PDA Good Digital Manufacturing Conference 2025

Agenda

Tuesday, 20 May

CEST Daylight Time (UTC +2:00)

08:00 – 17:30	**Registration Open** Topaz & Topaz Foyer
09:00 – 09:10	**Welcome and Introduction** Ballraum 2&3 **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*
09:10 – 09:20	**Welcome from the Co-Chairs** Ballraum 2&3 **Co-Chair: Marilyn Romieux** , Strategy Director - Pharma segment, *Merck KGaA* **Co-Chair: Timothy W Hsu MHSA** International Expert on Health Industry | Vice President Industry & Emerging Technologies *UNIDO|AAMI*

Opening Plenary

Ballraum 2&3

This conference will show a larger picture of our industry's raison d'être. Regardless of whether we work for a drug manufacturer, a materials supplier, a software developer, or a consulting firm; whether our roles lie in drug discovery, manufacturing, quality control, or IT; and whether we identify as scientists, engineers, IT specialists, or strategists, we all unite our efforts to enhance human health. At the end of the value chain stand patients in hope for advancements in their treatment. We want to highlight the impact our industry's progress has on healing people. Innovations in digital technology, the implementation of automation and robotics, and the applications of artificial intelligence are making a real difference in people's lives. We will hear insights from organizations dedicated to health, extending beyond the pharmaceutical sector, to understand this impact further.

Moderator: Marilyn Romieux , Strategy Director - Pharma segment, *Merck KGaA*

09:20 – 11:15	09:20 – 09:45	**Beyond Safety, Efficacy, and Compliance: The Human Impact of Digital Innovation** Ballraum 2&3 • **Keynote Speaker: Stacey Tinianov MPH**, Patient Advocate, Founder, *Advocates for Collaborative Education*
	09:45 – 10:10	**AI in Life Sciences: When Innovation Comes From the Unimaginable** Ballraum 2&3 • **Academic Presenter: Laura Adams MS**, Senior Advisor, *National Academy of Medicine*
	10:10 – 10:35	**How is AI Implemented at Swissmedic** Ballraum 2&3 • **Regulatory Presenter: Nicolas Löffler-Perez PhD**, Data Scientist, *Swissmedic*

10:35 – 11:15	**Plenary Discussion** Ballraum 2&3 - **Moderator: Marilyn Romieux** , Strategy Director - Pharma segment, *Merck KGaA* - **Panelist: Laura Adams MS**, Senior Advisor, *National Academy of Medicine* - **Regulatory Panelist: Nicolas Löffler-Perez PhD**, Data Scientist, *Swissmedic* - **Panelist: Stacey Tinianov MPH**, Patient Advocate, Founder, *Advocates for Collaborative Education*
11:15 – 11:45	**Networking Coffee Break, Poster Session & Exhibition** Topaz & Topaz Foyer

Session 1: Understanding Artificial Intelligence

Ballraum 2&3

In this session, we will explore the necessary foundations for successfully adopting artificial intelligence, including management and quality of data, organizational competencies and skillsets, and clear and focused adoption strategies. High-quality data is an essential ingredient for AI to robustly produce unbiased and accurate predictions, reliable insights, and effective decision-making. Technology and business domain competencies are both equally essential to understand the strengths, weaknesses, and risks of various technologies and ensure these are well-matched to the business processes and the nuanced meanings of the data. Solid adoption strategies will ensure foundations are in place and investments are focused to match business priorities.

