



2024 PDA Good Digitalization in Pharma Conference

Succeeding in Digitalization: The Next Era of Pharma?

04 – 05 June 2024

Antwerp / Belgium

Agenda

Tuesday, 04 June 2024

9:00	Welcome	Falk Klar, <i>PDA Europe</i>
9:10	Welcome from the Co-Chairs	Dieter Bachmann, <i>Johnson & Johnson</i> Marilyn Romieux, <i>Merck</i>
09:20 – 11:15 Opening Plenary: Artificial Intelligence in Society - Acceptance and Opportunities		Moderator: Marilyn Romieux, <i>Merck</i>
<p><i>One might be tempted to question and compare Artificial Intelligence with Human Intelligence. Intelligence is a defining attribute of humanity, what makes us unique. The idea of an artificial form of intelligence can be disconcerting and may lead to resistance to its adoption. Our opening session will focus on how Artificial Intelligence benefits and serves society, adding to Human Intelligence's unequalled ability to process massive amounts of data. We will initially discuss the adoption of this tool on a societal level, and then explore several cases where AI is being leveraged to enable an easier, more sustainable, and safer life for professionals of the pharmaceutical industry as well as for consumers of healthcare products and medical devices.</i></p>		
	The Human Factor of AI Implementation	Michael Gerlich, <i>SBS Swiss Business School</i>
	Leveraging NLP to Enhance Risk Assessment of Incoming Incident Reports	Nicolas Löffler-Perez, <i>Swissmedic</i>
	Digitalization and Sustainability in Manufacturing: Navigating the Path to Net-Zero Carbon	Alessandro Masiello, <i>Rockwell Automation</i>
	Plenary Discussion	
11:15	Networking Coffee Break, Poster Session & Exhibition	
11:45 – 13:15 Session 1: Digital Transformation Strategies		Moderator: Florian W. Huber, <i>TissUse</i>

Join us for an enlightening session on the latest strategies in digital transformation within the pharmaceutical manufacturing sector. The PDA Drug Manufacturing Digitalization (DMD) Task Force will outline its comprehensive approach to full digital implementation, highlighting its plans for a gap analysis, a review of



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statistical methods in production monitoring from an AI/ML perspective, and the development of a digital twin for drug manufacturing processes. Delve into the human side of digital transformation, understanding the roles and benefits for all organizational levels, from CEOs to lab employees, and the importance of holistic and agile implementation. We will see innovative initiatives of big pharma aimed at revolutionizing process development, production, and supply chain through modular factory layouts, networked systems, and real-time data integration, emphasizing the importance of a human-centric approach amidst these technological advancements. Discover the challenges, solutions, and future directions that will shape the industry's standards in this comprehensive session.

	On our Journey from MANUFACTURING to SMARTfacturing	Michelangelo Canzoneri, <i>Merck</i>
	Digital Transformation in Life Science – Obstacles and Time of Mind Changing	Daniel Borchert, <i>Körber</i>
	PDA Drug Manufacturing Digitalization Task Force	Toni Manzano, <i>Aizon</i>
	Q&A, Discussion	
13:15	Networking Lunch Break, Poster Session & Exhibition	
14:00	LIVE Guided Poster Walk Engage with our Poster Presenters in our Exhibition Hall	
14:30 – 16:10 Session 2: Regulatory Compliance		Moderator: Timothy W. Hsu, <i>UNIDO</i>
	Interactive Questionnaire	
	A Regulatory Framework Enabling Digital Innovation in Manufacturing	Monica Perea-Velez, <i>GSK</i>
	GMP Compliant Life Cycle Management of AI/ML Solutions	James Francum, <i>GxP-CC GmbH</i>
	Journey to Digitalization: How Digitalization Supports Quality Decisions	Laure Gurcel, <i>Sanofi</i>



