

Pre-filled Syringes, Injectable Drug Devices & Parenteral Systems 27 – 28 JUN 2024 Hotel Renaissance Barcelona, Spain











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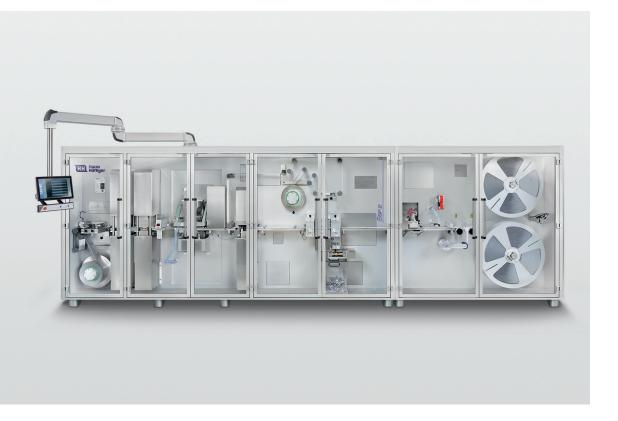
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InjectaSummit is the premier event uniting professionals from the pharmaceutical, medical device, and healthcare sectors in an exploration of the latest advancements in pre-filled syringes, injectable drug devices, and parenteral systems. Our summit is a vital hub for industry experts, decision-makers, and innovators to exchange insights, discuss regulatory compliance, delve into patient-centric design, explore emerging technologies, and address sustainability. It's where professionals learn, network, and collaborate with leaders in these fields. Join us in beautiful Barcelona on June 27-28, 2024, and be part of the conversation that's shaping the future of injectable drug delivery.

Harro Höfliger ALL YOU NEED

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We have many years of expertise in development and production equipment for drug delivery in inhalation and nasal applications. Our experts can support you in all aspects of the development and optimization of your inhalation product.

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- From clinical trials to commercial production
- Integration of dose verification and PAT

EPM Group Executive Summary



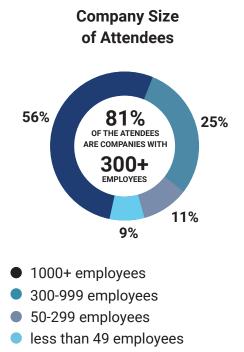


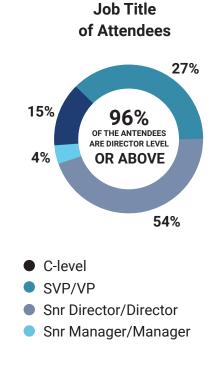
80+ Attendees

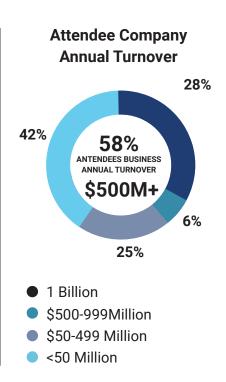
25+ Speakers

RATIO

 $\begin{array}{c} {}_{\text{Bio/pharmaceutical}} \, 65:35 \, \, \text{Vendor/Solution} \\ {}_{\text{Providers}} \end{array}$







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FEEDBACK

Quality of the speakers Sharing of the best practices Spectrum of industries Intimate atmosphere Short-quick presentations 98% WOULD RECOMMEND THE EVENT TO COLLEAGUES

Learn The Key Practical Points

Advanced Drug Delivery Technologies:
 Explore the latest advancements in drug delivery, including innovations in pre-filled syringes and injectable devices.

- **Biologics and Cell Therapies:** Gain insights into the use of pre-filled syringes for delivering biologics, cell therapies, and gene therapies.
- Regulatory Compliance in a Changing Landscape: Stay updated on the evolving regulatory requirements for pre-filled syringe manufacturing, including the impact of revised EU GMP Annex 1.
- Sustainability in Device Design: Learn about incorporating sustainability into the design and manufacturing of injectable drug devices, addressing environmental responsibility.
- Human Factors Engineering: Understand the importance of human factors studies in device design to enhance usability and patient safety.