Moderator: James R. Francum MBA, CEO, *GxP-CC*

11:45 – 13:15	11:45 – 12:05	**The Connections Between AI, Data Management, Data Integrity, and Knowledge Management** Ballraum 2&3 - **Presenter: James L Vesper PhD, MPH**, Director, Learning Solutions, *ValSource, Inc.*
	12:05 – 12:25	**AI-Powered Data: Revolutionizing Real-Time Release and Quality by Design** Ballraum 2&3 - **Presenter: Fabrizio Maniglio** , Industry and Business Development Director, *Honeywell*
	12:25 – 12:45	**On Our Journey From MANUfacturing to SMARTfacturing | Miss the Shift - Miss the Future** Ballraum 2&3 - **Presenter: Michelangelo Canzoneri PhD**, Global Head of Group Smart Manufacturing, *Merck KGaA Darmstadt, Germany*
	12:45 – 13:15	**Q&A, Discussion** Ballraum 2&3 - **Moderator: James R. Francum MBA**, CEO, *GxP-CC* - **Panelist: Michelangelo Canzoneri PhD**, Global Head of Group Smart Manufacturing, *Merck KGaA Darmstadt, Germany* - **Panelist: Fabrizio Maniglio** , Industry and Business Development Director, *Honeywell* - **Panelist: James L Vesper PhD, MPH**, Director, Learning Solutions, *ValSource, Inc.*

LIVE Guided Poster Walk Engage with our Poster Presenters in our Exhibition Hall

Topaz & Topaz Foyer

Moderator: Tom J.B de Man MSc, Head of Omics and Machine Learning R&D, *Merck*

13:15 – 13:30	**Transform Your Inspection from Excellent to Genius** Topaz & Topaz Foyer • **Poster Presenter: Christian Haenlein M.Sc.**, Senior Product Owner, *Körber Pharma Inspection*
13:15 – 13:30	**RAGulating Compliance: A Multi-Agent Knowledge Graph Approach for Regulatory QA** Topaz & Topaz Foyer • **Poster Presenter: Alex Kaplunov** , ,
13:15 – 13:30	**DIGITAL CPV - An Implementation Case Study** Topaz & Topaz Foyer • **Poster Presenter: Maria Batalha MSc**, Senior Consultant, *ValGenesis*
13:15 – 13:30	**In-Silico Process Development and Scale-Up Simulations for the Manufacturing of a Late-Phase Vaccine Product** Topaz & Topaz Foyer • **Poster Presenter: Antonio Castro PhD**, Senior Scientist, *Johnson & Johnson - Innovative Medicine*
13:15 – 13:30	**Traceability Solutions for Smart Manufacturing** Topaz & Topaz Foyer • **Poster Presenter: Ali Badiei MSc**, Head of Digital Supply Chain Solutions, *Gerresheimer*
13:15 – 13:30	**AI and Automation in Microbiological Environmental Monitoring: Standardization, Savings and Other Benefits** Topaz & Topaz Foyer • **Poster Presenter: Nicole Schepis** , ,

The **13:15 – 13:30** label spans the above block on the left.

13:30 – 14:30	**Networking Lunch Break, Poster Session & Exhibition** Topaz & Topaz Foyer

Session 2: Speed Talks - Enabler for Manufacturing

Ballraum 2&3

This dynamic session features concise and impactful "Speed Talks," providing attendees with rapid exposure to essential innovations and best practices shaping the future of pharmaceutical manufacturing. Expert speakers will present focused insights into advanced technologies and methods, including artificial intelligence for trend detection in quality processes, big data and IoT for predictive maintenance, comprehensive digitalization for environmental monitoring, and an overview of PDA Technical Report 22, which covers the latest guidance on equipment qualification and validation. Designed to facilitate quick learning and encourage active participation, this session delivers actionable knowledge and practical strategies that enhance operational efficiency, ensure compliance, and drive continuous improvement in manufacturing processes.

Moderator: Maria Batalha MSc, Senior Consultant, *ValGenesis*

14:30 – 14:45	**Interactive Questionnaire Session** Ballraum 2&3 • **Moderator: Maria Batalha MSc**, Senior Consultant, *ValGenesis*
	AI in Action: NLP & GenAI for Pharma Manufacturing

