Connecting a World of Pharmaceutical Knowledge

# The Future of European Pharma – Flexible, Agile and Sustainable
## ISPE Brussels Conference

***Monday 30 September and Tuesday 1 October 2013***

<table>
<tr><th colspan="5">DAY 1</th></tr>
<tr><td>08.45</td><td>09.00</td><td colspan="3">Introduction<br><br>Honorary Chair: Gert Mølgaard<br>Vice President (VP), Strategy Development<br>NNE Pharmaplan, Past Chair for ISPE, Denmark<br><br>Chair: Thomas Zimmer, Former SVP EHS & Sustainability of Boehringer Ingelheim,<br>CEO of ZS.CTIS Consulting GmbH, Germany<br>Co-chair: Robert J E Bowen, Director, Facilities Integration Ltd, UK</td></tr>
<tr><td>09.00</td><td>09.40</td><td colspan="3">The Road Ahead... Trends, Implications and Strategy for Pharma Manufacturing and Supply Organizations<br><br>Speaker: Louis Schmukler,<br>President, Global Manufacturing and Supply, Bristol-Myers Squibb, USA</td></tr>
<tr><td>9.40</td><td>10.20</td><td colspan="3">Responsiveness of Facilities – How to Create More Agility?<br><br>Dr. Gabriele Schönberger, Director, Boehringer Ingelheim, Germany</td></tr>
<tr><td>10.20</td><td>10.50</td><td colspan="3">Networking Break</td></tr>
<tr><td>10.50</td><td>11.30</td><td colspan="3">New EMA Drafts:<br>GMP Guideline Chapters 3 and 5<br>Guideline on Setting Health-Based Exposure Limits<br><br>Dr. Andreas Flückiger, Chief Occupational Health Officer, F. Hoffmann-La Roche Ltd., Basel</td></tr>
<tr><td>11.30</td><td>12.00</td><td colspan="3">Panel Discussion<br>Moderated Session with the Keynote Speakers + Q&A</td></tr>
<tr><td>12.00</td><td>13.00</td><td colspan="3">Lunch</td></tr>
<tr><th colspan="5">BREAKOUT SESSIONS</th></tr>
<tr><th colspan="3">Operations<br>Track Leader: Chris Mullen</th><th>Plants and Facilities<br>Track Leader: Jean-François Duliere</th><th>IT and Automation<br>Track Leader: Chris Reid</th></tr>
<tr><td>13.00</td><td>13.40</td><td>What are the Challenges of Operating Flexible and Shared Production Plant?</td><td>How do Microreactors and Continuous Processes Impact Facility Design?</td><td>Establishing Automation Strategies for Flexible Facilities</td></tr>
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| | | **Chris Mullen,** Head of Operations, Fujifilm Diosynth Biotechnologies, UK | **Patrice Coumet**, Senior Pharmaceutical Engineering and GXP Compliance Expert, Technip Life Sciences, France<br>**Marc Bertrand,** Department Manager - Life Sciences Engineering, Technip Life Sciences, France | **Dr Peter Iles-Smith,** Manufacturing IT Technical Director - Global Manufacturing & Supply IT, GSK, UK |
| 13.40 | 14.20 | **Cleaning Standards in Multi-Product Facilities**<br><br>**Dr. Andreas Flueckiger,** Chief Occupational Health Officer, F. Hoffmann-La Roche Ltd, Switzerland | **How to Increase the Flexibility by Standardisation for Vaccine Facility Design (Case Study)**<br><br>**Klaus Hermansen**, Senior Technology Partner, Vaccines, NNE Pharmaplan, Denmark | **Benefits and Challenges when Moving from a Batch Process to Continuous**<br><br>**Ivo Backx,** Business Development Solutions for Life Sciences Industries**,** Siemens AG, Belgium |
| 14.20 | 15.00 | **Cleaning Validation**<br><br>**Colin Gall,** Fujifilm Diosynth Biotechnologies, UK | **Planning the Optimal Pharma-Production Facility Using Software Tools**<br><br>**Ingrid Hutter,** Scientific Professional, Pixon, Switzerland | **Establishing Environmental Controls in Shared/Flexible Facilities**<br><br>**Gregory Weddle,** Global Dir., Life Sciences Advanced Solutions Johnson Controls, Inc., Netherlands |
| 15.00 | 15.30 | **Networking Break** | | |
| 15.30 | 16.10 | **Filling Systems for the Future**<br><br>**Klaus Ullherr,** Packaging Technology, Product Manager, Robert Bosch GmbH, Germany<br>**Isabelle Uettwiller,** Head of Validation Lab, Sartorius Stedim Biotech, France | **Key Topics in Sustainable Environmental Control and HVAC (Addressing Air Exchange Rates, Filtration and Cross-Contamination Control)** | **Maintaining Compliance with a Flexible Operation**<br><br>**Chris Morse**, Product Manager, Honeywell Process Solutions, UK |
| 16.10 | 16.50 | **Aseptic Manufacturing – RABS vs. Isolators: What is the Future Standard?**<br><br>**Niall O'Meara,** Director of Manufacturing, Amgen, Ireland | **Disposable-Stainless Steel Hybrid Facilities Challenges, Risks and Gains for Bioprocess Development and Production**<br><br>**Joachim Baer,** Associate Director of Upstream Manufacturing Sciences, Boehringer Ingelheim GmbH Biopharmaceutical Operations, Germany | **Facilitating Flexible Manufacturing through IT Data Standards**<br><br>**David Stokes,** Consultant, Percipient, UK<br>**Yves Samson**, Director, Kereon AG, Switzerland |
| 16.50 | 17.30 | **Buffer and Media Preparation for New and Expanding Facilities**<br><br>**Adam Sokolnicki,** Biomanufacturing Engineer, EMD Millipore, USA | **Economic Risk Minimisation of Single Use Cell Culture – Scale Up vs. Scale Out**<br><br>**Miriam Monge,** Vice President Sales & Marketing**,** Biopharm Services Ltd, France | |

