2018 ISPE EUROPE ANNUAL CONFERENCE

19 – 21 March 2018 · Conference **Rome** · Italy
22 March 2018 · Plant Tours

LEAD AND MANAGE A PARADIGM SHIFT

MONDAY, 19 March 2018 - PM	
EXECUTIVE FORUM	
13.00 - 13.10	**Welcome** Chair: Thomas Zimmer, VP European Operations, ISPE
13.10 - 13.50	**Industry 4.0 - How the Electronics Industry Approaches It** Gunter Beitinger, Site Head, Siemens
13.50 - 14.30	**The Trend behind Industrie 4.0 and Its Impact for Existing Value Chains** Thomas Uslaender, Head of Department Information Management and Production Control, Fraunhofer IOSB
14.30 - 15.10	**Healthcare of the Future** Roman Hipp, Partner Strategy & Organisation, Porsche Consulting
15.10 - 15.30	**Networking Coffee Break**
15.30 - 16.10	**Impact of Brexit on Pharmaceutical Operations and on Relevant Regulation** Arielle North, Regulatory Affairs Europe (Former EMA)
16.10 - 16.50	**Implementation of Mass Serialisation - Chances, Risks and Challenges** Andre Overmeyer, Head of Logistics, Merck
16.50 - 17.30	**View of the European Commission: Will Mass Serialisation Meet its Goals in Europe?** Andreas Walter, Director General, European Medicines Verification Organisation (EMVO)

TUESDAY, 20 March 2018 - AM	
KEY NOTES	
07.30 - 08.15	**Welcome Coffee**
08.15 - 08.45	**Welcome** Chair: Jean-François Duliere, Pharmaceutical Process Technologist, Technip Life Science Co-chair: Brendan Cuddy, Head of Manufacturing and Quality Compliance, European Medicines Agency (EMA) John Bournas, ISPE President and CEO Giorgio Bruno, President of CMOs Group, Farmindustria (Italian Association of Pharmaceutical Industries)
08.45 - 09.20	**Future of Pharma Operations in Europe** Philippe Luscan, Executive Vice President Global Industrial Affairs, Sanofi
09.20 - 09.55	**From Industry 4.0 to Pharma Operations 4.0 - The New Holistic Manufacturing Control Strategy** Christian Wölbeling, Senior Director Global Accounts, WERUM IT Solutions
09.55 - 10.20	**Networking Break in the Exhibition Area**
10.20 - 10.30	**AIFA Welcome (invited)**
10.30 - 10.55	**Regulatory Update and EMAs Future Vision** Brendan Cuddy, Head of Manufacturing and Quality Compliance, EMA
10.55 - 11.20	**Annex 1 Revision Update** Andy Hopkins, Expert Inspector, Medicines & Healthcare Products Regulatory Agency (MHRA)
11.20 - 11.45	**FDA Perspective: Current Sterile Manufacturing Issues** Rick Friedman, Deputy Director, Science & Regulatory Policy, USFDA/CDER/OC/OMQ
11.45 - 12.05	**ISPE Young Professionals' View on Pharma 4.0 - Next Generations Challenge on Execution** Robert Landertinger, Production Plant Manager Assistant, Sanofi
12.05 - 12.10	**Announcement of 2018 FOYA Winners** Tim Howard, Vice President, CAI, 2017-2018 Chair, ISPE Board of Directors Jim Breen, Vice President Project Lead Biologics Expansion, Janssen Pharmaceuticals
12.10 - 12.30	**ISPEs Award-winning Facilities of the Year - Key Success Factors for Winners** Jim Breen, Vice President Project Lead Biologics Expansion, Janssen Pharmaceuticals
12.30 - 13.30	**Networking Break in the Exhibition Area**

