

PDA Good Digital Manufacturing Conference 2025 Agenda



Tuesday, 20 May

CEST Daylight Time (UTC +2:00)

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| 08:00 – 17:30 | Registration Open |
| 09:00 – 09:10 | Welcome and Introduction Committee Member: Falk Klar PhD, General Manager, Vice President Europe, <i>Parenteral Drug Association</i> |
| 09:10 – 09:20 | Welcome from the Co-Chairs Co-Chair: Marilyn Romieux , Strategy Director - Pharma segment, <i>Merck KGaA</i> Co-Chair: Timothy W Hsu MHSA International Expert on Health Industry Vice President Industry & Emerging Technologies <i>UNIDO AAMI</i> |
| 09:20 – 11:15 | Opening Plenary Moderator: Marilyn Romieux , Strategy Director - Pharma segment, <i>Merck KGaA</i> |
| | Beyond Safety, Efficacy, and Compliance: The Human Impact of Digital Innovation 09:20 – 09:45 <ul style="list-style-type: none">• Keynote Speaker: Stacey Tinianov MPH, Patient Advocate, Founder, <i>Advocates for Collaborative Education</i> |
| | AI in Life Sciences: When Innovation Comes From the Unimaginable 09:45 – 10:10 <ul style="list-style-type: none">• Academic Presenter: Laura Adams MS, Senior Advisor, <i>National Academy of Medicine</i> |
| | How is AI Implemented at Swissmedic 10:10 – 10:35 <ul style="list-style-type: none">• Regulatory Presenter: Nicolas Löffler-Perez PhD, Data Scientist, <i>Swissmedic</i> |
| | Plenary Discussion 10:35 – 11:15 <ul style="list-style-type: none">• Moderator: Marilyn Romieux , Strategy Director - Pharma segment, <i>Merck KGaA</i>• Panelist: Laura Adams MS, Senior Advisor, <i>National Academy of Medicine</i>• Regulatory Panelist: Nicolas Löffler-Perez PhD, Data Scientist, <i>Swissmedic</i>• Panelist: Stacey Tinianov MPH, Patient Advocate, Founder, <i>Advocates for Collaborative Education</i> |
| 11:15 – 11:45 | Networking Coffee Break, Poster Session & Exhibition |
| | Session 1: Understanding Artificial Intelligence Moderator: James R. Francum MBA, CEO, <i>GxP-CC</i> |
| | The Connections Between AI, Data Management, Data Integrity, and Knowledge Management |

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| 11:45 – 13:15 | 11:45 – 12:05 | <ul style="list-style-type: none">• Presenter: James L Vesper PhD, MPH, Director, Learning Solutions, <i>ValSource, Inc.</i> |
| | 12:05 – 12:25 | AI-Powered Data: Revolutionizing Real-Time Release and Quality by Design <ul style="list-style-type: none">• Presenter: Fabrizio Maniglio , Industry and Business Development Director, <i>Honeywell</i> |
| | 12:25 – 12:45 | On Our Journey From MANUFACTURING to SMARTfacturing Miss the Shift - Miss the Future <ul style="list-style-type: none">• Presenter: Michelangelo Canzoneri PhD, Global Head of Group Smart Manufacturing, <i>Merck KGaA Darmstadt, Germany</i> |
| | 12:45 – 13:15 | Q&A, Discussion <ul style="list-style-type: none">• Moderator: James R. Francum MBA, CEO, <i>GxP-CC</i>• Panelist: Michelangelo Canzoneri PhD, Global Head of Group Smart Manufacturing, <i>Merck KGaA Darmstadt, Germany</i>• Panelist: Fabrizio Maniglio , Industry and Business Development Director, <i>Honeywell</i>• Panelist: James L Vesper PhD, MPH, Director, Learning Solutions, <i>ValSource, Inc.</i> |
| 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, <i>Merck</i> | | |
| 13:15 – 13:30 | 13:15 – 13:30 | Transform Your Inspection from Excellent to Genius <ul style="list-style-type: none">• Poster Presenter: Christian Haenlein M.Sc., Senior Product Owner, <i>Körber Pharma Inspection</i> |
| | 13:15 – 13:30 | RAGulating Compliance: A Multi-Agent Knowledge Graph Approach for Regulatory QA <ul style="list-style-type: none">• Poster Presenter: Alex Kaplunov , , |
| | 13:15 – 13:30 | DIGITAL CPV - An Implementation Case Study <ul style="list-style-type: none">• Poster Presenter: Maria Batalha MSc, Senior Consultant, <i>ValGenesis</i> |
| | 13:15 – 13:30 | In-Silico Process Development and Scale-Up Simulations for the Manufacturing of a Late-Phase Vaccine Product <ul style="list-style-type: none">• Poster Presenter: Antonio Castro PhD, Senior Scientist, <i>Johnson & Johnson - Innovative Medicine</i> |
| | 13:15 – 13:30 | Traceability Solutions for Smart Manufacturing <ul style="list-style-type: none">• Poster Presenter: Ali Badiei MSc, Head of Digital Supply Chain Solutions, <i>Gerresheimer</i> |
| | 13:15 – 13:30 | AI and Automation in Microbiological Environmental Monitoring: Standardization, Savings and Other Benefits <ul style="list-style-type: none">• Poster Presenter: Nicole Schepis , , |
| 13:30 – 14:30 | Networking Lunch Break, Poster Session & Exhibition | |
| Session 2: Speed Talks - Enabler for Manufacturing Moderator: Maria Batalha MSc , Senior Consultant, <i>ValGenesis</i> | | |
| | Interactive Questionnaire Session | |