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	Q&A, Discussion	
16:10	Networking Coffee Break, Poster Session & Exhibition	
16:40 – 18:10 Session 3: Drug Development		Moderator: Sesethu Dowiasch, <i>Rockwell Automation</i>
<p>Unleashing the Power of Digital Drug Development - Automated assays on multi-organ chips generate massive data, fueling AI simulations and predictions that revolutionize preclinical studies and digital drug development. Explore real-time tumor organoid-on-chip drug response monitoring and holistic in silico assessments of novel small protein therapeutics. Witness the synergy of long-term organoid cultivation, dynamic cancer drug treatment, and real-time respiration sensing, unlocking kinetic insights for drug discovery.</p>		
	Holistic in Silico Developability Assessment of Novel Classes of Small Proteins Using Publicly Available Sequence-Based Predictors	Maria Batalha, <i>Valgenesis</i>
	Tumour Organoid-On-Chip for Real-Time Measurements of Drug Response	Katja Uhlig, <i>Fraunhofer Institut</i>
	Digitizing Preclinical Studies: Towards Digital Drug Development with Automated Multi-Organ Chips	Florian W. Huber, <i>TissUse</i>
	Q&A, Discussion	
18:10	End of Conference Day 1 & Networking Event	
Wednesday, 05 June 2024		
9:00	Welcome Back from the Co-Chairs	Dieter Bachmann, <i>Johnson & Johnson</i> Marilyn Romieux, <i>Merck</i>
09:05 – 10:35 Session 4: AI in Manufacturing		Moderator: Scott Deckebach, <i>Lachman Consultants, Inc.</i>
<p><i>In this session, we will explore examples of how modern digital solutions are improving our manufacturing processes today and the promise they hold for the future. Specifically, the session presentations will explore</i></p>		



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how robotics are employed to remove humans from sterile operations for cell and gene therapy, how vision systems are leveraged to improve line clearance, and how RFID is being applied to the individual unit tracking for syringes. The panel discussion will further explore the benefits and essential elements of a successful implementation and entertain audience questions regarding these technologies or manufacturing.

	Digitalization Technologies – Use Cases, Benefits and Constraints	Tod Urquhat, <i>cim.as</i>
	Unlocking the Full Potential of Existing Data Acquisition Capabilities in Pharmaceutical Manufacturing: Case Study on a Filling Line for RTU RFID-Enabled Containers	Daniel Sturm, <i>Syntegon</i> Yacine Haddadi, <i>BD</i>
	Tackling Manufacturing Issues in Cell & Gene Therapy With a Modular Robotics Approach	Fabian Stutz, <i>Pharmabotix</i>
	Q&A, Discussion	
10:35	Networking Coffee Break, Poster Session & Exhibition	
11:05 – 12:35 Session 5: Application of Digitalization in Drug Testing		Moderator: Maria Batalha, <i>Valgenesis</i>
<p><i>This session will explore advancements in the application of digitalization in drug testing. The first session will explain how we can leverage AI for real-time process control, a crucial aspect of Industry 4.0 adoption. Next, discussions will delve into the advantages and hurdles of automating QC labs, highlighting increased efficiency and data integrity alongside concerns like compatibility and consumables. Finally, the focus will be on how to accelerate Adventitious Virus Testing in vaccine production. The session will present a promising in silico platform using bioinformatics for faster and GMP-compliant virus detection.</i></p>		
	Process Control Through the Use of Vision Based Technology & Artificial Intelligence Software	Mark Quinn, <i>Canty</i>
	Future QC Testing Using Automation and Robotics – A Digitalized Foundation of Sterility Testing	Anke Hossfeld, <i>Merck</i>
	Digital and Automated Adventitious Virus Testing	Hon Q. Tran, <i>IDT Biologika</i> (remote)



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	Q&A, Discussion	
12:35	Networking Lunch Break, Poster Session & Exhibition	
13:35 – 16:30 Closing Plenary: Succeeding in Digitalization - Opportunities and Next Steps		Moderator: Dieter Bachmann, <i>Johnson & Johnson</i>
	Round Table Discussion	
14:35	Networking Coffee Break, Poster Session & Exhibition	
15:05	Passport Raffle	
	Driving Continuous Improvement in Manufacturing Quality through Digitalization	<i>Tara Goen Bizjak, U.S. FDA (remote)</i>
	Plenary Discussion <i>Join our Discussion with Experts from the Industry and Regulatory</i> <ul style="list-style-type: none"> - Michelangelo Canzoneri, <i>Merck</i> - Michael Gerlich, <i>SBS Swiss Business School</i> - Tara Goen Bizjak, <i>U.S. FDA</i> 	
	Conference Summary from the Co-Chairs	Dieter Bachmann, <i>Johnson & Johnson</i> Marilyn Romieux, <i>Merck</i>
	Closing Remarks & Farewell	Dieter Bachmann, <i>Johnson & Johnson</i> Marilyn Romieux, <i>Merck</i>
16:30	End of Conference	

The agenda is subject to change without notice, speakers are invited pending confirmation.