Innovation-US FDA Perspective <b>Speaker:</b> <ul style="list-style-type: none"> <li>Joel Welch, Ph.D., Associate Director for Science and Biosimilar Strategy, Chair of the Emerging Technology Team, CDER/OPQ/OBP, USFDA</li> </ul>	
Session 6 19:10–19:55 hrs IST	<b>Panel Discussions</b> - Immediate, actionable next steps to help improve the uptake of Continuous Manufacturing	
	<b>Moderator</b>	Atul Dubey, Ph.D., Director - PCM, Manufacturing Services, USP
	<b>Panellists</b>	<ul style="list-style-type: none"> <li>Joel Welch, Ph.D., Associate Director for Science and Biosimilar Strategy, Chair of the Emerging Technology Team, CDER/OPQ/OBP, USFDA</li> <li>Dirk Leutner, Ph.D., EDQM</li> <li>Srividya Ramakrishnan, Ph.D., Head, Vice President - Process Engineering (API), Dr. Reddy's Laboratories</li> <li>Moheb N. Nasr, Ph.D., FAAPS, Principal, Nasr Pharma Regulatory Consulting (NPRC)</li> <li>C. Oliver Kappe, Ph.D., Professor, Flow Chemistry R &amp; D, Univ. of Graz, Austria</li> </ul>
19:55–20:05 hrs IST	<b>Summary of workshop</b> <ul style="list-style-type: none"> <li>Mr. Shirish Belapure, Sr.Technical Advisor at Indian Pharmaceutical Alliance, India</li> <li>Mr. Girish Kapur, Vice President - India Site Operations &amp; Site Head, USP, India</li> </ul>	