TUESDAY, 20 March 2018 - PM

	TRACK 1 : Factories of the Future and Aseptic Processing Jean François Duliere, Technip Life Science Gert Moelgaard, Moelgaard Consulting Marick Paris-Cadet, YP France		TRACK 2 : Pharma 4.0 Christian Wölbeling, WERUM IT Solutions Teresa Minero, LifeBee Thorsten Boehle, YP Germany Federico Poli, YP Italy		TRACK 3 : Data Integrity Heather Watson, GlaxoSmithKline Chris Reid, Integrity Solutions Matteo Pracchia, YP Italy		TRACK 4: Anticounterfeiting and Mass Serialisation - Challenges in implementation Fatma Taman, MS Pharma Vee Revithi, F. Hoffmann - La Roche Abdelghani Meqdad, YP France	
	Continuous Manufacturing		**Readiness & Maturity**				**Country Input**	
13.30 - 13.40	**Welcome** Chairs		13.30 - 13.40	**Welcome** Chairs	13.30 - 13.40	**Welcome** Chairs	13.30 - 13.40	**Welcome** Chairs
13.40 - 14.20	**Supply Chains of the Future Through Collaboration** Clive Badman, Head of Pre-Competitive Collaboration, GSK		13.40 - 14.20	**Pharma 4.0 Industry Survey** Teresa Minero, Founder & CEO, LifeBee - President ISPE Italy, Hosting Affiliate - Chair ISPE European Affiliate Council	13.40 - 14.20	**Regulatory Updates** Ib Alstrup, IT Medicines Inspector, Danish Medicines Agency	13.40 - 14.20	**Regulators View on Status of Mass Serialisation Implementation and Anti-Counterfeiting** Domenico Di Giorgio, AIFA Agenzia Italiana del Farmaco
14.20 - 15.00	**Next Generation Downstream Processing for mAbs Production** Nicolas Laroudie, BioManufacturing Engineer, Merck Marine Maszelin, EMEA Process Development Scientist, Merck Group Participation: Goraz Hibar, NextBiopharm DSP Peter Satzer, University of Vienna		14.20 - 15.00	**Pharma 4.0 - A Holistic Approach** Christian Wölbeling, Senior Director Global Accounts, WERUM IT Solutions	14.20 - 15.00	**Ensuring Data Integrity for your GxP Suppliers** Danilo Neri, Owner, Pharma Quality Europe (PQE)	14.20 - 15.00	**Global Pharma Serialisation Overview - Pharma Packaging Trends** Lars Olsen, Global Technology Partner, NNE
15.00 - 15.30	**Networking Coffee Break in the Exhibition Area**							
15.30 - 16.05	**Steris / Clean a Challenge in Continuous Manufacturing** Elisabeth Rivera, Technical Services Manager, STERIS Corporation		15.30 - 16.10	**Readiness and Maturity for Pharma 4.0** Uli Kuchenbrod, Innovation Management, Vetter Pharma	15.30 - 16.10	**Global Implementation of Data Integrity / Archives and Data Integrity** Philippe Lenglet, IS Chief Quality Officer, Servier	15.30 - 16.00	**Serialisation- Challenges and Opportunities for a CDMO** Francesco Castellazzi, Director Projects & Operational Excellence, Recipharm Staffan Widengren, Director Corporate Projects, Recipharm
16.05 - 16.40	**Continuous Lyophilisation** Thomas De Beer, Professor, University of Gent		16.10 - 16.50	**From Process Mapping to Data Mapping** Volker Roeder, Senior Manager Quality, Risk & Compliance, Arcondis AG - ISPE SIG Pharma 4.0	16.10 - 16.50	**Data Lifecycle: Conducting a Risk Assessments to Identify Data/Records** Mogens Høgsboro Østergaard, Senior Project Manager, Novo Nordisk	16.00 - 16.30	**New Legislation on Anti-counterfeiting in Russia** Igor Falkovskiy, Head of GEP Department, FSI "SID & GP
16.40 - 17.15	**Novasep Chromatography Densification** Thomas Flouquet, Product Manager and Application Specialist, NOVASEP		16.50 - 17.30	**Business Process Standardisation and Harmonisation as a Premise for Pharma 4.0**	16.50 - 17.30	**Data Integrity Through Maturity**	16.30 - 17.00	**Mass Serialisation in the MENA Region** Wesal Salem Al-Haqaish, Jordan FDA

