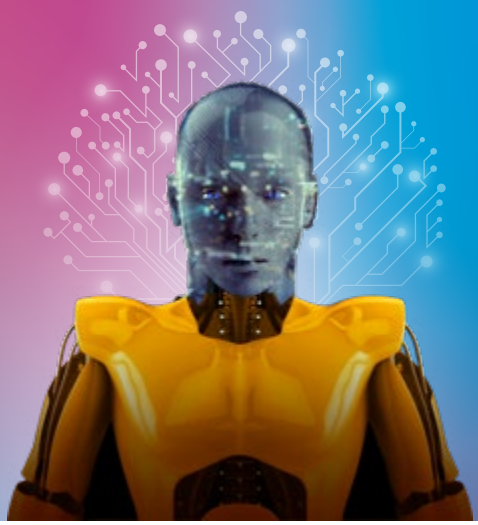
2022 PDA

ROBOTICS AND AUTOMATION CONFERENCE

DIGITAL EVOLUTION WITHIN THE PHARMA INDUSTRY- FROM PITFALLS TO FAST TRACK IMPLEMENTATION

pda.org/EU/2022Robotics

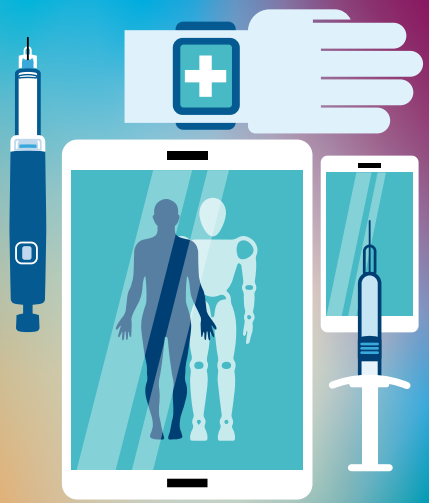


2022 PDA

MEDICAL DEVICES AND CONNECTED HEALTH CONFERENCE

COLLABORATIONS – THE KEY TO A NEW ERA

pda.org/EU/2022MedDev



16-17 MAY 2022
DUBLIN, IRELAND

EXHIBITION: 16-17 MAY
TRAINING: 18-19 MAY
WORKSHOP: 18 MAY

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WELCOME TO 2022 PDA

ROBOTICS AND AUTOMATION CONFERENCE & MEDICAL DEVICES AND CONNECTED HEALTH CONFERENCE

COVID-19 PERSONAL PRECAUTIONARY MEASURES

PDA is committed to delivering safe and secure in-person events. In conjunction with the venue and vendors supporting our event, PDA strictly adheres to all national, provincial, and local government regulations.

ROBOTICS AND AUTOMATION – WELCOME FROM THE CHAIRS

Dear Colleagues,

On behalf of the Scientific Program Planning Committee and PDA, we are proud to invite you to the second edition of the **Robotics and Automation Conference** to take place face-to-face in **Dublin, Ireland on 16-17 May 2022.**

While concepts of robots and automation might have been considered nice to have a few years ago, the global pandemic has accelerated the importance of speed while maintaining our standards of safety. We will cover a wide range of topics ranging **from artificial intelligence and machine learning applied to biopharmaceutical processes, digital transformation drivers, laboratory automation initiatives, and robotization in drug manufacturing.**

Robots and automation are expected to be faster, reduce human errors by significant factors and mitigate contamination risks to a minimum. These technologies cover for the worker shortages that some areas experience and they can do tasks in dangerous settings. The question we usually get, though, is whether these technologies are truly safe, robust, and beneficial for the patients. It's necessary to understand that the heart and soul of automation and robot orchestration lie in multiple elements like artificial intelligence built out from human feedback and a careful initial setup, connectivity, cloud, and sensors. These technologies are not set up in a vacuum and they continue to get reviewed and refined by humans. We are not replacing human knowledge but rather augmenting our capacity to create and innovate to bring our ideas to reality in a way that is safer and faster than ever before. Furthermore, we want to listen to your voice and a dynamic session will be managed to gather your thoughts.

Regulatory bodies are ready for these technologies, too. The industry has the task to measure, record, trace, and analyze all data to continuously improve the quality, efficiency, and safety of our drugs. Smart systems can help us manage the variability and complexity of this new reality.

We are very much looking forward to hearing from each of you about the ideas you have for the opportunities in this space, the technical solutions you have discovered, and the challenges you would like to overpass. There can no longer be any doubt that digitization and automation and the discussions we have here will help catapult our life science organizations into this brave new world.