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| 17.30 | 18.30 | **Networking Drinks** |
| 19.00 | 22.00 | **Networking Dinner** |

| DAY 2 | | | | |
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| **BREAKOUT SESSIONS** | | | | |
| **Operations**<br>**Track Leader: Chris Mullen** | | | **Plants and Facilities**<br>**Track Leader: Jean-Francois Duliere** | **IT and Automation**<br>**Track Leader: Chris Reid** |
| 08.30 | 09.10 | **Ballroom Concept**<br><br>**Julian Wilkins,** Founder and Vice President, PharmaConsult Us Inc., USA | **New Strategies for Aseptic Filling for Emerging Markets**<br><br>**Benoît Verjans,** Scientific Advisor , Aseptic Technologies, Belgium<br>**Lilja Jan,** Director Commercial Management, Key Plants, Sweden | **The Impact of Evolving Serialisation Requirements on the Broader Pharmaceutical Industry**<br><br>**Liam O'Riordan,** Serialisation Director**,** ESP, Ireland |
| 09.10 | 09.50 | **ConsiGma™, the Continuous Manufacturing Platform for Flexible Pharmaceutical Solid Dosage Production**<br><br>**Kris Schoeters,** Product Manager Continuous Processing, GEA Pharma Systems, Belgium | **Modular Plant Design – Cheaper and More Efficient?**<br><br>**Robert Dream,** Principal, HDR COMPANY LLC, USA | **Integrated PAT Data Management as a Key Enabler for Continuous Manufacturing in Life Sciences**<br><br>**Jan Verelst**, Business Development Manager SIPAT / PAT-QbD / Pharma / Life Sciences, Siemens, Belgium |
| 09.50 | 10.20 | **Networking Break** | | |
| 10.20 | 11.00 | **Continuous Flow Reactors: An Opportunity for the Development of Flexible and Sustainable Production Processes**<br><br>**Dr Charlotte Wiles,** Chief Technology Officer, Chemtrix, UK | **Transforming the Sourcing Biologics**<br><br>**Bart van Praag,** CEO, Dove Tail Integrated Systems, Netherlands | **Implementation of Quality by Design Using MES**<br><br>**Philip Rees MSc**, Senior Manager, Aston Life Sciences, Switzerland |
| 11.00 | 11.40 | **Outsourcing – Breakdown of Responsibilities between Contractor and Contract Giver** | **Sustainability and Resource Efficiency of the Flexible Facility** | **Model-Based Design and Simulation Tool Demonstration** |

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| | | **Dr. Andreas Rothmund**, Qualified Person, Vetter Pharma-Fertigung GmbH & Co. KG, Germany | **Kia Salin,** Environmental Strategist, Swedish Medical Products Agency, Sweden | **Damien Marchand,** Technical Sales Specialist Dassault Systèmes, France |
| 11.40 | 12.20 | **Continuous Processing in Biotech Production: An Alternative to a Modern Single Use, Batch, Facility?**<br><br>**Thomas Daszkowski,** VP Process Development and Optimisation, Bayer Technology Services | **How to Design and Size Equipment to Implement Lean Production Organisation**<br><br>**Robert J E Bowen**, Director, Facilities Integration Ltd, UK | **Validation through Industrial Virtualisation**<br><br>**Philippe Baron,** adn Europe |
| 12.40 | 13.20 | **Update of the EMA Workshop on Dedicated Facilities**<br><br>**Stephanie Wilkins**, PE, Owner, PharmaConsult US, Inc, USA | | |
| 13.20 | 14.20 | **Lunch** | | |
| 14.20 | 15.40 | **Demonstrator Workshops**<br><br>**Richard Denk**, Hecht Technologie GmbH, Germany<br><br>**Dr Rob Lammens**, Consultant, University of Bonn, Germany, **Stephen Boswell,** Director S3 Process Limited, UK, **Hartmut vom Bay**,Vice President Gerteis, Switzerland<br><br>**Jean-Pascal Zambaux**, Président, Disposable-Lab SAS, France | | |
| 15.40 | 16.20 | **Quality Assurance Agreements**<br>– Challenges for the Development, Manufacture, Testing, Storage and Distribution of Intermediates, Active Pharmaceutical Ingredients and Investigational Products<br><br>**Barry Oliver**, Head of Quality, Commercial Business, Fujifilm Diosynth Biotechnologies, UK | **What Challenges Regulatory Requirements Set from Plant and Facility Design Perspective? Impact of New Chapters 3-5 and Toolkit for Toxicology**<br><br>**Peter Marshall,** Principal Technology Engineer, AstraZeneca, UK | **Paperless Lab to Support Quality by Design (QbD) Initiatives**<br><br>**Peter Boogaard,** Founder, Industrial Lab Automation, Netherlands |
| 16.20 | 16.50 | **Networking Break** | | |
| 16.50 | 17.20 | **Wrap-Up: How Easy it is to Move from Down-Scale to Up-Scale Process with Flexible Manufacturing?**<br>**Chris Mullen,** Head of Operations, Fujifilm Diosynth Biotechnologies, UK | | |

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| | | **Jean-François Duliere,** Pharmaceutical Process Technologist, Technip Life Sciences, France<br>**Chris Reid,** Owner, Integrity Solutions Ltd, UK |
| 17.20 | 17.50 | **Flexible Manufacturing – A Way Forward?**<br><br>**Thomas Zimmer,** Senior Vice President, Boehringer Ingelheim GmbH, Germany |
| 17.50 | | **Conference Adjourns** |