- Combination Product Development: Explore strategies for the development of combination products and navigate the challenges associated with drug-device combinations.
- Quality Assurance and Safety: Focus on maintaining high standards of quality, safety, compatibility, and stability in parenteral systems.
- Innovation in Large Volume and Highly Viscous Drug Delivery: Discover advancements in devices designed for large volume and highly viscous drug administration.
- **Digital Health Integration:** Explore the integration of digital health technologies in pre-filled syringes and injectable drug devices for enhanced patient-centric solutions.
- Patient-Centric Design and Secondary Packaging: Delve into the development of patient-centric designs and considerations in secondary packaging for combination



Meet The Speakers





Aaron Mann Chief Executive Officer at Windgap Medical



Philipp Richard

Account & Business Development Manager at Ypsomed



Louisa Harvey Founder and Principal at Harvey Medical (a ClariMed company)

Sanjay

Head of Technology

Device Combination

Product at Biocon

Biologics

Transfer of Drug

Rout



Bjarne Sørensen Director, Front End Innovation at Phillips-Medisize



Beate Treffler

Regional Sales Manager Healthcare Europe at Avient



Devendra Ridhurkar

R&D Director, complex generics Adalvo



Richard Denk

Senior Consultant Aseptic Processing & Containment at SKAN AG



Geelanie Briones Managing Director at Athena Life Science



Emily Lorcheim Project Manager at ClorDiSys



Alberto Calzadilla

Hospital Injectables Director at Ethypharm



Henri Bodeau

Business Development Manager at Crossject



Venkata Goli

Research fellow, formulation and process development at ten23health



René Holm

Professor at University of Southern Denmark



Enrico Barichello

Product Manager, Syringe Platform – DCS Glass at Stevanato Group



Mark Hassett

Vice President of Business Development at Credence MedSystems, Inc.



Tom Oakley

VP Design and Development at Springboard, a Sanner Group company

Scientific **Agenda**

DAY 0 JUN 26.2024

18:00 - 20:00 RESCON Europe & INJECTA Summit Gala Dinner CRU Restaurant at Renaissance Barcelona Hotel

DAY 1 JUN 27.2024

08:30 – 08:50 INJECTA Summit Registration

08:50 – 09:00 Opening of INJECTA Summit 2024

Session 1

Exploring Future Trends in Drug Delivery

Morning Chairperson:

René Holm, University of Southern Denmark

09:00 – 09:30 Onbody delivery systems: latest news and trends

Tom Oakley

VP Design and Development at Springboard, a Sanner Group company 09:30 – 10:00 Pharmaceutical Industry: The Future of the Next Decade

> Alberto Calzadilla Hospital Injectables Director at Ethypharm

- 10:00 10:30 Speed Networking
- **10:30 11:00** Morning Coffee-Break
 - **10:40** Harro Höfliger Sponsor Presentation (5min)

10:50 Vectura Sponsor Presentation (5min)

Session 2 Innovative Approaches to Drug Delivery

11:00 – 11:30 Solutions for emerging challenges in Injectable drug delivery

Mark Hassett

Vice President of Business Development at Credence MedSystems, Inc.

11:30 – 12:00 Long acting injectible formulations - what are the pharmaceutical options?

René Holm

Professor at University of Southern Denmark

Session 3

Sustainable Solutions for Injection Devices

12:00 – 12:30 Injecting Sustainability into Drug Delivery: Patient at the Center

Aaron Mann CEO & President at Windgap Medical

12:30 - 13:00 T

The Journey Towards Sustainable Self-Injection Devices: Where Do We Stand?

Philipp Richard

Account & Business Development Manager YDS at Ypsomed AG

13:00 – 14:00 Lunch Break

Afternoon Chairperson: Venkata Goli, ten23health

14:00 – 14:30 ⊤

The Influence of colorants on the performance of injectable devices and the importance of a stringent change management

Beate Treffler

Regional Sales Manager Healthcare Europe at Avient

Session 4

Insights into Pre-filled Syringe Technology

14:30 – 15:00 Needle-free Auto-injection: A New Paradigm in Drug Delivery

Henri Bodeau

Business Development Manager at Crossject

15:00 – 15:30 Plunger Stopper Movement in Pre-Filled Syringes & Cartridges: Critical Factors and Mitigations

Venkata Goli

Research fellow, formulation and process development at ten23health

15:30 – 16:00 Potential Contribution of Plunger Stopper Position in Prefilled Cartridge/Syringe Drug Device Combination Product Delivery System

Sanjay Kumar Rout

Senior Manager [HOD Technology Transfer of Drug device combination product MSAT) at Biocon Biologics Ltd

- **16:00 16:30** Afternoon Coffee-Break Berry Global Sponsor Presentation (5min)
- **16:30 17:30** Panel discussion: Future Directions in Drug Delivery-Innovations, Sustainability, and Regulatory Challenges