We look forward to seeing you take part in this highly engaging and interactive conference!

Sincerely,
The Chairs

Martin Düblin,
Conference Chair, One One Eleven

Toni Manzano,
Conference Chair, Aizon

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Toni Manzano, *Aizon, Chair*
Martin Düblin, *One One Eleven, Chair*
Dieter Bachmann, *Janssen J&J*
Mag Corduff, *Odyssey VC*
Yvonne Duckworth, *CRB Group*
Christine Eckardt, *PM Group*
Reyk Horland, *TissUse*
Marilyn Romieux, *Merck KGaA*
Philipp Schmid, *CSEM*
Kevin Smyth, *IPS*
Glenn Wright, *PDA*
Falk Klar, *PDA*
Stefanie Nebelin, *Manager Programs & Events, PDA*

CONFERENCE AGENDA – ROBOTICS AND AUTOMATION

15. Feb 2022

MONDAY, 16 MAY 2022		09:00 – 18:00 CEST
09:00	**Welcome and Introduction**	Falk Klar, *PDA*
	Welcome from the Chairs	Toni Manzano, *Aizon* Martin Düblin, *One One*
	Opening Keynote **Beyond Robotics: State of the Art Automation Solutions for Pharma**	*Pharmabotix*

OPENING PLENARY: Regulatory Updates / Current State of the Industry — *Moderator:* **Toni Manzano,** *Aizon*

Digitization led by acronyms such as AI, AR, VR, IoT, and many more is creating a new layer of cognition on top of existing robots that is having an astonishing impact on the industry, to the point that it has triggered a new industrial revolution. During the sessions of this second edition of the PDA Robotics, we will delve into the impact of the new robotization in the pharmaceutical industry and what better way to start than by analyzing the state of the art and the regulatory vision in this field.

	Updates on the Current Regulatory Framework	*Speaker invited*
	What can be Automated will be Automated	*Stäubli Tec-Systems*
	Panel Discussion	Moderator: Toni Manzano, *Aizon*
11:15	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

SESSION 1: Digital Transformation — *Moderator:* **Yvonne Duckworth,** *CRB Group*

Digital transformation is a very exciting trend that integrates digital technology into all areas of a business. Our first presentation will provide an innovative case study that will highlight alternative and efficient solutions removing paper-based documentation while allowing real-time data recording using technology to generate reports automatically. The second presentation will provide an exciting case study showing the digitization of a paper-based GMP process, as well as the adoption of a cloud-based tool to improve efficiencies and facilitate regulatory compliance.

	Enhanced Data Integrity and Real-Time Recording in Microbiological Quality Control	*salamanderU & Merck KGaA*
	Digital Transformation: Utilization of Cloud-Based Digital Tools to Improve Efficiencies & Facilitate GxP Compliance	*Odyssey VC*
	Q&A, Discussion	Moderator: Yvonne Duckworth, *CRB Group*
13:05	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	

SESSION 2: Lab Automation — *Moderator:* **Dieter Bachmann,** *Janssen J&J*

Production is not only the manufacturing step, it is to the same extent sampling and analytics of samples. When talking about automation and robotics in pharmaceutical production, exploring the opportunities here, is more than worth the effort. Join this session to learn about the latest developments and outlook for robotics and automation in the lab and production process. Hear about how automation progress in EM can address the increased requirements for continuous and online monitoring of environmental conditions.

	Future of Robotics & Automation in Quality Control	*Merck KGaA*
	Aseptic Processing - Digital Twinning Opportunities	*PM Group*

	A Glimpse in the Future of Automated in Environmental Monitoring	*Novatek & Merck KGaA*
	Q&A, Discussion	Moderator: Dieter Bachmann, *Janssen J&J*
15:30	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

SESSION 3: Manufacturing Processes *Moderator:* **Marilyn Romieux,** *Merck KGaA*

Robots have entered the manufacturing floor and are shaping the facility of the future. Through 3 real cases from renowned pharmaceutical companies, we will explore some of the available technologies and understand how robots can improve the reproducibility, productivity, safety, throughput and sustainability of specific manufacturing operations. This session will also open the debate on how to overcome some challenges of bringing robots into environments that have been designed for humans. Join us and take part in a discussion with suppliers and users on implementing robotics solutions in manufacturing processes.

