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SMi Group Proudly Present the 14th Annual Conference...

Pre-Filled Syringes and Injectable Drug Devices

The Future of Drug Delivery and Combination Product Device Design

FOCUS DAY: 11TH
CONFERENCE:
12TH - 13TH
JAN
2022

Venue to be confirmed, London, UK

NEW FOR 2022

Focus Day: Sustainability for Drug Delivery Devices

11TH JANUARY 2022

FOCUS DAY CHAIR:

Els Ducheyne,
Senior Manager Material Compliance & EPR, Environmental Product Compliance & Sustainability, **Johnson & Johnson**

FEATURED SPEAKERS:

- **Sriman Banerjee,** Head of Packaging Development & Commercial Device Engineering, **Takeda**
- **Fiona Adshead,** Chair, **Sustainable Healthcare Coalition**
- **Martin Townsend,** Global Head of Sustainability and Circle Economy, **BSI Group**
- **Conor O'Neill,** Head of Packaging Development, **GSK**
- **Stephen Chamberlain,** Director, Device Engineering, **GSK**
- **Niels Otterstrøm Jensen,** Associate Director - Corporate Environmental Strategy, **Novo Nordisk**
- **Cedric Gysel,** Manager, Healthcare Solutions Design, **Johnson & Johnson**
- **Christina Greever,** Sustainability Program Manager, **My Green Lab**

CHAIRS FOR 2022:

Bjørg Kaae Hunter,
Department Manager, RA CMC & Device; RA NextGen Drug-Device, **Novo Nordisk**

Daniel Latham,
Head Connected Health Product Development, **Novartis**

FEATURED 2022 SPEAKERS INCLUDE:

- **David Braun,** Head of Connected Health and Medical Devices Business Solutions, **Merck Group**
- **Louise Place,** Director, Devices, **GSK**
- **Jochen Zenker,** Head of Laboratory Process Engineering, Device Development, **Boehringer Ingelheim**
- **Joel Richard,** Chief Development Officer, **MedinCell**
- **Sachin Dubey,** Head of Drug Product and Analytical Development, **Ichnos Sciences**
- **Raphael Nudelman,** Director of Chemical and Computational Toxicology, **Teva Pharmaceuticals**
- **Richard Simcock,** Human Factors Scientist, CPD, **Teva**
- **Michael Becker,** Packaging Engineer, Launch + Transfer Operations, **Boehringer Ingelheim Pharma GmbH & Co. KG**
- **Arabe Ahmed,** Medicinal Technical Expert, **BSI**

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LETTER FROM THE CHAIRS:

Dear Colleagues,

It is with great pleasure and delight that we welcome you to SMi's highly anticipated Pre-Filled Syringes and Injectable Drug Devices conference taking place on the 12th-13th of January 2022 in London.

The 14th annual conference will bring together expertise from individuals in multiple disciplines in the field addressing key areas with recent developments in the industry including connectivity for drug delivery, insights into fragile molecules and long acting injectables, parenteral delivery design approaches and digitalization in device development.

With the recent implementation of the EU MDR, notified bodies, regulators and industry will discuss their experiences of the new standard. The past year has seen accelerated progress in connected healthcare in light of the pandemic and industry leaders will be addressing the growing developments in connected drug delivery devices. Furthermore, panel discussions will explore considerations and strategies in accelerating innovation in the drug delivery landscape as well as an insight into the landscape of delivery for novel drug products, fragile molecules and long acting injectables, while experts from academia will assess the potential of injectable medicine as a route to COVID-19 therapy.

As co-chairs of this event, we look forward to welcoming you to this must-attend conference in London this coming January.

Yours sincerely,

Bjørg Kaae Hunter,
Department Manager,
RA CMC & Device;
RA NextGen Drug-Device,
Novo Nordisk

Daniel Latham,
Head Connected Health
Product Development
Novartis

08.00 **Registration & Coffee**

09.00 **Chairs' Opening Remarks**
Bjorg Hunter, RA NextGen Drug-Device Department Manager, **Novo Nordisk**
Daniel Latham, Head - Connected Health Product Development, Connected Health, Data & Digital, **Novartis**

09.10 **OPENING ADDRESS**
On the regulatory interface of digitalisation and drug-device combination products
- How do we manage regulatory submissions of drug-device combination products in the interface of digitalisation ?
- Engaging with regulators on areas of uncertainty to improve guidance for all parties
- How can we create harmonization across global regulations that can keep up with rapid development?
- What does the future hold in this space?