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| 14:30 – 15:55 | 14:30 – 14:45 | <ul style="list-style-type: none"> • Moderator: Maria Batalha MSc, Senior Consultant, <i>ValGenesis</i> |
| | 14:45 – 14:55 | AI in Action: NLP & GenAI for Pharma Manufacturing <ul style="list-style-type: none"> • Presenter: Mehran Kamkarhaghighi PhD, Senior Data Scientist, <i>F. Hoffmann-La Roche Ltd</i> |
| | 14:55 – 15:05 | From Downtime to Uptime: Predictive Maintenance for Operational Efficiency <ul style="list-style-type: none"> • Presenter: Joel Nuñez , Product Manager / Marketing Manager, <i>Syntegon Telstar</i> |
| | 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 <ul style="list-style-type: none"> • Presenter: Florian Morillon , Global solution manager, <i>3PEnterprise, bioMérieux</i> |
| | 15:15 – 15:25 | Updates on PDA Technical Report 22: Most Relevant Changes of the New Approved Version <ul style="list-style-type: none"> • Presenter: Patrizia Muscas PhD, Director Sterility Assurance , Global TS/MS (SAT), <i>Eli Lilly and Company</i> |
| | 15:25 – 15:55 | Q&A, Discussion <ul style="list-style-type: none"> • Moderator: Maria Batalha MSc, Senior Consultant, <i>ValGenesis</i> • Panelist: Mehran Kamkarhaghighi PhD, Senior Data Scientist, <i>F. Hoffmann-La Roche Ltd</i> • Panelist: Florian Morillon , Global solution manager, <i>3PEnterprise, bioMérieux</i> • Panelist: Patrizia Muscas PhD, Director Sterility Assurance , Global TS/MS (SAT), <i>Eli Lilly and Company</i> • Panelist: Joel Nuñez , Product Manager / Marketing Manager, <i>Syntegon Telstar</i> |
| 15:55 – 16:25 | Networking Coffee Break, Poster Session & Exhibition | |
| 16:25 – 17:40 | Session 3: Artificial Intelligence: From Validation to Compliance Moderator: Sesethu Dowiasch MBA , Life Science Industry Account Manager, <i>Rockwell Automation</i> | |
| | 16:25 – 16:40 | Embracing the Digital Revolution: A Strategic Framework for Transforming Pharmaceutical Manufacturing <ul style="list-style-type: none"> • Presenter: Scott Deckebach MBA, Senior Director, Data Integrity, Governance and Advanced Digital Compliance, <i>Lachman Consultant Services, Inc.</i> |
| | 16:40 – 16:55 | The Integration of AI and GMP in the Pharmaceutical Industry: Advancements, Challenges, and Regulatory Perspectives <ul style="list-style-type: none"> • Presenter: Stefan Marc Pauli PhD, SME Data Science, <i>VTU Engineering</i> |
| | 16:55 – 17:10 | Enhancing Pharmaceutical Manufacturing with AI - From Process Intelligence to Compliance <ul style="list-style-type: none"> • Co-Presenter: Davide Botta BS Environmental Engineering, Director, Site Lead, <i>Recordati Ireland Ltd</i> • Co-Presenter: Maria Zunica , Head of Quality and Regulatory Affairs, <i>Recordati Industria Chimica e Farmaceutica SpA</i> |
| | | Q&A, Discussion <ul style="list-style-type: none"> • Moderator: Sesethu Dowiasch MBA, Life Science Industry Account Manager, <i>Rockwell</i> |