14:30 – 15:55	14:45 – 14:55	Ballraum 2&3 • **Presenter: Mehran Kamkarhaghighi PhD**, Senior Data Scientist, *F. Hoffmann-La Roche Ltd*
	14:55 – 15:05	**From Downtime to Uptime: Predictive Maintenance for Operational Efficiency** Ballraum 2&3 • **Presenter: Joel Nuñez** , Product Manager / Marketing Manager, *Syntegon Telstar*
	15:05 – 15:15	**Leverage your QC Operational Efficiency Thanks to a Comprehensive Digitalization of your Environmental Monitoring Process to meet the High Standard of Compliance and Optimize Resource Allocation** Ballraum 2&3 • **Presenter: Florian Morillon** , Global solution manager, 3PEnterprise, *bioMérieux*
	15:15 – 15:25	**Updates on PDA Technical Report 22: Most Relevant Changes of the New Approved Version** Ballraum 2&3 • **Presenter: Patrizia Muscas PhD**, Director Sterility Assurance , Global TS/MS (SAT), *Eli Lilly and Company*
	15:25 – 15:55	**Q&A, Discussion** Ballraum 2&3 • **Moderator: Maria Batalha MSc**, Senior Consultant, *ValGenesis* • **Panelist: Mehran Kamkarhaghighi PhD**, Senior Data Scientist, *F. Hoffmann-La Roche Ltd* • **Panelist: Florian Morillon** , Global solution manager, 3PEnterprise, *bioMérieux* • **Panelist: Patrizia Muscas PhD**, Director Sterility Assurance , Global TS/MS (SAT), *Eli Lilly and Company* • **Panelist: Joel Nuñez** , Product Manager / Marketing Manager, *Syntegon Telstar*
15:55 – 16:25		**Networking Coffee Break, Poster Session & Exhibition** Topaz & Topaz Foyer
		Session 3: Artificial Intelligence: From Validation to Compliance Ballraum 2&3 This session explores the integration of AI and digital solutions in the pharmaceutical industry, focusing on validation and compliance strategies. Presentations will cover practical approaches to managing AI and automation within a cGMP framework, leveraging validation model tools. A case study from a pharmaceutical company will demonstrate how AI and digital technologies enhance process optimization and quality assurance, improving compliance and productivity. Attendees will gain insights into innovative validation strategies, regulatory compliance, and the transformative power of digital technologies in pharmaceutical manufacturing. **Moderator: Sesethu Dowiasch MBA**, Life Science Industry Account Manager, *Rockwell Automation*
	16:25 – 16:40	**Embracing the Digital Revolution: A Strategic Framework for Transforming Pharmaceutical Manufacturing** Ballraum 2&3 • **Presenter: Scott Deckebach MBA**, Senior Director, Data Integrity, Governance and Advanced Digital Compliance, *Lachman Consultant Services, Inc.*
		The Integration of AI and GMP in the Pharmaceutical Industry: Advancements, Challenges, and Regulatory Perspectives

	16:40 – 16:55	Ballraum 2&3
16:25 – 17:40		• **Presenter: Stefan Marc Pauli PhD**, SME Data Science, *VTU Engineering*
	16:55 – 17:10	**Enhancing Pharmaceutical Manufacturing with AI - From Process Intelligence to Compliance** Ballraum 2&3 • **Co-Presenter: Davide Botta BS Environmental Engineering**, Director, Site Lead, *Recordati Ireland Ltd* • **Co-Presenter: Maria Zunica** , Head of Quality and Regulatory Affairs, *Recordati Industria Chimica e Farmaceutica SpA*
	17:10 – 17:40	**Q&A, Discussion** Ballraum 2&3 • **Moderator: Sesethu Dowiasch MBA**, Life Science Industry Account Manager, *Rockwell Automation* • **Panelist: Davide Botta BS Environmental Engineering**, Director, Site Lead, *Recordati Ireland Ltd* • **Panelist: Scott Deckebach MBA**, Senior Director, Data Integrity, Governance and Advanced Digital Compliance, *Lachman Consultant Services, Inc.* • **Panelist: Stefan Marc Pauli PhD**, SME Data Science, *VTU Engineering* • **Panelist: Maria Zunica** , Head of Quality and Regulatory Affairs, *Recordati Industria Chimica e Farmaceutica SpA*
17:40 – 21:30		**End of Conference Day 1 & Networking Event** Ballraum 2&3