Session 5 Advancements in Smart Devices				
08:50 – 09:00	Opening of Injecta Summit 2 nd day			
DAY 2	JUN 28.2024			
20:00	RESCON Europe & Injecta Summit Gala Dinner			
17:30	End of the Injecta Summit 1st day			
	Moderated by: René Holm, Professor at University of Southern Denmark			
	Medical • Louisa Harvey, Harvey Medical • Beate Treffler, Avient			
	 Bjarne Sørensen, Phillips- Medisize Aaron Mann, Windgap 			
	Panelists: • Geelanie Briones, Athena Life Science			
	technology • Sustainability initiatives and implications • Regulatory considerations for novel delivery systems			

Philipp Richard, Ypsomed

09:00 – 09:30 Using Artificial Intelligence to Design a User-Centered Injection Device

	Louisa Harvey Founder and Principal at Harvey Medical (a ClariMed company)	11:30 – 12:00	Building a robust Quality system for a sustainable business
Session 6 Biologics and Pre-Filled Syringes			Geelanie Briones, Managing Director at Athena Life Science
09:30 – 10:00	Innovative Solutions in Pre-Filled Syringes for Biologics Enrico Barichello	12:00 – 13:00	Panel discussion: Navigating High-Dose Drug Delivery: Challenges and Opportunities
	Product Manager Syringes Platform DCS – Glass at Stevanato Group		• Large-Volume Delivery Device Perspectives • Exploring Delivery Method
10:00 – 10:30	Ambient Temperature Sterilization of Cold-Chain, Product Filled Syringes with Chlorine Dioxide		Potential • Strategies for Safe and Usable Delivery
	Emily Lorcheim Project Manager at ClorDiSys		Panelists: • Bjarne Sørensen, Phillips-Medisize • Enrico Barichello,
10:30 - 11:00	Morning Coffee-Break		Stevanato Group • Sanjay Kumar Rout,
10:40	Credence MedSystems, Inc. Sponsor Presentation (5min)		Biocon Biologics Ltd • Venkata Goli, ten23health • Richard Denk, SKAN AG
Session 7 Regulatory Comp Landscape	liance in a Changing		Moderated by: Clemens Guenther, Bayer AG
11:00 - 11:30	Annex 1 requirements for	13:00 – 14:00	Lunch Break

Pre Filled Syringes Fill/ Finish

Richard Denk

Senior Consultant Aseptic Processing & Containment at SKAN AG

Session 8 Safety and Compliance Considerations

Afternoon Chairperson:

Clemens Guenther, Bayer

14:00 – 14:30 Safety Assessment of Impurities and Extractables & Leachables for PFS

> Clemens Guenther Senior Expert Nonclinical Safety at Bayer AG

14:30 – 15:00 High Dose Injectable Drug Delivery - A Route to Better Usability and Sustainability

> Bjarne Sørensen Director, Front End Innovation at Phillips-Medisize

15:00Closing Remarks and End
of Injecta Summit 2024



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Aaron Mann Chief Executive Officer at Windgap Medical

Aaron Mann is the esteemed CEO of Windgap Medical, a privately-held drug delivery company with a focus on simplifying, automating, and expediting the delivery of challenging-to-mix drugs. Under his leadership, Windgap Medical collaborates with leading biopharmaceutical companies to provide solutions that liberate patients, families, and complex therapies from the constraints of current delivery systems. Previously, Aaron served as the CEO at Kindeva Drug Delivery, a prominent global CDMO for biopharmaceutical companies. Leading a team of over 1000 talented colleagues, he successfully steered the company through its spin-off from 3M in 2020, with backing from Altaris Capital Partners. Kindeva's comprehensive capabilities encompass inhalation, transdermal, and microneedles, spanning pre-clinical development, regulatory processes, and approval, all the way to commercial scale and supply, with operations in the US and the UK.



Louisa Harvey Founder and Principal at Harvey Medical (a ClariMed company)

Louisa Harvey is a thought leader in the Human Factors/ Usability space and tries to find any route to push boundaries. Louisa has been in the medical device and pharmaceutical industry for 20 years. She has an MSc in Industrial Pharmaceutical Science. She developed her own AI app for enhancing human factors research, which is commercially available. Louisa runs the Medical HUman Factors Network in the UK.



Bjarne Sørensen Director, Front End Innovation at Phillips-Medisize

Bjarne Sørensen is a director of front-end innovation at Phillips-Medisize, based in the company's development centre in Denmark. With more than 35 years of experience within product, strategy, and business development, Bjarne has a very visible track record within different business areas. At Phillips-Medisize, he participates in customer projects, typically involving electronic injectors and connected health systems. He is also deeply involved in new electronic platform programs, especially on conceptual, technical, and sustainability aspects.