	The Facility on Robotics for Aseptic Manufacturing	*SKAN & Takeda*
	Fully Automated Handling: Through the Inspection Process Without Operator Intervention	*Körber Pharma Inspection & Eli Lilly*
	Autonomous Movement of Robots Between CNC and Grade D Areas	*Takeda*
	Q&A, Discussion	Moderator: Marilyn Romieux, *Merck KGaA*
18:00	**END OF CONFERENCE DAY 1 & NETWORKING EVENT**	

CONFERENCE AGENDA – ROBOTICS AND AUTOMATION

TUESDAY, 17 MAY 2022		09:00 – 16:30 CEST
SESSION 4: From AI in R&D to Process Control in CG		*Moderator:* **Christine Eckardt,** *PM Group*
This session is about the trickiness of implementing AI into high-regulated Pharma production and the process control within bioprocessing. It is always a challenge to come from dummy data to realistic data, which will work under different aspects. Process control is essential to make sure that the processes are always running properly. Two very special presentations are in this slot.		
	On-line Monitoring of Cellular Dynamics in Culture Bioreactors	*Ovizio Imaging Systems*
	Synthetic Data Generation Utilizing Artificial Intelligence - Proven Opportunities for Biopharma and Robotics	*CSL Behring*
	Q&A, Discussion	Moderator: Christine Eckardt, *PM Group*
10:30	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
SESSION 5: Round Table Discussions		*Moderator:* **Reyk Horland,** *TissUse*
	Multiple interactive IG Sessions	
	Summary of Round Tables & Take-Home Message	
12:30	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	
CLOSING PLENARY: Current State of the Art in the Pharma Industry and Next Steps		*Moderator:* **Martin Düblin,** *One One Eleven*
The disruptive technologies presented during the 2nd edition of the PDA Robotics are progressing and they offer more and more opportunities for life science operations. Independent which area is focussed and addressed, there are robotic solutions, digital workstreams, AI strategies, and highly integrated smart automation systems available. And if that is not enough, the speed of all developments is of high pace which requests wise and sensible decisions for the needs coming. During the previous sessions, the speakers brought light to answer questions like: What is the current level the market has reached, and what harmony with authority expectations are gained? In this closing session, the following presentations address the various technical streams and provide a closer understanding of the current state of the art bringing advanced initiatives oriented to the future by applying breakthroughs to improve drug manufacturing.		
	AI Good Practices in CPV: The Path to Integrate Multivariate Control Automation in Biopharmaceutical Manufacturing	Aizon
	Laying the Foundation for Modern Robotics - An Introduction to the Robotics Network Team and Current Projects	*F. Hoffmann - La Roche*
14:30	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
	mRNA Drug Manufacturing Controlled by a Digital Twin	*Imperial College of London*
	Closing Panel Discussion	Moderator: Martin Düblin, *One One Eleven*
	Conference Summary and Take-Home Message	Toni Manzano, *Aizon* Martin Düblin, *One One Eleven*
	Closing Remarks & Farewell	Falk Klar, *PDA*
16:30	**END OF CONFERENCE**	

Agenda is subject to change without notice, all speakers invited and pending confirmation

MEDICAL DEVICES AND CONNECTED HEALTH – WELCOME FROM THE CHAIRS

Dear Colleagues,

On behalf of the Scientific Program Planning Committee and PDA, we are proud to present the second edition of the **2022 PDA Medical Devices and Connected Health Conference** and warmly welcome you to **Dublin/Ireland.**

Connected Health solutions involving **data platforms, connectivity, software, and sensors for health** have the potential to ensure better individual patient care through the provision of **more effective treatments,** while at the same time reducing efforts for healthcare professionals to improve **efficiency in healthcare systems.**

Effective and efficient means that digital health is also confronted with the variety and complexity of the medical device and pharmaceutical **regulatory scheme, the insurance/reimbursement setup** as well as the **management of data security** and information misuse. Although success has been demonstrated in many areas, there are also challenges in showing effectiveness, especially at scale in real-world situations with the evidence that meets stringent demands of the various healthcare stakeholders and which also **aligns cost with benefit.**

What kinds of opportunities and threats are associated with digital healthcare from the industry as well as from the regulators' point of view? Which experiences and learnings are emerging from previous work and particularly from the recent pandemic situation? And finally – which options exist for digital solutions to leave a positive impact on healthcare, while reducing its environmental footprint?

We are convinced that an open dialogue and experience exchange between all parties involved in the most appropriate way to "unleash the power" of medical devices and connected health.

We have received excellent speaker abstracts and believe that we have put together an engaging conference program that focuses on these issues and will provide an ideal environment for an interactive discussion around the opportunities and challenges offered by connected health solutions.

