



Agenda

PDA Good Digital Manufacturing Conference 2025

Tuesday, 20 May

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, *UNIDO*

09:20 – 11:15

Opening Plenary

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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 – 09:45

Beyond Safety, Efficacy, and Compliance: The Human Impact of Digital Innovation

Keynote Speaker: Stacey Tinianov, MPH, Patient Advocate, Founder, *Advocates for Collaborative Education*

09:45 – 10:10

What is Happening in the Broader Areas Next to the Pharma Manufacturing World?

Academic Co-Presenter: Laura Adams, MS, Senior Advisor, *National Academy of Medicine*

Co-Presenter: Rene Quashie

10:10 – 10:35

Title to be Announced

Regulatory Presenter: Nicolas Löffler-Perez, *Swissmedic*

10:35 – 11:15



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Plenary Discussion

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

Panelist: Laura Adams, MS, Senior Advisor, *National Academy of Medicine*

Regulatory Panelist: Nicolas Löffler-Perez, *Swissmedic*

Panelist: Rene Quashie

Panelist: Stacey Tinianov, MPH, Patient Advocate, Founder, *Advocates for Collaborative Education*

11:15 – 11:45

Networking Coffee Break, Poster Session & Exhibition

Topas & Topas Foyer

11:45 – 13:15

Session 1: Understanding Artificial Intelligence

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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: Scott Deckebach, MBA, Senior Director, Data Integrity, Governance and Advanced Digital Compliance, *Lachman Consultant Services, Inc.*

11:45 – 12:05

The Connections Between AI, Data Management, Data Integrity, and Knowledge Management

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

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

Presenter: Michelangelo Canzoneri, PhD, Global Head of Group Smart Manufacturing, *Merck KGaA Darmstadt, Germany*

12:45 – 13:15

Q&A, Discussion



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Moderator: Scott Deckebach, MBA, Senior Director, Data Integrity, Governance and Advanced Digital Compliance, *Lachman Consultant Services, Inc.*

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.*

13:15 – 13:30

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

Topas & Topas Foyer

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

13:30 – 14:30

Networking Lunch Break, Poster Session & Exhibition

Topas & Topas Foyer

14:30 – 15:55

Session 2: Speed Talks - Enabler for Manufacturing

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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: Michelangelo Canzoneri, PhD, Global Head of Group Smart Manufacturing, *Merck KGaA Darmstadt, Germany*

14:30 – 14:45

Interactive Questionnaire Session

Moderator: Michelangelo Canzoneri, PhD, Global Head of Group Smart Manufacturing, *Merck KGaA Darmstadt, Germany*

14:45 – 14:55

AI in Action: NLP & GenAI for Pharma Manufacturing

Presenter: Mehran Kamkarhaghighi, PhD, Senior Data Scientist, *Roche*

14:55 – 15:05

From Downtime to Uptime: Predictive Maintenance for Operational Efficiency

Presenter: Joel Nuñez, Product Manager / Marketing Manager, *Syntegon Telstar*



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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

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

Presenter: Patrizia Muscas, PhD, Director Sterility Assurance, Global TS/MS (SAT), *Eli Lilly and Company*

15:25 – 15:55

Q&A, Discussion

Moderator: Michelangelo Canzoneri, PhD, Global Head of Group Smart Manufacturing, *Merck KGaA Darmstadt, Germany*

Panelist: Mehran Kamkarhaghighi, PhD, Senior Data Scientist, *Roche*

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

Topas & Topas Foyer

16:25 – 17:40

Session 3: Artificial Intelligence: From Validation to Compliance

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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: Dieter Bachmann, PhD, Director Aseptic Processing, *Johnson & Johnson*

16:25 – 16:40

Embracing the Digital Revolution: A Strategic Framework for Transforming Pharmaceutical Manufacturing

Presenter: Scott Deckebach, MBA, Senior Director, Data Integrity, Governance and Advanced Digital Compliance, *Lachman Consultant Services, Inc.*

16:40 – 16:55



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The Integration of AI and GMP in the Pharmaceutical Industry: Advancements, Challenges, and Regulatory Perspectives

Presenter: Stefan Marc Pauli

16:55 – 17:10

Enhancing Pharmaceutical manufacturing with AI - From Process Intelligence to Compliance

Co-Presenter: Davide Botta, BS Environmental Engineering, Director, Site Lead, *Recordati Ireland Ltd*

Co-Presenter: Maria Zunica

17:10 – 17:40

Q&A, Discussion

Moderator: Dieter Bachmann, PhD, Director Aseptic Processing, *Johnson & Johnson*

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

Panelist: Maria Zunica

17:40 – 22:00

End of Conference Day 1 & Networking Event

Ballraum 2&3

Wednesday, 21 May

08:00 – 08:45

Update of the Interest Group Advanced Manufacturing and Applied Process Digitalization

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Moderator: Peter J. Makowskyj, 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, *UNIDO*

09:05 – 10:35



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Session 4: With an Eye Towards Digital Operations

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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, *F. Hoffmann-La Roche Ltd*

09:05 – 09:25

AI and Machine Learning in Pharmaceutical Manufacturing

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

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

Academic Presenter: Patrick Courtney

10:05 – 10:35

Q&A, Discussion

Moderator: Stephanie Knüppel, PhD, Head Sterile Manufacturing & Packaging - E2E Value Stream Lead, *F. Hoffmann-La Roche Ltd*

Academic Panelist: Patrick Courtney

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

Topas & Topas Foyer

11:05 – 12:15

Session 5: Sustainability



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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

Presenter: Toni Manzano, Co-Founder and CSO, *Aizon*

11:25 – 11:45

The Next Generation of Healthcare: Expanding Access for All

Presenter: Daniel Guedelha, Founder & CEO, *Generation Health - GenH*

11:45 – 12:15

Q&A, Discussion

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

Panelist: Daniel Guedelha, Founder & CEO, *Generation Health - GenH*

Panelist: Toni Manzano, Co-Founder and CSO, *Aizon*

12:15 – 13:15

Networking Lunch Break, Poster Session & Exhibition

Topas & Topas Foyer

13:15 – 14:15

Closing Plenary Session Part I

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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, *UNIDO*

13:15 – 13:35

Regional Approach to Digital Transformation in Health

Regulatory Presenter: Nora Markova, DPhil, MBA, International Expert on Health Industry, *UNIDO*



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13:35 – 14:15

Plenary Discussion

Regulatory Moderator: Timothy W Hsu, MHSA, International Expert on Health Industry, *UNIDO*

Regulatory Panelist: Nicolas Löffler-Perez, *Swissmedic*

Regulatory Panelist: Nora Markova, DPhil, MBA, International Expert on Health Industry, *UNIDO*

Panelist: James L. Vesper, PhD, MPH, Director, Learning Solutions, *ValSource, Inc.*

14:15 – 14:45

Networking Coffee Break, Poster Session & Exhibition

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14:45 – 14:50

Passport Raffle Announcement

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14:50 – 14:55

Best Poster Presenter

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14:55 – 16:25

Interactive Round Table Session

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16:25 – 16:35

Conference Summary from the Co-Chairs

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

Co-Chair: Timothy W Hsu, MHSA, International Expert on Health Industry, *UNIDO*

14:55 – 16:35

Closing Plenary Session Part II

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Regulatory Moderator: Timothy W Hsu, MHSA, International Expert on Health Industry, *UNIDO*

16:35 – 16:40



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Closing Remarks & Farewell

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Committee Member: Falk Klar, PhD, General Manager, Vice President Europe, *Parenteral Drug Association*

16:40 – 16:40

End of Conference