PDA Parenteral Drug Association	# Agenda
	PDA Good Digital Manufacturing Conference 2025

09:00 – 09:10

Welcome and Introduction

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

09:10 – 09:20

Welcome 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*

09:20 – 11:15

Opening Plenary

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**

> 09:45 – 10:10
>
> What is Happening in the Broader Areas Next to the Pharma Manufacturing World?
>
> **Academic Co-Presenter: Laura Adams**
>
> **Co-Presenter: Renee Quashie**

> 10:10 – 10:35
>
> Title to be Announced

> 10:35 – 11:15
>
> Plenary Discussion
>
> **Moderator: Marilyn Romieux**, Strategy Director - Pharma segment, *Merck KGaA*
>
> **Panelist: Renee Quashie**
>
> **Panelist: Laura Adams**
>
> **Panelist: Stacey Tinianov**

11:15 – 11:45

Networking Coffee Break, Poster Session & Exhibition

11:45 – 13:15

Session 1: Understanding Artificial Intelligence

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
>
> Title to be Announced
>
> > **Presenter: Michelangelo Canzoneri**, **PhD**, Global Head of Group Smart Manufacturing, *Merck KGaA Darmstadt, Germany*
>
> 12:45 – 13:15
>
> Q&A, Discussion
>
> > **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

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

13:30 – 14:30

Networking Lunch Break, Poster Session & Exhibition

14:30 – 15:55

Session 2: Speed Talks - Enabler for Manufacturing

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

Trend Detection in Pharmaceutical Deviation Reports with NLP Techniques

Presenter: Mehran Kamkarhaghighi

14:55 – 15:05

Innovating Pharma: IoT & Big Data for Predictive Maintenance

Presenter: Joel Nuñez

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: Ylhem Logon

15:15 – 15:25

Updates on PDA Technical Report 22

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

Panelist: Ylhem Logon

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

Panelist: Joel Nuñez

15:55 – 16:25

Networking Coffee Break, Poster Session & Exhibition

16:25 – 17:40

Session 3: Artificial Intelligence: From Validation to Compliance

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

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

Presenter: Stefan Marc Pauli

16:55 – 17:10

Driving Excellence: Revolutionizing Pharmaceutical Manufacturing with Intelligent Batch Records and AI-Driven Predictive Platforms

Co-Presenter: Davide Botta

Co-Presenter: Maria Zunica

17:10 – 17:40

Q&A, Discussion

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

Panelist: Davide Botta

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

Wednesday, 21 May

08:00 – 08:45

Interest Group Morning Session

09:00 – 09:05

Welcome Back by 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*

09:05 – 10:35

Session 4: With an Eye Towards Digital Operations

Moderator: Stephanie Knüppel

> 09:05 – 09:25
>
> AI and Machine Learning in Pharmaceutical Manufacturing
>
> > **Presenter: Mónica Perea-Vélez**, **MSc, PhD**, CMC Advocacy and Policy Director, *GSK*
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> 09:25 – 09:45
>
> Accelerating In-Silico Process Optimization Across the Product Lifecycle Feled by Operational Data
>
> > **Co-Presenter: Fabian Feidl**
> >
> > **Co-Presenter: Sesethu Dowiasch**, **MBA**, Life Science Industry Account Manager, *Rockwell Automation*
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>
> 09:45 – 10:05
>
> TraceBot: Sterility Testing Automation With Traceable Robotics
>
> > **Academic Presenter: Patrick Courtney**
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>
> 10:05 – 10:35
>
> Q&A, Discussion
>
> > **Moderator: Stephanie Knüppel**
> >
> > **Academic Panelist: Patrick Courtney**
> >
> > **Panelist: Sesethu Dowiasch**, **MBA**, Life Science Industry Account Manager, *Rockwell Automation*
> >
> > **Panelist: Fabian Feidl**

Panelist: Mónica Perea-Vélez, **MSc, PhD**, CMC Advocacy and Policy Director, *GSK*

10:35 – 11:05

Networking Coffee Break, Poster Session & Exhibition

11:05 – 12:15

Session 5: Sustainability

Moderator: Christian Haenlein

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

Sustainable Digitalization: Expanding Healthcare Access for All

Presenter: Daniel Guedelha

11:45 – 12:15

Q&A, Discussion

Moderator: Christian Haenlein

Panelist: Daniel Guedelha

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

12:15 – 13:15

Networking Lunch Break, Poster Session & Exhibition

13:15 – 14:15

Closing Plenary Session Part I

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

13:35 – 14:15

Plenary Discussion

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

Regulatory Panelist: Nora Markova

14:15 – 14:45

Networking Coffee Break, Poster Session & Exhibition

14:45 – 14:50

Passport Raffle Announcement

14:50 – 14:55

Best Poster Presenter

14:55 – 16:25

Interactive Round Table Session

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

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

16:35 – 16:40

Closing Remarks & Farewell

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

16:40 – 16:40

End of Conference