We would like to thank the Scientific Program Planning Committee and PDA for setting up this excellent agenda as well as all contributors and presenters for their insightful input into the conference.

Join us in learning, discussing, and contributing to the emerging benefits of digital health, and be invited to enjoy two interesting and insightful conference days with us!

Sincerely,
The Chairs

Stephanie Göbel,
Conference Chair,
Beyond Conception

Iain Simpson,
Conference Chair,
Phillips Medisize

SCIENTIFIC PROGRAM PLANNING COMMITTEE

Iain Simpson, *Phillips Medisize, Chair*
Stephanie Göbel, *Beyond Conception, Chair*
Geraint Davies, *F. Hoffmann-La Roche*
Paul Greenhalgh, *Team Consulting*
Quentin Le Masne, *Merck Group*
Scott Mullen, *Consultant*
Egmont Semmler, *TÜV Süd*
Paul Upham, *Roche/Genentech*
Andrei Yosef, *Eitan Medical*
Josh Eaton, *PDA*
Falk Klar, *PDA*
Caroline Lynar, *Jr. Manager Programs and Events, PDA*

CONFERENCE AGENDA – MEDICAL DEVICES AND CONNECTED HEALTH

15. Feb 2022

MONDAY, 16 MAY 2022 — 09:00 – 17:45 CEST

09:00	**Welcome and Introduction**	Falk Klar, *PDA*
	Welcome from the Chairs	Iain Simpson, *Phillips Medisize,* Stephanie Göbel, *Beyond Conception*

OPENING PLENARY: Regulatory Aspects

Moderator: **Egmont Semmler,** *TÜV Süd*

Today, we face the big advantage that the technological capabilities in developing connected, smart, or even self-learning devices are within easy reach. However, these technological advances are significantly restrained by two factors. First, the human population and its access to tech knowledge are very heterogeneous, and the acceptance and capabilities of using and applying new technology are subject to large variability. Second, the regulations and regulators are struggling to keep up the pace of current developments, with practically very little or no guidelines at all. Established regulatory processes are slow in adapting to the current speed of innovation and the patient's demand for technologically obvious solutions. The Opening is going to highlight pathways and provide regulatory updates on how to address these innovative devices from both angles.

	Opening Keynote **Adding Electronics to Drug Delivery Devices:** **Satisfying the Needs of Patients, Healthcare Professionals, and Regulators**	*Propeller Health*
	Addressing Changing Human Factors Regulations in China	*Worrell*
	Regulatory Landscape of Artificial Intelligence Medical Devices	*Beyond Conception*
	Q&A, Discussion	Moderator: Egmont Semmler, *TÜV Süd*
11:15	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

SESSION 1: Connected Delivery Devices

Moderator: **Paul Upham,** *Roche/Genentech*

At the heart of many digital health solutions are connected delivery devices that generate data at the point of use along with other patient-centered features. In this session you will learn about what it takes to scale these device-focused solutions and what the role of a connected delivery device can be as part of an integrated solution.

	Connected Drug Delivery Devices – **Roadmap from Commercial Pilots to Mass Adoption, Use Cases from Different Geographies**	*BIOCORP*
	Benefits of Integrated Digital Therapy Management Systems: **Data-driven Interventions and the Roles of Connected Injection Devices**	*Ypsomed*
	Q&A, Discussion	Moderator: Paul Upham, *Roche/Genetech*
13:05	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	

SESSION 2: Patient Experience

Moderator: **Paul Greenhalgh,** *Team Consulting*

Learn about the patient-centric approaches being applied to the development of novel connected devices and digital companion apps. Hear how development teams are building on insights and learnings gained during HF and UX studies to ensure solutions provide the functionality and experience required to drive higher levels of user acceptance, device usage, medication adherence, and persistence.

	Including Patient Reported Data in Connected Device / SaMD Applications to Drive Medication Adherence	*Rip Road*

	Using Patient Centric Design to Develop a Connected Digital Device Solution	*Roche*
	Q&A, Discussion	Moderator: Paul Greenhalgh, *Team Consulting*
15:30	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

SESSION 3: Digital Applications from R&D to Market *Moderator:* **Andrei Yosef,** *Eitan Medical*

Every new digital product starts with a novel idea leading to a possible project with a clear wish to become a product. On the way, the project needs to grow in R&D while facing the challenges from changing the digital environment, changing use cases, changing users' digital acceptance, smarter packaging, and more. Hear about those topics from our experts that researched and overcame those challenges.