Devendra Ridhurkar R&D Director, complex generics Adalvo

Dr Ridhurkar is a Biopharmaceutical Subject Matter Expert based in Barcelona, Spain. He boasts over 17 years of invaluable scientific leadership and management expertise in the complex formulation development and manufacturing of small and biological compounds. Renowned for his proficiency in steering projects encompassing Biosimilar, Protein and Peptides, Proprietary and Generic drugs, including 505b2, Hybrid, Complex, Specialty, and Branded formulations, he has significantly impacted Pharma-Biotech companies worldwide.



Geelanie Briones Managing Director at Athena Life Science

Geelanie Briones is an experienced professional and leader with almost 25 years of experience in the Life Science Industry, with a particular focus on quality, compliance, operations, sustainability, and organizational transformation and development. She has been in the quality area and leading teams for 22 years and was a member of Xellia's Executive Leadership Team for 8 years. Her mission is to build robust and resilient organizations that deliver high-quality products, ensure compliance with global standards, and foster a culture of continuous improvement and innovation.



Emily Lorcheim Project Manager at ClorDiSys

Emily Lorcheim, PMP is Project Manager at ClorDiSys. She works with manufacturers and engineers to generate sterilization strategies to fit their unique needs. Emily works with clients from design and material selection through routine processing and scale up. This includes initial lethality testing, material compatibility, developing protocols,validations, and regulatory guidance. Emily is part of standards development with The Association for the Advancement of Medical Instrumentation® and participates in several Working Groups. Emily has authored various articles and studies as well as has conducted many education sessions on the technology and science.



Alberto Calzadilla Hospital Injectables Director at Ethypharm

Highly motivated, results driven professional with brand and generics experience. Proven track record in business development, contract negotiations, operations, cost savings initiatives, risk management, supply chain. Expertise in external supply operations, APIs, excipients, agricultural commodities and petrochemicals as it relates to the Pharmaceutical industry.

Specialties: Licensing and Supply Agreements, Pricing Negotiations, Supplier Management, Operations, Risk Analysis, Budget Forecasting, Strategy Creation and Implementation, Supply Chain, Alternate Source Qualification, Project Management



Philipp Richard Account & Business Development Manager at Ypsomed

Philipp Richard has been with Ypsomed since 2009 in various roles in product- and key account management with pharma companies to develop and bring to market innovative self-injection systems. He studied electrical engineering at the Federal Institute of Technology in Lausanne, Switzerland. Before joining the world of medical devices, he has worked in the area of contactless bearing technology for high-speed turbomachines. Since 2011, his main focus has been on defining platform-based product

offerings and on implementing customized injection devices with a growing base of pharma customers. As key account manager, he has managed the transition from project to market supply including ramp-up with several autoinjector customers. Ypsomed Delivery Systems continues to focus on the development and manufacture of next generation pens, autoinjectors, patch injectors, smart device technologies and therapy management services.



Sanjay Rout Head of Technology Transfer of Drug Device Combination Product at Biocon Biologics

Sanjay Kumar Rout, currently serving as the Head of Technology Transfer of Drug Device Combination Product at Biocon Biologics MSAT, brings a wealth of knowledge and expertise with 17 years of experience in drug product manufacturing and packaging. His proficiency extends to the development of combination devices, such as pens and autoinjectors, process validation, commercialization, shipping validation, and life cycle development and sustainability programs. With a Bachelor's degree in Pharmacy, Sanjay excels in visual inspection, packaging, medical device design, technology transfer, and Design History File (DHF) filling.



Beate Treffler Regional Sales Manager Healthcare Europe at Avient

After studying chemical engineering Beate joined Clariant's Plastic Additives division over 30 years ago. After holding various positions in technical service, development and marketing, Beate took over the lead of the dedicated Healthcare Polymers Solutions team of Clariant Masterbatches in 2015, which focuses on enhancing and protecting healthcare products. Since 2021 she is heading the healthcare sales team in Europe. Born of the collective strength of PolyOne & Clariant Masterbatches since July 1st 2020, Avient is a leading provider of plastics colors & additives.



Richard Denk Senior Consultant Aseptic Processing & Containment at SKAN AG

Richard Denk is working at the company SKAN AG, headquartered in Allschwil Switzerland in the position Senior Consultant Aseptic Processing & Containment. Richard is Member of the PDA ATMP Advisory Board and chair of the PtC of the Manufacturing of ATMPs. Richard is member of the PDA Isolator Expert Group and publisher of the PDA Paper "Isolator Surfaces and Contamination Risk to Personnel and Patient". Furthermore, Richard is member of the ISPE Annex 1 and PIC/s Annex 2A commenting group, Founded the ISPE CoP Containment and SIG Future Robotics. Richard is Member of the ISPE European Leadership Team and Member of the ISPE CoP Sterile Product Processing. Richard is a global recognized subject matter expert on Aseptic Processing, ATMPs and Containment and has developed the containment pyramid.



