2023 PDA Robotics & Automation Conference

A Roadmap to Digitalization Designed for Drug Manufacturing

Amsterdam / The Netherlands

03 – 04 May 2023

Wednesday, 03 May 2023		**09:00 – 17:15**
09:00	Welcome and Introduction	Falk Klar, *PDA Europe*
09:05	Welcome by the Chairs	Dieter Bachmann, *Janssen Johnson & Johnson* Toni Manzano, *Aizon*
Opening Plenary: Regulatory Guidelines for Drug Manufacturing		**Moderator:** Dieter Bachmann, *Janssen Johnson & Johnson*
Pharmaceutical industry, and sterile injectables, is seeing tremendous changes. The development of different new classes of drugs and new forms of therapies as well as an increased demand for automation and digitalization leads to new innovative technologies. At the same time the regulatory framework is under review and changing significantly. The latest in a row of many updates comes with the new EU GMP Annex 1, which on one hand provides opportunity for new technologies to be established and at same time sets the stage for the next decade on regulatory expectations. This session will take a deeper look at these expectations and especially how this will translate for robotics, automation, and AI applications. Case studies will offer an opportunity to see advantageous integration into Contamination Control Strategy.		
09:25	EMA Approach to Support the Translation of Innovative Technologies	Roberto Conocchia, *EMA*
09:55	Robotic and Automation the Enabler for Higher Quality and Annex 1 CCS Compliance	Richard Denk, *SKAN &* Julian Petersen, *Groninger*
10:20	Advances in Robotics and Open Interoperability Accelerates Innovation in Biopharm Manufacturing	Patrick Courtney *SiLa*
10:45	Q&A; Discussion	
11:15	Coffee Break, Poster Session & Exhibition	
Session 1: Digitalization in Manufacturing		**Moderator:** Marilyn Romieux, *Merck*
Digitalization in manufacturing spans many applications and can be implemented at many different levels. We will review how the holistic digitalization of Product Lifecycle Management (PLM) through fully integrated PLM digital tools allows to bring together the many processes, systems, organizations, users, and data involved in the lifecycle of a product, from its initial specifications to its disposal. We will then look at a specific use-case for digitalization in pharmaceutical manufacturing: the serialization of primary containers using radio-frequency identification (RFID) technology as an enabler for automation and improvement of several operations in Fill/Finish, allowing to limit human intervention, reduce risk and improve overall operational efficiency. Join us and take part in a discussion with our consultant and supplier speakers on the benefits of implementing digitalization solutions in manufacturing processes.		
11:45	Interactive Questionnaire	
11:50	Data Visibility and Traceability Throughout a Product Lifecycle	Adam Keyes, *Kalypso* *-remote presentation-*
12:15	Unit Level Syringe Identification as a Foundation for Industry 4.0 in the Fill/Finish and Beyond	Hervé Soukiassian, *BD*
12:40	Q&A; Discussion	
13:10	Lunch Break, Poster Session & Exhibition	
13:55	Guided Poster Walk – Engage with our Poster Presenter in our Exhibition Hall	**Moderator:** Florian W. Huber
Session 2: Digital Twins		**Moderator:** Timothy Hsu, AFDO/RAPS Healthcare Products Collaborative

This session contains 2 approaches that are pushing forward to take advantage of blending together advanced data analytics, automation, and best practices to create (and use) digital/virtual twins. We will examine how the application of digital twins has broad impact in device modelling and engineering for development and product quality as well as how it has been used as a solution for pre-clinical testing. Our session will take you on a deep dive in methodology, advantages, best practices, and lessons learned in bringing these technologies and methodologies to multiple aspects of our industry.		
14:25	Interactive Questionnaire	
14:35	Data-Driven Process Optimization and Digital Twins: Harnessing Data from a Complex System to Drive Quality and Efficiency Gains	Anders Meister, *cim.as* Roger de Reus, *Novo Nordisk*
15:00	Towards a Digital Twin in Preclinical Trials - How Automation and Continuous Data Acquisition Enables AI-supported in Silico Models	Florian W. Huber, *TissUse*
15:25	Q&A; Discussion	
15:55	Coffee Break, Poster Session & Exhibition	
Session 3: Virtual Reality and Augmented Reality		**Moderator:** Sesethu Dowiasch, *Rockwell Automation*
This session unpacks real-life use cases of how Extended Reality is applied within Global Manufacturing and Supply Chain. The presenters will go through the pain points that lead to the use cases, enabling technologies and the selection process for a vendor and technology provider. Additionally, some insights will be shared on the benefits of the of the solution, lessons learnt through the project lifecycle as well as possible roadmaps for the future regarding further automation and standardization of training and assessment.		
16:25	How is Takeda Exploiting the Benefits of Extended Reality in Global Manufacturing and Supply Chain?	Enxhi Gjini & Alice Caranchini, *Takeda*
16:50	Error Coverage and Error Detection Accuracy as Key Drivers for Automated Training in Virtual Reality	Sebastian Scheler, *Innerspace*
17:15	Q&A; Discussion	
17:45	End of Conference Day 1 & Networking Event	

