2022 PDA Aseptic Processing of Biopharmaceuticals Conference

Tuesday, 25 October 2022

09:00-09:15	**Opening Ceremony**
09:15-12:50	**Manufacturing I**
09:15-09:20	**Introduction by the Moderator |** Moderator: Oh DeokSeok (South Korea)
09:20-09:50	**Isolator Technology - Overview of Functionality, VHP Technology and Industry Trends,** Matthias Poslovski, Vice President Sales, Sales, OPTIMA pharma GmbH (Germany)
09:50-10:20	**No-Touch-Transfer: Introduction of RTU Containers Into Aseptic Filling Environments,** Holger Kranenburg, Senior Scientist – GMP Compliance, Franz Ziel (Germany)
10:20-10:50	Coffee Break
10:50-11:20	**Innovative Isolator Design for High Toxic and Biological Risk Aseptic Productions,** Marco Preus, Aseptic Processing, Sales Director Asia-Pacific, IMA S.p.A. Life Division (Italy)
11:20-11:50	**Glove Leak Rate and Detection,** Tema Sinergie
11:50-12:20	**Striving for Zero Defects with Use of Quality-by-Design Principles,** Ashwini Bhisikar, Datwyler (Singapore)
12:20-12:50	**Q&A and Discussion**
12:50-13:50	Lunch Break
13:50-15:55	**Manufacturing II**
13:50-13:55	**Introduction by the Moderator |** Moderator: Marco Preus (Italy)
13:55-14:25	**Janssen's Case Study on Aseptic Operations with Focus on EU GMP Annex 1 Requirement,** Lee Sooho, Janssen Vaccines (South Korea)
14:25-14:55	**A Roadmap for Developing a Pass Thru Decon Best Practice**, Jim Polarine, Senior Technical Service Manager, Life Science Technical Service, STERIS (USA)
14:55-15:25	**Case Studies Using Robots in RABS, Isolators and Other Equipment Used in the Aseptic Processing of Biopharmaceuticals,** Martin Dueblin, Managing Director, One One Eleven (Switzerland)
15:25-15:55	**Q&A and Discussion**
15:55-16:15	Coffee Break
16:15-18:20	**Industry 4.0**
16:15-16:20	Introduction by the Moderator | Moderator: Javier Camposano
16:20-16:50	**Plug and Produce – Getting the Most Out of the Machine Data by Cooperating with Machine Builders - Bausch+Ströbel,** Tobias Wetzel, Area Sales Manager, Bausch + Ströbel (Germany)
16:50-17:20	**Inspectiv AI (Used Case),** Uwe Schaefer, Area Sales Manager, Koerber Pharma Inspection (Germany)
17:20-17:50	**Aseptic Filling,** Siemens
17:50-18:20	**Q&A and Discussion**
18:20	End of Day 1

2022 PDA Aseptic Processing of Biopharmaceuticals Conference

Wednesday, 26 October 2022

09:00-11:00	**Advancements in Glass Technology**
09:00-09:05	**Introduction by the Moderator** | Moderator: Gabriele Peron (Italy)
09:05-09:35	**PDA TR 43 Revision Update,** Jack Gill, Senior Manager Supplier Quality, Quality Operations, Pfizer (USA)
09:35-10:05	**What Are Regulatory Agencies Asking for When Dealing With Extractables & Leachables Testing on Pharmaceutical Packaging Systems,** Kevin Breesch, Partnership Manager, E&L Laboratory, Nelson Labs (Belgium)
10:05-10:35	**How to Achieve Low Dead-volume on Glass Pre-fillable Syringes: A PFS Manufacturing Perspective,** Enrico Barichello, Product Manager - Syringe Platform, Stevanato Group (Italy)
10:35-11:00	**Q&A and Discussion**
11:00-11:30	Coffee Break
11:30-13:30	**Regulatory Updates**
11:30-11:35	**Introduction by the Moderator** | Moderator: Max Fernandez (China)
11:35-12:05	**Regulatory Updates: South Korea,** Dr Park In-Sook, Director General, Biopharmaceuticals & Herbal Medicine Evaluation Department, National Institute of Food and Drug Safety Evaluation, Ministry and Food and Drug Safety (South Korea)
12:05-12:35	**Best Practices When Managing Regulatory Inspections/ Inspectors,** Jo Wang and James P. Stumpff, Parexel (South Korea)
12:35-13:05	**Regulatory Updates: Europe**
13:05-13:30	Q&A and Discussion
13:30-14:30	Lunch Break
14:30-17:05	**Quality Assurance and Biotherapy Production**
14:30-14:35	**Introduction by the Moderator** | Moderator: Ivy Louis
14:35-15:05	**Building Assurance through Managing Risks,** Yoon Seung Yil, VP of DP DevelopmentSamsung Bioepis (South Korea)
15:05-15:35	**Aseptic Operations in Vaccine Manufacturing,** Ashish Sahai, Director, Viral Vaccine Production, Serum Institute of India (India)
15:35-16:05	**BioManufacturing: Implementation of Novel Systems,** Dr Alison Armstrong, Senior Director and Global Head, Technical and Scientific Solutions, Merck (UK)
16:05-16:35	**Smart Quality Monitoring in Pharmaceutical Industry,** Biomerieux (Singapore)
16:35-17:05	**Q&A and Discussion**
17:05-17:10	Closing Remarks