Wednesday, 21 May

CEST Daylight Time (UTC +2:00)

08:00 – 16:00	**Registration Open** Topaz & Topaz Foyer
08:00 – 08:45	**Update of the Interest Group Advanced Manufacturing and Applied Process Digitalization** Ballraum 2&3 **Moderator: Peter J Makowenskyj MEng**, Senior Director of Design Consulting, *G-CON*
09:00 – 09:05	**Welcome Back by the Co-Chairs** Ballraum 2&3 **Co-Chair: Marilyn Romieux** , Strategy Director - Pharma segment, *Merck KGaA* **Co-Chair: Timothy W Hsu MHSA** International Expert on Health Industry	Vice President Industry & Emerging Technologies *UNIDO|AAMI*
	Session 4: With an Eye Towards Digital Operations Ballraum 2&3 The pharmaceutical industry is undergoing a digital transformation, leveraging AI, machine learning, and automation to enhance manufacturing efficiency, quality, and compliance. This track explores cutting-edge advancements driving this shift, providing insights into AI and machine learning applications in pharmaceutical manufacturing, the role of operational data in

accelerating in-silico process optimization across the product lifecycle, and the latest innovations in sterility testing automation with traceable robotics. These talks offer a forward-looking perspective on digital operations, equipping industry professionals with the knowledge to optimize processes and ensure regulatory alignment.

Moderator: Stephanie Knüppel PhD, Head Sterile Manufacturing & Packaging - E2E Value Stream Lead,

09:05 – 10:35		
	AI and Machine Learning in Pharmaceutical Manufacturing	
09:05 – 09:25	Ballraum 2&3	
	• **Presenter: Mónica Perea-Vélez MSc, PhD**, CMC Advocacy and Policy Director, *GSK*	
09:25 – 09:45	**Accelerating In-Silico Process Optimization Across the Product Lifecycle Fuelled by Operational Data**	
	Ballraum 2&3	
	• **Co-Presenter: Fabian Feidl PhD**, CTO and co-founder, *DataHow AG*	
	• **Co-Presenter: Sesethu Dowiasch MBA**, Life Science Industry Account Manager, *Rockwell Automation*	
09:45 – 10:05	**TraceBot: Sterility Testing Automation With Traceable Robotics**	
	Ballraum 2&3	
	• **Presenter: Patrick Courtney MBA PhD**, Lecturer, *King's College London*	
10:05 – 10:35	**Q&A, Discussion**	
	Ballraum 2&3	
	• **Moderator: Stephanie Knüppel PhD**, Head Sterile Manufacturing & Packaging - E2E Value Stream Lead,	
	• **Panelist: Patrick Courtney MBA PhD**, Lecturer, *King's College London*	
	• **Panelist: Sesethu Dowiasch MBA**, Life Science Industry Account Manager, *Rockwell Automation*	
	• **Panelist: Fabian Feidl PhD**, CTO and co-founder, *DataHow AG*	
	• **Panelist: Mónica Perea-Vélez MSc, PhD**, CMC Advocacy and Policy Director, *GSK*	

10:35 – 11:05	**Networking Coffee Break, Poster Session & Exhibition** Topaz & Topaz Foyer

11:05 – 12:15	**Session 5: Sustainability**
	Ballraum 2&3

Join us for an insightful session on sustainability as we explore how AI can drive sustainable operations, while also learning from healthcare and how sustainable digitization is impacting it. Our speakers will share insights on balancing process improvement, both for regulatory compliance and cost savings in manufacturing, with sustainability practices and long-term benefits. This session is perfect for anyone passionate about leveraging technology for a greener, more efficient future.

