ISPE Germany | Austria | Switzerland Affiliate

ISPE D/A/CH Workshop

Pharma's Journey to Digital Manufacturing and Supply

Please note that the schedule, the speakers, as well as the presentation titles are preliminary and therefore subject to change.

Monday, March 4th, 2024

SITE VISIT [1]	
14:00 – 14:15	Arrival & Welcome at Lonza, Visp, Switzerland Safety instructions
14:15 – 14:40	Site Visit Briefing
14:40 – 16:40	Site Visit, three groups 1. Biologics Facility 2. Small Molecules Facilities 3. mRNA/ Ibex Solutions®
16:40	End of Site Visit

[1] Limited number of participants.

Please note that dinner is not provided on March 4th, 2024. Attendees are responsible for their own meals. There are several dining options available nearby and we encourage you to explore local restaurants.

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Tuesday, March 5th, 2024

9:00 – 9:30	Arrival and Welcome Coffee
INTRODUCTION	
09:30 – 10:00	Session moderators: Viktor Mettler, Ursula Busse **Welcome to Visp** Renzo Cicillini, Site Head Visp, Lonza **Welcome from ISPE** Christian Wölbeling, Körber Pharma Software, COP Pharma 4.0 Founder and Chair, Roger Nosal, Consultant and former VP CMC at Pfizer
KEYNOTE PRESENTATIONS	
10:00 – 11:00	General overview from different perspectives (regulatory, industry, academia, consultancies) for the promises, implementation statuses, and risks of AI. Session moderators: Viktor Mettler, Ursula Busse **The promise of AI and ML in Pharma Manufacturing** Anna Fournier, Principal Data Scientist, Swiss Data Science Center (ETH Zürich/EPFL) **From Digitization to Digital Performance – Unlocks to Accelerate Impact** Ulf Schrader, Senior Partner, McKinsey **AI in Pharma Manufacturing – Balancing Risks, Benefits, and the Perils of AI in Action** Jérôme Zürcher, Lecturer at ETH Zurich and Managing Director at LastingImpact.AI **Regulatory Considerations** TBA
11:00 – 12:00	**Panel Discussion** • All morning speakers • Michelangelo Canzoneri, Merck KGaA • Hadj Latreche, Roche
12:00 – 13:30	**Lunch Break**

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DATA / AI, ML STRATEGIES & USE CASES IN BIOTECHNOLOGY	
13:30 – 15:15	Session chair: Viktor Mettler In this session, you will hear about the current digital transformation and the pivotal role AI plays in reshaping the technological landscape for the manufacturing of biologics. The focus will be on how to use models to create algorithms that provide an advanced process control strategy to improve yield by optimizing the control of process and material variability in a GxP context. **Using data combined with biological insights to design the next generation of cell line production platforms** Alessandro Di Cara, Head of Bioinformatics & Data Science, Lonza **Predictive Control of Yield & Titer and Quality: From Big Data to Shop Floor** Hadj Latreche, Digital Transformation Senior Leader, Roche Panelists • Speakers • TBA
15:15 – 16:00	Coffee Break
DATA / AI, ML STRATEGIES & USE CASES IN DEVELOPMENT, TECHNOLOGY TRANSFER AND LAUNCH	
16:00 – 17:30	Session chair: TBC, Lonza This session will discuss hybrid modeling in the context of launch/new product where limited data is available. This includes new cutting-edge technologies such as synthetic data or generative data used to increase model accuracy and overcome lack of data. In addition, a comprehensive approach on how to develop a structured framework to dynamically identify, assess and mitigate risks related to AI/ML based solutions will be presented. The presentations will be followed by a discussion on Quality Risk Management for AI/ML with an authority representative. **Toward Predictive Native Process Using Hybrid Modeling** Jonathan Ritscher, Digital Strategy Delivery Specialist, Roche **Value of topic modeling techniques applied to process deviation management activities** Maria Sedykh, Principal Data Scientist, Lonza

	Risk Management for AI/ML Stefan Muench, GAMP D/A/CH and VP Validation & Qualification, Körber Pharma Panelists • Speakers • Anna Fournier, Principal Data Scientist, Swiss Data Science Center • Regulators/ GMP inspectors: TBA
19:00 – 21:30	Dinner

