ISPE India Advances & New Frontiers in Sterile Manufacturing Technology Friday 17th April 2020, Mumbai, India	
Educational Programme	
Friday, 17th April, 2020	
08.00	Registration
08.50	Welcome & Introduction - Gopal Nair, Director & Secretary - ISPE India
09.00	What has changed in Annex 1 - It's implications & Challenges for Sterile Manufacturing-Richard Denk – Skan AG, Switzerland
09.40	Challenges in Implementing New EU GMP Annex 1 Draft requirements for sterile manufacturing - Dr. Nagarjuna AKULA, Vice President & Head Quality Operations, – A division of Biotechnology, Sanofi, India.
10.20	Networking Break
10.50	How to make QRM of Aseptic Processing Better- Rishikesh Jaiwant, Director, Manufacturing & Operations – BAXTER
11.30	Microbiological Implications of the EU Annex 1 Revision - Ziva Abraham, Microrite, Inc, USA
12.10	Rapid and Alternative Testing Methods – How to Implement quality and data integrity in a Modern Lab -Dr Lucia Ceresa, Senior Technology Manager, Charles River, USA
12.50	Networking Lunch Break
01.50	Data based approach to Continuous Control Strategy and Real-Time Release-Vipul Doshi - President Global Quality Assurance, - Cadila Healthcare Limited
02.30	Low Endotoxin Recovery (LER) – Facts and Myths Explained -Alan Hoffmeister, Senior Global Technology Manager, Charles River
03.10	Pharmaceutical Product Quality: Visual Inspection – Dr. A. Rama Mohana Rao – Chief Quality Officer –Aurobindo Pharma
03.50	Networking Break
04.15	Approaches to Regulating Innovation: Industry Perspective on CMC Challenges and Opportunities -Nina S. Cauchon, Director Regulatory Affairs CMC, Amgen Inc
04.55	Data Management throughout the Monitoring of a Sterile Manufacturing Environment - Rob Lutskus, Associate Director, Commercial Operations for Lonza Bioscience Informatics,
05.30	End of Day One

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08.00	Registration
08.45	HPAPI Production Suite and Lyophilization Processes- Critical Design considerations & Qualifications - Richard Denk – Skan AG, Switzerland
09.25	Technology Transfer Essentials for Bio Pharmaceuticals- Sarel Chen Tov, CEO Biopharmax Group, USA
10.05	How to Manage Clean Room Cost - Quality and Environmental Sustainability without compromises - Keith Beattie, Director, EECO2 - Energy Efficiency Consultancy Group Limited, UK
10.45	Networking Break
11.10	USFDA Inspectional trends related to smoke studies and points to consider - Daniel J. Roberts, Senior Specialist, Hogan Lovells US LLP
11.50	FDA citation trends with respect to Sterile Product Manufacturing – Ziva Abraham, Microrite, Inc, USA
12.30	Automation in Sterile Processing - Ganadhish Kamat Global Head Quality & Executive Vice President, Dr. Reddy's Laboratories
01.10	Networking Lunch Break
02.10	Overview of Global Pharmacopoeial Requirements and Recent Changes for Pharmaceutical Water for Injection- Brian White, Director-Process Engineering, IPS
02.50	Single-use systems for commercial drug production: Navigating the evolving regulatory expectations-Swapnil Ballal Member, Disposables COP- ISPE, Partner CRAMbridge E-learning & Q-Exl Partners
03.30	Networking Break
04.00	Proper Use of Extractables Data for Single Use Systems – Aspects Beyond Measurement – Dr. Armin Hauk Lead Scientist at Sartorius Stedim Biotech GmbH, Goettingen
04.40	Current state and future prospective of integrity testing of Single Use systems- Dharti Pancholi, Co-Chair, ISPE Disposable-COP, Founder, Omni Consulting, Chief Operations Officer at Advent Engineering Services
05.20	End of Conference