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| | <p><i>Automation</i></p> <ul style="list-style-type: none"> • Panelist: Davide Botta BS Environmental Engineering, Director, Site Lead, <i>Recordati Ireland Ltd</i> • Panelist: Scott Deckebach MBA, Senior Director, Data Integrity, Governance and Advanced Digital Compliance, <i>Lachman Consultant Services, Inc.</i> • Panelist: Stefan Marc Pauli PhD, SME Data Science, <i>VTU Engineering</i> • Panelist: Maria Zunica , Head of Quality and Regulatory Affairs, <i>Recordati Industria Chimica e Farmaceutica SpA</i> |
| 17:10 – 17:40 | |
| 17:40 – 21:30 | End of Conference Day 1 & Networking Event |

Wednesday, 21 May

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| 08:00 – 16:00 | Registration Open |
| | Update of the Interest Group Advanced Manufacturing and Applied Process Digitalization |
| 08:00 – 08:45 | Moderator: Peter J Makowskyj MEng , Senior Director of Design Consulting, <i>G-CON</i> |
| | Welcome Back by the Co-Chairs |
| 09:00 – 09:05 | Co-Chair: Marilyn Romieux , Strategy Director - Pharma segment, <i>Merck KGaA</i> Co-Chair: Timothy W Hsu MHSA International Expert on Health Industry Vice President Industry & Emerging Technologies <i>UNIDO AAMI</i> |
| | Session 4: With an Eye Towards Digital Operations |
| | Moderator: Stephanie Knüppel PhD , Head Sterile Manufacturing & Packaging - E2E Value Stream Lead, |
| | <div> <div> <div>09:05 – 09:25</div> <div> AI and Machine Learning in Pharmaceutical Manufacturing <ul style="list-style-type: none"> • Presenter: Mónica Perea-Vélez MSc, PhD, CMC Advocacy and Policy Director, <i>GSK</i> </div> </div> </div> |
| | <div> <div> <div>09:25 – 09:45</div> <div> Accelerating In-Silico Process Optimization Across the Product Lifecycle Fuelled by Operational Data <ul style="list-style-type: none"> • Co-Presenter: Fabian Feidl PhD, CTO and co-founder, <i>DataHow AG</i> • Co-Presenter: Sesethu Dowiasch MBA, Life Science Industry Account Manager, <i>Rockwell Automation</i> </div> </div> </div> |
| 09:05 – 10:35 | <div> <div> <div>09:45 – 10:05</div> <div> TraceBot: Sterility Testing Automation With Traceable Robotics <ul style="list-style-type: none"> • Presenter: Patrick Courtney MBA PhD, Lecturer, <i>King's College London</i> </div> </div> </div> |
| | <div> <div> <div>10:05 – 10:35</div> <div> Q&A, Discussion <ul style="list-style-type: none"> • Moderator: Stephanie Knüppel PhD, Head Sterile Manufacturing & Packaging - E2E Value Stream Lead, • Panelist: Patrick Courtney MBA PhD, Lecturer, <i>King's College London</i> • Panelist: Sesethu Dowiasch MBA, Life Science Industry Account Manager, <i>Rockwell Automation</i> • Panelist: Fabian Feidl PhD, CTO and co-founder, <i>DataHow AG</i> • Panelist: Mónica Perea-Vélez MSc, PhD, CMC Advocacy and Policy Director, <i>GSK</i> </div> </div> </div> |