Venkata Goli Research fellow, formulation and process development at ten23health

Venkata working as a research fellow, formulation and process development at ten23health. He worked previously as a senior scientist at Thermo Fisher Scientific, Italy (2021-2023), Biocon Biologics (2019-2021) and Pfizer biologics development center (2014-2019). He has a pharmaceutical background and holds a M.S degree in Pharmaceutics from NIPER, Mohali (India). He has extensive knowledge in formulation development, container closure selection, lyophilization and process development & characterization. Through career, he played a key role in platform formulation and process development. This knowledge being further strengthened with active involvement in the innovation projects at ten23 health related to surfactants, container closure systems characterization, formulation knowledge base creation.



René Holm Professor at University of Southern Denmark

Dr. René Holm is a professor in pharmaceutical physical chemistry at the University of Southern Denmark. After receiving Master and PhD degree in pharmaceutics from the University of Copenhagen, Denmark, in 2002, he started his carrier in the pharmaceutical industry at H.Lundbeck in 2001 and changed to Janssen in 2016. Dr. Holm has worked within pharmaceutical development, formulations for nonclinical testing in drug discovery, physical chemistry and material science covering both small and large molecules. In 2021 Dr. Holm engaged into a carrier change and became a full professor. Dr. Holm is (co-) author of more than 230 original articles in peer-reviewed journals and patents in the field of biopharmaceutics, preformulation, formulation and physical pharmacy and book chapters and is co-inventor on 13 published patents.



Enrico Barichello Product Manager, Syringe Platform – DCS Glass at Stevanato Group

With a background in Industrial Engineering and a Master's in Management at the University of Padua, Enrico Barichello acquired broad-spectrum skills in technical concepts and complex processes. He joined Stevanato Group in 2017 as a Product Management Specialist for the Syringe platform. He defined and coordinated all the activities required to bring the products to market, bridging gaps between different company functions and aligning the involved teams. He has been responsible for the roadmap and execution of the innovative platform Alba®. Since 2023 he is Product Manager for the Glass Syringe Platform.



Mark Hassett Vice President of Business Development at Credence MedSystems, Inc.

Mr. Hassett has 30+ years' experience in the medical device industry. In that time, he has functioned as Global VP Sales, Marketing, and Business Development for IVAC Corporation, Block Medical, Medication Delivery Devices, Safety Syringes, Venetec Int'l, Unilife Medical, and ROVI Contract Manufacturing (EU). His responsibilities

included commercialization of infusion pumps, injectable devices (PFS), wearable devices, and autoinjectors. He has injectable device experience in multiple markets to include, acute care, alternate site, and more specifically for Pharmaceutical and Biotech the last 20 years. He holds a BS degree from Georgia State University in Atlanta, GA.



Tom Oakley VP Design and Development at Springboard, a Sanner Group company

Tom Oakley is co-founder and VP Design and Development at Springboard, a Sanner Group company, a leading medical device development company. His first degree was a Master of Engineering from Cambridge University, and he was later appointed the Choate Fellow in human physiology and pathology at the Harvard School of Public Health. Since 2001, he has focused on creating safetycritical designs for mass production and is named inventor on dozens of medical device patents.



Henri Bodeau Business Development Manager at Crossject

Henri has a background in International Business Development and Graduated from Manchester MU Business School & Burgundy School of Business, with 7 years of experience in the Pharmaceutical industry. Henri has been involved in several business development projects for innovative assets for emergency use based on needle free auto-injection. The main areas for this projects have been global with a strong focus on North America, Europe, Australasia to bring to the market these patient centered drug/device combination products.

CREDENCE MEDSYST INNOVATION WITHOUT CHANGE SOLUTIONS TO EMERGING TRENDS AND CHALLENGES IN INJECTABLE DRUG DELIVERY SEQUENTIAL INJECTION SCALING Two liquids stored separately... nd delivered sequentially manufacturing COMPANIO has arrived DUAL CHAMBER COMPANION User-preferred, end-of-dose cues, RECONSTITUTION automatic needle retraction Single-step mixing and Credence MedSystems, Inc. +1-844-263-3797 | info@CredenceMed.com www.CredenceMed.com



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