	Digital Companion Use Case	*S3 Connected Health*
	The Importance of User Insights in Digital Product Design	*Team Consulting*
	Smart Packaging: Overcoming Implementation Challenges	*Roche*
	Q&A, Discussion	Moderator: Andrei Yosef, *Eitan Medical*
17:45	**END OF CONFERENCE DAY 1 & NETWORKING EVENT**	

CONFERENCE AGENDA – MEDICAL DEVICES AND CONNECTED HEALTH

TUESDAY, 17 MAY 2022		09:00 – 16:30 CEST
SESSION 4: Clinical Trials		*Moderator:* **Stephanie Göbel,** *Beyond Conception*
Get to know how apps and digital solutions support in clinical trials to ensure a successful outcome for patients as well as for the trial´s stakeholders. Join us in learning about the importance of digital endpoints and how to handle the "laziness" of task completion.		
	The Role of Medical Devices and Connected Health in Clinical Trials	*Novartis*
	Meaningful Measures: Digital UX in Clinical Trials	*Team Consulting*
	Human Factors Considerations for Connected Injection Devices in Clinical Operations	*BD*
	Q&A, Discussion	Moderator: Stephanie Göbel, *Beyond Conception*
10:30	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	
SESSION 5: Commercialization Strategies to Enter the Real World		*Moderator:* **Quentin Le Masne,** *Merck Group*
How can digital solutions and the generated data be used to address the needs of patients and clinicians? Join this session to get insights on opportunities to integrate digital solutions into clinical care pathways for better-informed treatment decisions, improved medication adherence, and data-driven interventions relying on connected devices.		
	Development and Integration of Digital Health Solutions in Clinical Care Pathways	*S3 Connected Health*
	Management of Regulated Connected Product in Pharma	*Novartis*
	Q&A, Discussion	Moderator: Quentin Le Masne, *Merck Group*
12:30	**LUNCH BREAK, POSTER SESSION & EXHIBITION**	
CLOSING PLENARY		*Moderator:* **Iain Simpson,** *Phillips Medisize*
Learn about the important topics of cyber security and the need to improve the sustainability of medical and connected devices. Better design and a move to reusable devices can reduce their environmental impact. Furthermore, connected health solutions can improve the efficiency and effectiveness of healthcare treatments offering the potential for additional sustainability benefits. The closing will conduce with a panel discussion that will cover these topics and other key questions including those raised by the audience.		
	Interactive Questionnaire	*Via Mentimeter*
	PDA Cross-industry Collaboration: TR 73 Addendum on MDR Annex I Compliance for a Pre-filled Syringe	*WEST*
	Challenges in Digital Health – Cybersecurity for Medical Devices	*Khera Consultants*
14:30	**COFFEE BREAK, POSTER SESSION & EXHIBITION**	

	Improving the Sustainability of Connected Medical Devices	*Kinneir Dufort*
	Panel Discussion	Moderator: Iain Simpson, *Phillips Medisize*
	Conference Summary	Iain Simpson, *Phillips Medisize* Stephanie Göbel, *Beyond Conception*
	Closing Remarks & Farewell	Falk Klar, *PDA*
16:30	**END OF CONFERENCE**	

Agenda is subject to change without notice, all speakers invited and pending confirmation

VENUE

CROWNE PLAZA DUBLIN AIRPORT
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SPECIAL REQUIREMENTS

If you require special accommodations to fully participate, please attach a written description of your needs with your registration form. Specific questions can be directed to info@pda.org.

PDA EUROPE

UPCOMING CONFERENCES AND EVENTS

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2022

15. Feb 2022

26-27 APR 2022	2022 PDA Visual Inspection Forum	Berlin, Germany
16-17 MAY 2022	2022 PDA Medical Devices and Connected Health Conference	Dublin, Ireland
16-17 MAY 2022	2022 PDA Robotics and Automation Conference	Dublin, Ireland
18-19 MAY 2022	2022 PDA Annex 1 Workshop	Dublin, Ireland
02-03 JUN 2022	2022 PDA Parenteral Packaging Conference	Basel, Switzerland
20-21 JUN 2022	2022 PDA Virus Conference	Brussels, Belgium
22-23 JUN 2022	2022 PDA Advanced Therapy Medicinal Products Conference	Brussels, Belgium
20-21 SEP 2022	2022 PDA BioManufacturing Conference	Amsterdam, The Netherlands
22-23 SEP 2022	2022 PDA Annex 1 Workshop	Amsterdam, The Netherlands
05-06 OCT 2022	2022 PDA Quality and Regulations Conference	Amsterdam, The Netherlands