Bjørg Kaae Hunter, Department Manager, RA CMC & Device; RA NextGen Drug-Device, **Novo Nordisk**
Mathilde BarBeau, Senior Regulatory Professional, RA CMC & Device, **Novo Nordisk**

CONNECTIVITY FOR DRUG DELIVERY DEVICES

09.50 **SPOTLIGHT SESSION**
Navigating connected health to enhance drug portfolio
- Opportunities to enhance current treatment offerings with Connected Health
- Development of connected ecosystems and impacting the patient journey
- Overcoming challenges in developing a successful connected parenteral delivery portfolio

Daniel Latham, Head - Connected Health Product Development, Connected Health, Data & Digital, **Novartis**

10.30 **Morning Coffee Sponsored by Zeon** ZEON

11.00 **SPOTLIGHT SESSION**
Connected delivery device value creation
- An insight into the current landscape and examples of connected health and delivery devices
- Design thinking and optimising value creation
- Challenges and opportunities in data generation for personalised treatments

David Braun, Global Head of Connected Health and Medical Devices, **Merck**

11.40 **Can Behavioral Science be the key to unlocking patient adherence?**
- The continued challenge of patient adherence and engagement to treatment - impact on patient outcomes and health system
- Historic informational material - one size does not fit all
- Two applied examples - development of digital solutions effective in on boarding users onto treatments and enabling successful self-management of their treatments over time
- Key learnings - implementation lessons learned of applying
- Behavioural Science to instructional material development and technologies used to assess the intervention effectiveness
- Project significance - Generation of medical solutions that better meet user needs and engage users with their treatments

Andrea Pisa, Usability Design Lead, **Crux Product Design** crux

FRAGILE MOLECULES AND LONG ACTING INJECTABLES

12.20 **Long-acting injectable medicine as a potential route to COVID-19 therapy** COVID-19 SPOTLIGHT
- The use case for a long-acting intervention in COVID-19
- Repurposing an existing drug as a long-acting injectable therapy to treat COVID-19
- Requirements for a successful long-acting injectable antiviral candidate
- The critical importance of early work to establish availability of COVID-19 therapies in low- and middle-income countries?

Andrew Owen, Director, Centre of Excellence in Long acting Therapeutics (CELT), **University of Liverpool**

13.00 **Networking Lunch**

14.00 **Tackling high-volume administration challenges with a smart, sustainable on-body injector platform**
- Challenges facing modern drug delivery devices
- Delivering large volumes at home in sustainable and user-friendly way
- A differentiated approach in the wearables' landscape: Nemera Symbioze platform

Severine Duband, Global Category Director, Devices, **Nemera** Nemera

14.40 **Long acting injectable, application of aqueous suspensions**
- Long acting injectables – why?
- Which compounds fits the technology
- PK and formulation considerations
- Biopharmaceutical considerations of LAIs

René Holm, Professor, Physics, Chemistry and Pharmacy, **University of Southern Denmark**

15.20 **Challenges of injectable delivery for fragile molecule**
- An industry outlook of in situ forming implant technologies
- Overcoming challenges of molecular structure for fragile molecule delivery
- Unmet needs for delivery technologies
- Examples of current approaches for fragile molecule delivery

Joel Richard, Chief Development Officer, **MedinCell**

16.00 **Afternoon Tea Sponsored by Zeon** ZEON

16.30 **PANEL DISCUSSION**
Assessing the landscape of delivery for novel drug products, fragile molecules and long acting injectables
- The current landscape of fragile molecule formulations and delivery
- Considerations and strategies for successful long acting injectable delivery
- Key barriers facing development in industry and strategies in overcoming hurdles of novel drug product delivery
- Selecting appropriate technology for a molecule of interest
- Opportunities offered by therapeutic areas where long acting injectable do not yet exist and future industry trends for optimal novel and sustained injectable delivery