Thursday, 04 May 2023 09:00 – 16:45

Session 4: Sustainability		**Moderator:** Yvonne Duckworth, *CRB Group*
The session on Sustainability will be kicked off by UNIDO, the United Nations Industrial Development Organization (UNIDO) which is a specialized agency of the United Nations that assists countries in economic and industrial development. This presentation provides an overview of UNIDO´s Health Industry Framework including essential medicines, vaccines, medical equipment, and diagnostics, followed by how they will break down the way innovation & technologies can promote sustainable growth. The next presentation will focus on the impact of considering the full life cycle of a product for a holistically sustainable solution for products and businesses, how this is currently being enabled, and how others can do the same.		
09:00	Advancing Sustainability in Health Industry: UNIDO Approaches and Experiences	Alejandro Rivera-Rojas, *UNIDO*
09:30	Environmentally Conscious Design	Bernhard Gerl, *Körber*
09:55	Q&A; Discussion	
10:25	Coffee Break, Poster Session & Exhibition	

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Session 5: Artificial Intelligence		**Moderator:** David Hubmayr, *Takeda*
The session on Artificial Intelligence is kicked off by hearing about opportunities for applied modeling to maximize use of data and drive explicit knowledge generation and sharing as well as lowering the barrier to use models with fit for purpose tools as part of end-to-end Model Factory. Following an Outline and Art of the Possible as well as a discussion on typical challenges companies face when contemplating Technology-enabled Post Market Quality Transformations will be presented. Pragmatic solutions and illustrative case studies, enabled by advanced Artificial Intelligence and Machine Learning (AI/ML) technologies, with tangible benefits, will be shared.		
10:55	Interactive Questionnaire	
11:00	Driving a Culture of Explicit Knowledge Generation in BioTherapeutics Development - One Byte at a Time	Steve Mehrman, *Janssen*
11:25	A Pragmatic Approach to AI-Enabled Post Market Quality Transformation	Salil Thakar, *Pricewaterhouse Coopers*
11:50	Q&A; Discussion	
12:20	Lunch Break, Poster Session & Exhibition	
Closing Session: Digital Transformation Journey in GMP Environment		**Moderator:** Toni Manzano, *Aizon*
Digitization has made it possible to drive automation and robotics towards the concept of smart manufacturing. It thus becomes the value-added mechanism throughout the entire manufacturing process to consistently deliver the expected drug to patients with the industry's current performance settings. This session will delve into some regulatory aspects around the role of digitization in GMP contexts.		
13:20	Interactive Questionnaire	
13:30	Revised PDA Technical Report 60 and Links with Artificial Intelligence Applications	Mauro Giusti, *Eli Lilly*
13:55	Accelerating Digital Transformation Securely by Ensuring Data Integrity in a Regulated Environment	Sesethu Dowiasch, *Rockwell Automation*
14:20	Coffee Break, Poster Session & Exhibition	
14:50	Passport Raffle	PDA Europe
14:55	Digital Transformation and Path to Regulatory Compliance	Krishna Ghosh, *US FDA* *-remote presentation-*
15:25	Achieving Data Integrity and Governance Amidst Pharma's Digital Revolution	Scott Deckebach, *Lachman Consultant Services, Inc.*
15:50	Q&A & Final Panel Discussion ✓ Krishnakali Ghosh, *US FDA* ✓ Mauro Giusti, *Eli Lilly* ✓ Scott Deckebach, *Lachman Consultant Services* ✓ Salil Thakar, *Pricewaterhouse Coopers* ✓ Sebastian Scheler, *Innerspace* ✓ Yvonne Duckworth, *CRB Group*	**Moderator:** Toni Manzano, *Aizon*
16:30	Chairs Conference Summary	Dieter Bachmann, *Janssen Johnson & Johnson* Toni Manzano, *Aizon*
16:40	Closing Remakes & Farewell	Falk Klar, *PDA Europe*
16:45	End of Conference Day 2	

The agenda is subject to change without notice, Speakers are invited pending confirmation!