## Agenda

**ISPE Workshop ‘Pharma’s Journey to Digital Manufacturing’**  
**OWN it – DRIVE it – WIN it!**  
*ISPE DACH homepage*  
Novartis Campus Basel, Auditorium WSJ-510  
4-5 March 2020

**Wednesday, 4 March 2020**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>08:30 - 09:00</td>
<td>Registration</td>
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| 09:00 - 09:10 | **Moderators: Viktor Mettler & Ursula Busse, Novartis**  
Welcome & introduction |
| **09:10 – 09:50** | **Moderator: Viktor Mettler, Novartis**  
Digital Transformation, a Fad, or the Future?  
Digital as a blockbuster  
Ralf Altenburger, Roche  
Ulf Schrader, McKinsey |
| **09:50 – 11:00** | **Moderator: Heike Röder, Bayer AG**  
FAIRy Tales - Why is FAIRification of data important  
Roche Clinical Development Cloud Platform  
SOP of the future – From Documents to Data  
Heike Röder, Bayer AG |
| **11:00 - 11:30** | Coffee Break |
| **11:30 - 12:45** | **Moderator: Christian Wölbeling, Werum**  
Standardization & Process Life Cycle Management as cornerstones of the interface with a digital manufacturing  
Non-conformance digital diagnostics  
Bayer Lighthouse in Garbagnate  
Use of Data for Quality Analytics  
Quentin Grignet, GSK  
Christian Dubs, J&J  
James Thomas, Bayer  
Markus Zeitz, Novartis |
| **12:45 - 14:00** | Lunch Break |
| **14:00 - 15:00** | Coffee Break |
| **15:00 - 16:15** | **Moderator: Heike Röder, Bayer AG**  
How to bring Data Lakes to Life  
Gopi Sridharan, Roche  
SOP of the future – From Documents to Data  
Heike Röder, Bayer AG |
| **16:15 - 18:00** | **Moderator: Christian Wölbeling, Werum**  
Standardization & Process Life Cycle Management as cornerstones of the interface with a digital manufacturing  
Non-conformance digital diagnostics  
Bayer Lighthouse in Garbagnate  
Use of Data for Quality Analytics  
Quentin Grignet, GSK  
Christian Dubs, J&J  
James Thomas, Bayer  
Markus Zeitz, Novartis |
| **18:00 - 20:00** | Dinner & Networking |

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**KEYNOTE PRESENTATIONS: DATA & DATA-LAKES LIVE**

**STARTING THE JOURNEY: FROM DOCUMENTS TO DATA**

**INTEGRATING DATA INTO MANUFACTURING & CONTROL – PART 1**

**INTEGRATING DATA INTO MANUFACTURING & CONTROL – PART 2**
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<tr>
<td>14:00 - 15:30</td>
<td><strong>Moderator: Christian Dubs, J&amp;J</strong></td>
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<td>Francois Nebbia, Merck KGaA</td>
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<td>How to make a digital transformation a reality</td>
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<td>Michael Becker, Pfizer</td>
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<td>High Containment (HighCon) digital pharma production site</td>
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<td>Andreas Pribil, Sandoz</td>
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<td>Manufacturing the ‘Golden batch’ in biotech</td>
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<td>Sandra Guerreiro, Novartis</td>
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<td>Using Digital to create a new standard in batch release</td>
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<td>Q&amp;A</td>
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<td>15:30 - 16:00</td>
<td><strong>Coffee Break</strong></td>
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<td>16:00 - 17:30</td>
<td><strong>Moderator: Johannes Galatsanos, Novartis</strong></td>
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<td>AI “for dummies” – a very short introduction</td>
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<td>Johannes Galatsanos &amp; Arne Zilian, Novartis</td>
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<td>AI/ML to move from information generation to value generation</td>
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<td>Etzard Stolte, Roche</td>
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<td>AI use &amp; validation for complaints signal management via social media</td>
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<td>Renato Panza, Novartis</td>
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<td>Compliant AI - Making models behave</td>
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<td>Roger Burkhardt, Quantumblack</td>
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<td>ISPE GAMP initiatives in the AI space</td>
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<td>Sion Wyn, consultant ConformIT &amp; ISPE GAMP</td>
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<td>Q&amp;A</td>
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<td>17:30 - 19:30</td>
<td><strong>Networking Reception</strong></td>
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Thursday, 5 March 2020

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| 09:00 - 10:30 | **Moderator: Ursula Busse, Novartis**  
Digital as the new normal: Scaling digital operations at Novo Nordisk – Achievements and Learnings  
Smart, instead of Steel – Digital twin scheduling and AI on production line performance to avoid big CAPEX  
Spot On: Think big, start small, scale fast  
How to design Patient Driven Supply Network in Healthcare  
Q&A |
| 10:30 - 11:00 | **Coffee Break**                                                          |
| 11:00 - 12:25 | **Moderator: Patrick Gras, Roche**  
People, Organization and Leadership  
Digitalization Capabilities in Manufacturing – perspectives from Data Science and Manufacturing Systems  
Closing panel discussion  
Closing remarks |
| 12:25 - 12:30 | **End of workshop, networking lunch** |

**ARTIFICIAL INTELLIGENCE IN REGULATED ENVIRONMENTS - PART 2**

**OVERCOMING ROADBLOCKS TO FULFIL THE PROMISE OF THE DIGITAL ECOSYSTEM**
Afternoon program

Site visit of the Novartis Nerve Live cockpit, Moderator: Luca Finelli, Head DSAI Insights Strategy & Design, Novartis

Across the industry, clinical trial execution is typically managed through the consolidation of hundreds, if not thousands, of documents – the digital platform Nerve Live brings it all together every evening, displaying it intuitively at the click of a button in SENSE.

Two visits à 25 people each will be offered on March 5. On-site registration is required to participate, on a first come first serve basis. Visit times: 14:00 – 15:30 and 15:30 – 17:00.

About this workshop

The pharma industry is undergoing a significant transformation due to digital technologies. Techniques such as visualization, modeling, automation, machine learning and artificial intelligence are dematerializing traditional processes and facilities, and drive productivity through fewer errors, higher output and improved quality, safety and speed of operations.

Building on the success of the workshop in November 2018, ISPE D/A/CH will organize a second workshop on 4-5 March 2020 in Basel, Switzerland. The event will feature case studies, regulatory aspects, opportunities, successes and pitfalls faced in the digitalization journey, pointing to the urgency to accelerate the digital transformation.

This event is tailored for mid-senior level management, decision makers, and leaders who set strategy and direction for manufacturing, quality and CMC regulatory affairs in their organizations.

Chair: Viktor Mettler, Global Quality Head REFS, NBS & Country Quality | ISPE DACH Chapter representative
Co-Chair: Ursula Busse, Global Head Quality Intelligence & External Affairs, Novartis

About ISPE

Founded in 1980, ISPE (International Society for Pharmaceutical Engineering) is a nonprofit organization of close to 20,000 members worldwide. ISPE has significant influence on emerging regulatory and technical topics, involves active participation by major regulatory authorities and provides ample opportunities for benchmarking best industry practice.

About the ISPE DACH chapter

The largest affiliate in Europe with more than 1200 members and second worldwide was founded in 1992. The Germany/Austria/Switzerland affiliate has members in the committee of Pharma 4.0 or GAMP and is very actively contributing to many local and European ISPE conferences and guides.