Joel Richard, Chief Development Officer, **MedinCell**
René Holm, Professor, Physics, Chemistry and Pharmacy, **University of Southern Denmark**
Andrew Owen, Director, Centre of Excellence in Long acting Therapeutics (CELT), **University of Liverpool**
Raphael Nudelman, Director of Chemical and Computational Toxicology, **Teva pharmaceuticals**

17.10 **Challenges in Cell & gene therapy**
- An introduction into the landscape of cell and gene therapy
- Current challenges and barriers to delivery
- Potential benefits and challenges of a parenteral approach to delivery using pre-filled syringes
- Future development strategies for cell and gene therapy

Annie Zavadil, New Technologies Device Project Leader, **Novartis**

17.50 **Subcutaneous administration of biotherapeutics – pre-filled syringes and beyond**
- Subcutaneous as a route of administration
- Prefilled syringes for biologics
- Foreseeable development hurdles and strategies to overcome them
- Dual chamber systems as an alternative to liquid PFS

Sachin Dubey, Head of Drug Product and Analytical Development, **Ichnos Sciences**

18.30 **Chairs' Closing Remarks and Close of Day One**

08.00 Registration & Coffee

09.00 Chairs' Opening Remarks
Bjorg Hunter, RA NextGen Drug-Device Department Manager, Novo Nordisk
Daniel Latham, Head - Connected Health Product Development, Connected Health, Data & Digital, Novartis

REGULATORY AND NOTIFIED BODY INSIGHTS

OPENING ADDRESS

09.10 Industry Perspective: Implementation of the EU MDR
- Aligning with new regulatory requirements for stand-alone devices and combination products
- Case Study examples: GSK's vaccines/pharma portfolio
- Considerations and challenges in implementation of the MDR for injectables
- Assessing clarifications that are still needed to understand what is expected from industry

Louise Place, Director, Devices, GSK

09.50 Working with notified bodies – lessons learned and advice
- Experiences and takeaways from Team-NB over the past year
- Common challenges in applications for notified body opinions and guidance on working with notified bodies
- How industry can work more closely with regulators and notified bodies in implementation of new regulations
- What gaps have we seen since the EU MDR implementation and how can this be improved

Julia Frese, Director, TÜV SÜD Japan Ltd.

10.30 Morning Coffee Sponsored by Zeon

11.00 Notified Body Perspective: Regulatory updates following implementation of the MDR
- How has industry adapted with the full implementation of the EU MDR and Article 117
- Change management considerations for article 117 regulatory submissions
- Key takeaways from implementation of the MDR and what guidance is still needed
- Considerations for legacy products and implementation for device platforms

Arabe Ahmed, Medicinal Technical Expert, BSI

11.40 Selecting drug delivery systems for higher dose volume and higher viscosities
- High dose biologic formulations are pushing drug volume and viscosity beyond traditional self-injection design space limits (> 15 cP, > 1 ml dose volume), which can challenge patients' capabilities to administer their injections based on injection time or force
- We will discuss how ergonomic, manual, syringe-based injections can enable subcutaneous self-injections with characteristics that go beyond the traditional boundaries of volume and viscosity
- Important factors for development of combination products involving delivery of higher volumes (1-2 mL) are presented, including assembly, human factors, documentation, and platform considerations

Karima Yadi, Senior Marketing Manager, System Delivery Solutions, BD

12.20 Understanding updated guidelines on nitrosamine impurities
- Assessing the recent regulatory guidance for industry on nitrosamine impurities
- Understanding the risks and causes of nitrosamine impurities in drug device combination products
- Risk management strategies for identification and minimisation of nitrosamines in drug products
- Approaches to limit formation of nitrosamines through manufacturing and during shelf-life

Raphael Nudelman, Director of Chemical and Computational Toxicology, Teva Pharmaceuticals

13.00 Networking Lunch

PARENTERAL DELIVERY DESIGN APPROACHES

14.00 Session reserved for Zeon

14.40 Making a difference; considering usability throughout the design lifecycle
- Why it is important to identify factors affecting usability early in the design lifecycle
- How to make this a normal part of your processes
- The importance of usability testing
- Project examples of the importance and impact of good usability engineering

