ISPE India Advances & New Frontiers in Sterile Manufacturing Technology Friday 17th April 2020, Mumbai, India
Educational Programme
Friday, 17th April, 2020
Welcome & Introduction - Gopal Nair, Director & Secretary - ISPE India
What has changed in Annex 1 - It's implications & Challenges for Sterile Manufacturing. Richard Denk – Skan AG, Switzerland
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.
How to make QRM of Aseptic Processing Better- Rishikesh Jaiwant, Director, Manufacturing & Operations – BAXTER
Microbiological Implications of the EU Annex 1 Revision - Ziva Abraham, Microrite, Inc, USA
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
Data based approach to Continuous Control Strategy and Real-Time Release-Vipul Doshi - President Global Quality Assurance, - Cadila Healthcare Limited
Low Endotoxin Recovery (LER) – Facts and Myths Explained -Alan Hoffmeister, Senior Global Technology Manager, Charles River
Data Management throughout the Monitoring of a Sterile Manufacturing Environment - Rob Lutskus, Associate Director, Commercial Operations for Lonza Bioscience Informatics
Approaches to Regulating Innovation: Industry Perspective on CMC Challenges and Opportunities -Nina S. Cauchon, Director Regulatory Affairs CMC, Amgen Inc
Question & Answers
End of Day One

ISPE India Advances & New Frontiers in Sterile Manufacturing Technology Saturday 18th April 2020, Mumbai, India
Educational Programme
HPAPI Production Suite and Lyophilization Processes- Critical Design considerations & Qualifications - Richard Denk – Scan AG, Switzerland
Technology Transfer Essentials for Bio Pharmaceuticals- Sarel Chen Tov, CEO Biopharmax Group, USA
How to Manage Clean Room Cost - Quality and Environmental Sustainability without compromises - Keith Beattie, Director, EECO2 - Energy Efficiency Consultancy Group Limited, UK
USFDA Inspectional trends related to smoke studies and points to consider - Daniel J. Roberts, Senior Specialist, Hogan Lovells US LLP
FDA citation trends with respect to Sterile Product Manufacturing – Ziva Abraham, Microrite, Inc, USA
Automation in Sterile Processing - Ganadhish Kamat Global Head Quality & Executive Vice President, Dr. Reddy's Laboratories
Pharmaceutical Product Quality: Visual Inspection – Dr. A. Rama Mohana Rao – Chief Quality Officer –Aurobindo Chief Quality Officer, Aurobindo Pharma
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
Proper Use of Extractables Data for Single Use Systems – Aspects Beyond Measurement – Dr. Armin Hauk Lead Scientist at Sartorius Stedim Biotech GmbH, Goettingen
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
Questions & Answer Session
End of Conference