17.15 - 17.45	**Continuous Manufacturing from a QA Perspective** Eric Meier, Head QA Continuous Manufacturing, Novartis		Clemens Hohfelser, NTO Global Manufacturing Execution Process Owner, Novartis		Chris Reid, Global Chair, ISPE GAMP Director, ISPE Foundation Past Director, ISPE International Board CEO Integrity Solutions Limited	17.00 - 17.30	**Integration of Computerised Systems Along Manufacturing Operations and Supply Chain for Support of Mass Serialisation Implementation** Marcel De Grutter, Liaison Regulatory and Government Liaison, Abbott Laboratories Thomas Halfmann, Project Director, OPEN-SCS

WEDNESDAY, 21 March 2018 - AM

Aseptic Processing		Enablers & Elements				Mass Serialisation	
08.30 - 09.00	**Innovation in Education: Leveraging the Power of Virtual Reality** Crystal Mersh, CEO, Quality Executive Partners Inc	08.30 - 09.00	**New Technology Platform for Pharmaceutical Processing: Microreaction Technology** Joachim Heck, Managing Director, Ehrfeld Mikrotechnik	08.30 - 09.10	**Implementing an Effectibve Data Integrity Maturity Model** Nuala Calnan, Senior Associate, Lachman Consultants	08.30 - 09.00	**Data on Medicines (ISO IDMP Standards) - EMAs Implementation of ISO Standards** Jens Martin, Pharma TechOps Regulatory - Operations and Business Excellence, Roche
09.00 - 09.30	**Continuous Manufacturing at Johnson & Johnson, Italy: What Have We Learned?** Vanessa Cascioli, Director Engineering & Maintenance, Janssen Latina	09.00 - 09.30	**Pharma 4.0 - The Holistic Control Strategy Approach** Lorenz Binggeli, QM-IT, B. Braun Medical			09.00 - 09.30	**Mass Serialisation at Sanofi** Mongi Sakly, Sanofi
09.30 - 10.00	**Path Forward by Continuous Manufacturing – New Opportunities Going from Batch to CM** Gunther Bechmann, Sr. Manager Production Services, Pfizer	09.30 - 10.00	**The Manufacturing Control Strategy as an Enabler for Right first-time Design of a Smarter, Leaner and Predictable Production – A Pharma 4.0 Reality** Line Lundsberg-Nielsen, Global Technology Partner, NNE Martin Olander, Partner, Front End, NNE	09.10 - 09.50	**Regulatory Updates** David Churchward, Expert GMDP Inspector, Medicines & Healthcare Products Regulatory Agency (MHRA)	09.30 - 10.00	**Mass Serialisation Demployment in Countries and Global Governance** Lucy Osoegawa, Serialization Global Deployment Lead, Roche
10.00 - 10.30	**Comments on Annex 1 from Various Organisations to EMA** Jean-François Duliere, Pharmaceutical Process Technologist, Technip Life Science	10.00 - 10.30	**Plug and Produce - A Reality?** Wolfgang Dedden, Senior Project Manager, Bayer	09.50 - 10.30	**GAMP Italy Data Integrity Working Group - Practical Outcome: Considerations about Audit Trail Review Process.** Antonella Sfondrini, Azactam Plant Project Director, BMS	10.00 - 10.30	**Shall We Dream? ISPE France Experience** Nathalie Wardé, Senior Consultant and Founder, Nad Pharma Consulting
10.30 - 11.00	**Networking Coffee Break in the Exhibition Area**						
11.00 - 12.20	**Impact of the the New Annex 1: Q&A Session with EU and FDA Regulators** **Annex 1 Panel Discussion with Regulators** Andy Hopkins, Expert Inspector, MHRA Rick Friedman, Deputy Director, Science & Regulatory Policy, Office of Manufacturing Quality, FDA Regulators from NCAs in Europe	11.00 - 11.40	**How to Enable Your Manufacturing Workforce for the Digital Era** Teresa Rodo, SVP Pharma Operations, Merck	11.00 - 11.40	**Meeting the Pachyderm in the Room Head-on: Address Data Integrity and Production Metrics with Modern Quality Systems** Jonathan Burd, Director Strategy, Vault Quality Europe, Veeva Systems	11.00 - 11.40	**Identifying and Mitigating Risk of Errors in Serialisation and Encoding Processes** Andrea Zoppi, Global Quality System - Packaging and labelling, Eli Lilly
		11.40 - 12.20	**Young Professionals Pharma 4.0 - Hackathon Results** YP Team and Pharma 4.0 Track Speakers	11.40 - 12.20	**Data Integrity Gap Assessment & Remediation Approach in Quality Control** Sudip Debnath, QC Analytiker, QC Systems, GE Healthcare	11.40 - 12.20	**The EU Commission's Perspective** Andreas Walter, Director General, EMVO Medicines
12.20 - 14.00	**Networking Lunch in the Exhibition Area**						

