ISPE Europe Virtual Annual Conference 2020

COVID-19 and after

Impact on Innovation, Production, Quality and Supply chain

16 - 17 September 2020
chair: Jean Francois Duliere, France

16 September 2020

08.30 - 08.45	Welcome, Jean Francois Duliere
08.45 - 09.10	**ISPE in Europe - Mission, Vision, Strategy** Thomas Zimmer, ISPE VP European Operations
Track 1	**Factories of the future - Back up manufacturing, contingency plans, more local API production?**
	chairs: Gert Moelgaard, Marick Paris Cadet
09.10 - 09.35	**Sanofi category winner 2020** Speaker tbd
09.35 - 10.00	**Continuous manufacturing** John Groskoph, Executive Director, Global CMC, Pfizer
10.00 - 10.25	**Continuous manufacturing - a real operational example in the API world-Lilly** Speaker tbd
10.25 - 11.00	Interaction with Exhibitors
11.00 - 11.25	**Vaccines for the World - Insights into Design and Execution of a BSL2 Fill-Finish Facility** Matthias Angelmaier, Product Manager Isolator Technology, Bosch Rutger Vandiest, Sr. Director - Head of Sales, Bavarian Nordic Daryn Jenkins, Managing Director, EMEA, IPS
11.25 - 11.50	**Cell Therapy Journey from Research to Clinical Manufacturing** Christina Dragsbaek Ravn, Project Manager, Novo Nordisk Henriette Schubert, Managing Consultant, NNE

11.50 - 12.15	**Novel Therapies : Developing a single use adenovirus vector process through public-private collaboration** Dr. Sofiya Fedosyuk, Vaccine developer at Jenner Institute, UK Youness Cherradi, PhD, Senior Process Development Scientist at Merck
12.15 - 12.40	**ISPE Baseline Guide Water and Steam** Speaker from DACH affiliate tbd
12.40 - 13.00	Q&A Session with all speakers
13.00 - 13.30	Interaction with Exhibitors
Track 2	**Industrie's and regulators view on COVID-19 - impact on industry and regulation**
	chairs: Christian Woelbeling and Teresa Minero
13.30 - 13.55	**ISPE Global Strategy after COVID 19 - what is important** Tim Howard - President and CEO of ISPE
13.55 - 14.20	**FDA input on COVID-19 - Learnings and consequences** Carmelo Rosa and Juan Melendez, FDA
14.20 - 14.45	**Inhouse COVID Testing** Tobias Haas, Merck Healthcare KGaA, Global Head of Analytical Development
14.45 - 15.10	**Regulatory info sharing from Europe related to COVID-19** Jacques Morenas, ANSM
15.10 - 15.45	Interaction with Exhibitors
15.45 - 16.10	**How can Pharma 4.0 help to manage the COVID crisis?** Christian Woelbeling, chair ISPE Special Interest Group Pharma 4.0
16.10 - 17.30	**Panel Discussion with Speakers and Regulators** Introduction Johanna Gouws (WHO) - 10 min
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Track 3	**Quality management in crisis times - relevant regulation for industry, how to protect workers and products**
	chairs: Cristina Mazo, Eva Montana, Jean Francois Duliere

09.10 - 09.35	**Practical Implementation of Medical Devices, Apps and Digitisation - Company Perspective** María Jesús Salido, SocialDiabetes, S.L.
09.35 - 10.00	**"ICH Q 13 and FDA Guidance on continuous manufacturing - A jumpstart for new Quality Management Principles** Ron Ogilvie, Pfizer
10.00 - 10.25	**GMP Inspection Reliance: Experience to Date and Future Expectations** Anne Hayes & C. Schaerer & Jacques Morenas & Mark Birse
10.25 - 11.00	Interaction with Exhibitors
11.00 - 11.25	**"Virtual inspections - an option after Covid-19?** Anne Hayes & C. Schaerer & Jacques Morenas & Mark Birse
11.25 - 12.15	**REGULATORY PANEL SESSION** **Virtual Inspections and GMP Reliance** **10 min intro by 4-5 Regulators**
12.15 - 13.00	**REGULATORY PANEL SESSION** **Current situation on Drug shortages - COVID: one challenge more!**
13.00 - 13.30	Interaction with Exhibitors
Track 4	**New trends in CQV and impact on project delivery in times of Corona crisis**
	chairs: Michael Atzor, David Estape; Michael Hell
13.30 - 13.50	**New issue of ISPE guideline and impcat to C&Q.** Hazem El-Eskandarani, P.E. Project Director (J&J) Joerg Block, Program manager (Bayer AG)
13.50 - 14.10	**Data Integrity by Design in Qualification** Fritz Roeder, Merck Healthcare KGaA
14.10 - 14.30	**Engineering Change Management** Adnan Abosh, Associate Director, Equipment/Facility qualification, Apotex Inc
14.30 - 14.50	**FAT execution in times of COVID-19** Patrick Sullivan (CRB) and Douglas Arnold (Merck)
14.50 - 15.10	**Accelerating Project Execution Utilising GEP and Collaboration with Suppliers.** Lars Hovmand-Lyster, Novo Nordisk
15.10 - 15.45	Interaction with Exhibitors
15.45 - 16.05	**How to Interpret and Manage CQV Requirements – a Suppliers Viewpoint.** Matthias Naser, Optima Pharma GmbH
16.05 - 16.25	**Adaptive Qualification Approach for Cleaning Systems with Fuzzy Control Logic** Ralf Kretzschmar, CEO, Belimed Life Science AG

16.25 - 16.45	**The use of lean thinking in the execution of CQV for a cell and gene therapy and the benefit of applying single piece flow and visual management in the execution.** Joonleong Ng (Pierre Winnepenninckx contact person)
16.45 - 17.05	**Risk - and Lifecycle Management of Biopharmaceutical Operations: ICH Q12 on Legacy Products.** José C. Menezes, Madalena R. Testas, Sofia T. Santos, Marco Strohmeier
17.05 - 17.30	Q&A Session with all speakers