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| 10:35 – 11:05 | Networking Coffee Break, Poster Session & Exhibition |
| Session 5: Sustainability Moderator: Christian Haenlein M.Sc. , Senior Product Owner, <i>Körber Pharma Inspection</i> | |
| 11:05 – 12:15 | <div> <div>11:05 – 11:25</div> <div> AI: The Perfect Tool to Supervise 24x7 Sustainability Aspects in the Site <ul style="list-style-type: none"> Presenter: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i> </div> </div> |
| | <div> <div>11:25 – 11:45</div> <div> The Next Generation of Healthcare: Expanding Access for All <ul style="list-style-type: none"> Presenter: Daniel Guedelha , Founder & CEO, <i>Generation Health - GenH</i> </div> </div> |
| | <div> <div>11:45 – 12:15</div> <div> Q&A, Discussion <ul style="list-style-type: none"> Moderator: Christian Haenlein M.Sc., Senior Product Owner, <i>Körber Pharma Inspection</i> Panelist: Daniel Guedelha , Founder & CEO, <i>Generation Health - GenH</i> Panelist: Toni Manzano PhD, CSO and Compliance Officer, <i>Aizon</i> </div> </div> |
| 12:15 – 13:15 | Networking Lunch Break, Poster Session & Exhibition |
| Closing Plenary Session Part I Regulatory Moderator: Timothy W Hsu MHSA , International Expert on Health Industry Vice President Industry & Emerging Technologies, <i>UNIDO AAMI</i> | |
| 13:15 – 14:15 | <div> <div>13:15 – 13:35</div> <div> Regional Approach to Digital Transformation in Health <ul style="list-style-type: none"> Regulatory Presenter: Nora Markova DPhil, MBA, International Expert on Health Industry, <i>UNIDO</i> </div> </div> |
| | <div> <div>13:35 – 14:15</div> <div> Plenary Discussion <ul style="list-style-type: none"> Regulatory Moderator: Timothy W Hsu MHSA, International Expert on Health Industry Vice President Industry & Emerging Technologies, <i>UNIDO AAMI</i> Panelist: Daniel Guedelha , Founder & CEO, <i>Generation Health - GenH</i> Regulatory Panelist: Nora Markova DPhil, MBA, International Expert on Health Industry, <i>UNIDO</i> Panelist: Stacey Tinianov MPH, Patient Advocate, Founder, <i>Advocates for Collaborative Education</i> Panelist: James L Vesper PhD, MPH, Director, Learning Solutions, <i>ValSource, Inc.</i> </div> </div> |
| 14:15 – 14:45 | Networking Coffee Break, Poster Session & Exhibition |
| Passport Raffle Announcement | |
| 14:45 – 14:50 | Moderator: Melanie Decker , , <i>Parenteral Drug Association</i> |
| Closing Plenary Session Part II Regulatory Moderator: Timothy W Hsu MHSA , International Expert on Health Industry Vice President Industry & Emerging Technologies, <i>UNIDO AAMI</i> | |
| | <div> <div></div> <div> Interactive Round Table Session <ul style="list-style-type: none"> Moderator: Timothy W Hsu MHSA, International Expert on Health Industry Vice President </div> </div> |

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| 14:50 – 16:25 | 14:50 – 16:25 | Industry & Emerging Technologies, <i>UNIDO AAMI</i> |
| | | <ul style="list-style-type: none">• Moderator: Marilyn Romieux , Strategy Director - Pharma segment, <i>Merck KGaA</i> |
| | | Conference Summary from the Co-Chairs |
| | 16:25 – 16:35 | <ul style="list-style-type: none">• Co-Chair: Marilyn Romieux , Strategy Director - Pharma segment, <i>Merck KGaA</i>• Co-Chair: Timothy W Hsu MHSA, International Expert on Health Industry Vice President Industry & Emerging Technologies, <i>UNIDO AAMI</i> |
| Closing Remarks & Farewell | | |
| 16:35 – 16:40 | | Committee Member: Falk Klar PhD , General Manager, Vice President Europe, <i>Parenteral Drug Association</i> |
| 16:40 – 16:40 | End of Conference | |