WEDNESDAY, 21 March 2018 - PM							
Innovation		**Case Studies & Benefits**				**Mass Serialisation**	
14.00 - 14.30	**Development and Implementation of Control Strategy for an Automated Continuous Tablet Manufacturing Line** Stephan Sacher, Area Leader, Process and Manufacturing Science, RCPE	14.00 - 14.40	**Cyber Security Risks Implied by Industry 4.0** Enzo M. Tieghi, CEO, ServiTecno	14.00 - 14.40	**New GAMP Data Integrity Good Practice Guidance** Sion Wyn, Owner, ConformITy	14.00 - 14.40	**Global Implementation of Mass Serialisation at Bayer** Hans Walter Hoehl, Senior VP PS EIP, Bayer
14.30 - 14.55	**BPOG Roadmap** Gert Moelgaard, Senior Consultant, Moelgaard Consulting	14.40 - 15.20	**Baxter Maturity Case Study** Fabrizio Pasqua, Quality Director EMEA, Baxter Healthcare	14.40 - 15.20	**PIC/S Update** Lorella Chiappinelli, GMP Senior Inspector, Italian Medicines Agency - AIFA	14.40 - 15.20	**Medicinal Products Serialisation: Challenges and Opportunities of an Italian MAH&CMO** Tito Picotti, Pharmaceutical Plant Director and Q.P, Angelini Group Federico De Franceschi, Engineering & Maintenance Manager, Angelini Group
14.55 - 15.20	**Fast X-Ray Tomography Technics for Medical Devices in Line Inspection** Christophe Defrance, Business Development / Sales Manager, CyXplus - TechnipFMC						
15.20 - 16.00	**Networking Coffee Break in the Exhibition Area**						
16.00 - 16.40	**Facility of the Future Technologies in Small Molecule and Large Molecule Pharma** Dave DiProspero, Associate/Director of Pharmaceutical Process Technology, CRB Steve Attig, Lead Process Engineer, Associate, CRB	16.00 - 16.40	**A Strategy for Pharma 4.0 with Case Studies to Build Capabilities and Deliver Early Business Value** Alton D. Johnson, Vice President, Global Technology Services, TBS – Technology & Business Solutions, Pfizer	16.00 - 16.40	**Case Study: Implementing a Global Data Integrity Programme** Guy Wingate, Compliance Officer - Global Manufacturing & Supply Chain, GlaxoSmithKline	16.00 - 16.40	**Mass Serialisation in Belgium** Pasquale Tansella, Senior Manager - Serialisation Technologies MSAT - Manufacturing Technologies, GSK
16.40 - 17.20	**Closed Biotech Systems: A Life Cycle Approach** David Estapé, Technology Manager Life Sciences, M+W Group Lars Hovmand-Lyster, Senior Engineering Specialist, Novo Nordisk	16.40 - 17.20	**Digital Manufacturing - Case Studies** Andrea Fantaccione, Execution Systems Engineer, Janssen-Cilag (J&J)	16.40 - 17.20	**Case Study on Data Integrity Remediation for Manufacturing Systems** Darren Starr, Quality Assurance Associate, Astra Zeneca	16.40 - 17.20	**Implementation of Mass Serialisation and Track-and-Trace System in Turkey Membership of TMMDA to PIC/S and improvements** Timur Kabadayı, MD, CONVAL Group Gülsen Yilmaz, Quality Manager of Inspectorate, TMMDA Fatma Taman, Chief Technical Officer, MS Pharma
17.20 - 17.30	Closing Remarks	17.20 - 17.30	Closing Remarks	17.20 - 17.30	Closing Remarks	17.20 - 17.30	Closing Remarks