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Wednesday, March 6th, 2024

DATA / AI, ML STRATEGIES & USE CASES IN PACKAGED DRUG PRODUCT MANUFACTURING	
08:30 – 10:15	Session chair: Christian Wölbeling Manual quality control steps in pharmaceutical primary and secondary packaging are still the most critical and time-consuming value chain steps. Digital technologies allow the accurate processing of large amounts of data during the automated visual inspection processes. AI driven solutions improve detection accuracy and minimize false-eject-rates. This session will focus on visual inspection case studies using these AI models and their benefits. Presentations will be followed by a panel discussion involving GMP inspectors. Visual inspection Julien Janda, Head of Process & Technology, Takeda Visual inspection (qualification of automated VI system) Mario Holl, Managing Director, Koerber Pharma InspectifAI NN, Thermo Fischer Italy Panelists • Speakers • GMP inspectors tbc
10:15 – 10:45	Coffee Break
HARNESSING DIGITAL TWINS FOR QUALITY BY DESIGN: REAL-WORLD APPLICATIONS AND BUSINESS CASES	
10:45 – 12:15	Session chair: Laura Kuger Digital models, shadows, and twins offer valuable insights, such as predicting and optimizing the impact of parameter changes. Real-time monitoring and data analysis using digital twins allows for real-time adjustments and proactive problem-solving. Use of digital twins potentially streamline development and optimization times and costs, mitigate scale-up risks and deliver increased assurance of product quality. This track addresses the effective and real-world utilization of digital twins and models in bioprocess development and manufacturing, focusing on practical, end-to-end industry applications, business cases, and regulatory considerations. **End-to-End Digital Twins: A QbD Catalyst from Process Development to Manufacturing** Thomas Zahel, Head of CMC Innovation Consulting, Körber Pharma

	Digital Twin Models for Biologics USP David Moore, Senior Strategic Initiatives Manager, Merck KGaA **Digital Twin Models for ATMP Manufacturing** Antoine Maison, Head of Digital Innovation, Tigen Pharma Panelists • Speakers • Regulators: TBA
12:15 – 13:30	Lunch Break
TRANSLATING INNOVATIVE DIGITAL PARADIGMS FOR ADOPTION AND IMPLEMENTATION	
13:30 – 15:00	Session chair: Roger Nosal This session will focus on specific Process Analytical Technology examples where sensors that measure conductivity, flow, weight and pressure as well as probes like UV and NIR produce a stream of data that enables a process to be followed in real-time. Chemometrics models coupled with machine learning models (ML) ("Digital Twin") are capable of simulating time profiles of product attributes. These models systemically describe and can adjust for process variability. The data generated from these models can be used to as the basis for a robust drug product control strategy. The session will also discuss how these models, their algorithms and the digital data generated by them can be conveyed in regulatory applications and assessed during inspection. **A Regulatory Framework for Enabling Digital Innovation in Manufacturing – Two Case Studies** Matt Popkin, Senior Director CMC Excellence, GlaxoSmithKline Gert Thurau, Head of Manufacturing Technology Innovation, Roche Panelists • Speakers • Regulators: TBA
15:00 – 15:15	Coffee Break

ISPE Germany | Austria | Switzerland Affiliate

CLOSING PANEL DISCUSSION	
15:15 – 16:15	Session chair: Nick Lee, HPRA In this session, key outcomes from the panel sessions will be discussed in the context of how AI/ML approaches can convey increased assurance of quality. The discussion will seek to elaborate on how to convey the generation, control, and management of data through a holistic control strategy for regulatory assessment in an application and for inspection. The session will start with short key messages from each deep dive session: • Biotechnology – Viktor Mettler • Development/Tech Transfer – TBA, Lonza • Packaged DP manufacturing – Christian Wölbeling • Digital Twins – Laura Kuger • Translating innovative digital paradigms – Roger Nosal Panelists • Christian Wölbeling, Körber Pharma Software, CoP Pharma 4.0 Founder and Chair • Cristina De Simoni Klitgaard, Emerging Technology QA Director, Novo Nordisk • Regulators: TBA
16:15 – 16:30	Conclusion
from 16:30	Departure