Moderator: Christian Haenlein M.Sc., Senior Product Owner, *Körber Pharma Inspection*

11:05 – 11:25	**AI: The Perfect Tool to Supervise 24x7 Sustainability Aspects in the Site**
	Ballraum 2&3
	• **Presenter: Toni Manzano PhD**, CSO and Compliance Officer, *Aizon*
11:25 – 11:45	**The Next Generation of Healthcare: Expanding Access for All**
	Ballraum 2&3

	• **Presenter: Daniel Guedelha** , Founder & CEO, *Generation Health - GenH*
11:45 – 12:15	**Q&A, Discussion** Ballraum 2&3 • **Moderator: Christian Haenlein M.Sc.**, Senior Product Owner, *Körber Pharma Inspection* • **Panelist: Daniel Guedelha** , Founder & CEO, *Generation Health - GenH* • **Panelist: Toni Manzano PhD**, CSO and Compliance Officer, *Aizon*
12:15 – 13:15	**Networking Lunch Break, Poster Session & Exhibition** Topaz & Topaz Foyer
13:15 – 14:15	**Closing Plenary Session Part I** Ballraum 2&3 In an era where global health security relies on resilient and agile health product production, the UNIDO International Centre for Health Industry Readiness in Abu Dhabi is poised to become a key driver of regional and global preparedness for future pandemics and emergencies. This session will explore UNIDO's strategic approach to digital transformation in health, emphasizing the Centre's role in enhancing industrial readiness across the MENA region and beyond. Discussions will focus on how advanced manufacturing, digitalization, Fourth Industrial Revolution (4IR) technologies, regulatory harmonization, and technology transfer are shaping the future of regional health industry development. The Centre will serve as a collaborative platform for health regulators, pharmaceutical manufacturers, and global industry leaders, working to strengthen local and regional production capacities while ensuring sustainable, efficient, and high-quality healthcare solutions. **Regulatory Moderator: Timothy W Hsu MHSA**, International Expert on Health Industry	Vice President Industry & Emerging Technologies, *UNIDO|AAMI*

	13:15 – 13:35	**Regional Approach to Digital Transformation in Health** Ballraum 2&3 • **Regulatory Presenter: Nora Markova DPhil, MBA**, International Expert on Health Industry, *UNIDO*
	13:35 – 14:15	**Plenary Discussion** Ballraum 2&3 • **Regulatory Moderator: Timothy W Hsu MHSA**, International Expert on Health Industry | Vice President Industry & Emerging Technologies, *UNIDO|AAMI* • **Panelist: Daniel Guedelha** , Founder & CEO, *Generation Health - GenH* • **Regulatory Panelist: Nora Markova DPhil, MBA**, International Expert on Health Industry, *UNIDO* • **Panelist: Stacey Tinianov MPH**, Patient Advocate, Founder, *Advocates for Collaborative Education* • **Panelist: James L Vesper PhD, MPH**, Director, Learning Solutions, *ValSource, Inc.*

14:15 – 14:45	**Networking Coffee Break, Poster Session & Exhibition** Topaz & Topaz Foyer
14:45 – 14:50	**Passport Raffle Announcement** Ballraum 2&3 **Moderator: Melanie Decker** , , *Parenteral Drug Association*
	Closing Plenary Session Part II Ballraum 2&3

	Regulatory Moderator: Timothy W Hsu MHSA, International Expert on Health Industry | Vice President Industry & Emerging Technologies, *UNIDO|AAMI*	
14:50 – 16:25	14:50 – 16:25	**Interactive Round Table Session** Ballraum 2&3 • **Moderator: Timothy W Hsu MHSA**, International Expert on Health Industry | Vice President Industry & Emerging Technologies, *UNIDO|AAMI* • **Moderator: Marilyn Romieux** , Strategy Director - Pharma segment, *Merck KGaA*
	16:25 – 16:35	**Conference Summary from the Co-Chairs** Ballraum 2&3 • **Co-Chair: Marilyn Romieux** , Strategy Director - Pharma segment, *Merck KGaA* • **Co-Chair: Timothy W Hsu MHSA**, International Expert on Health Industry | Vice President Industry & Emerging Technologies, *UNIDO|AAMI*
16:35 – 16:40	**Closing Remarks & Farewell** Ballraum 2&3 **Committee Member: Falk Klar PhD**, General Manager, Vice President Europe, *Parenteral Drug Association*	
16:40 – 16:40	**End of Conference**	