Richard Simcock, Human Factors Scientist, CPD, Teva

15.20 Designing the First Impression of a Drug/Device Combination Product
- Packaging and Labelling is the first interface between the user and the combination product creating the first device impression at the user
- To develop user centric folding boxes, labels and "Instruction for Use"s the design control process can be useful
- Beside the needs of the users/patients regulatory requirements and the product protection must be considered and integrated into this development process making the product safe and effective

Michael Becker, Packaging Engineer, Launch + Transfer Operations, Boehringer Ingelheim Pharma GmbH & Co. KG

16.00 Afternoon Tea Sponsored by Zeon

PANEL DISCUSSION

16.30 Accelerating innovation in the drug delivery landscape
- How can device developers, big pharma and regulators work together to encourage innovations in parenteral delivery?
- How have we seen drug device combination product development evolve in recent years and where are the biggest growth areas in the space?
- Understanding when connectivity is beneficial for delivery devices and how can this be enhanced for improved patient experience?

Panel Moderator:
Bjorg Hunter, RA NextGen Drug-Device Department Manager, Novo Nordisk
Panelists:
Richard Simcock, Human Factors Scientist, CPD, Teva
Louise Place, Director, Devices, GSK
Arabe Ahmed, Medicinal Technical Expert, BSI

DIGITALIZATION IN DEVICE DEVELOPMENT

17.10 The use of digital twins in Pharma
- Potential of Digital Twins in Pharma
- Process of developing a Digital Twin
- Validation, Verification and Uncertainty Quantification of the Digital Twin
- Challenges Faced

Eleanor Kimber, Device Engineer, GlaxoSmithKline

17.50 Digitalization meets assembly process
- Lessons learned: Challenges of a machine guided PFS assembly process
- Machine parameter, device constituent parts and physical interactions are essential inputs for a robust assembly process
- Digital perspective on assembly processes evaluation
- Insights of closure integrity and behavior of rubber components associated with the assembly process

Jochen Zenker, Head of Laboratory Process Engineering, Device Development, Boehringer Ingelheim GmbH & Co Kg

18.30 Chairs' Closing Remarks and Close of Day Two

Pre-Filled Syringes and Injectable Drug Devices Conference

Focus Day | Tuesday 11th January 2022 www.pre-filled-syringes.com

Sustainability for Drug Delivery Devices

Strategies for circular economy in device development

Chaired by
Els Ducheyne, Senior Manager Material Compliance & EPR, Environmental Product Compliance & Sustainability, **Johnson & Johnson**

Focus day overview:
Part of the SMi's leading injectables series of events, this year will host a pre-conference focus day to explore and assess strategies for circular economy and sustainability in device development. Case studies, regulatory insights and academic perspectives will give a holistic insight into the industry's efforts to improve sustainability and circular economy. The focus day will open discussion for improved strategies to integrate sustainability in pharma while ensuring patient needs and safety are kept at the forefront in device design.

Topics Covered Will Include:
- **Hear** from leading big pharma on how they are already incorporating sustainable approaches to device development
- **Discover** the power of collaboration to enhance and deliver sustainable healthcare
- **Understand** current guidelines and how to work with regulators to embed circular economy in development practices
- **Engage** in case study examples and key learnings from drug delivery device take-back pilots in industry

08.30 **Registration & Coffee**

09.00 **Chairs' Opening Remarks**
Els Ducheyne, Senior Manager Material Compliance & EPR, Environmental Product Compliance & Sustainability, **Johnson & Johnson**

SUSTAINABILITY FOR DRUG DELIVERY DEVICES

OPENING ADDRESS

09.10 **The power of collaboration to deliver sustainable healthcare**
- The presentation will outline how the Sustainable Healthcare Coalition,a partnership of leading companies and public sector agencies, addresses some of the most pressing sustainability issues in global healthcare.
- Case studies of digital approaches and connected devices will demonstrate how healthcare sector industry partners can help the NHS achieve NetZero and bring together clinicians and industry to meet the challenges of improving sustainability through innovation.

Fiona Adshead, Chair, **Sustainable Healthcare Coalition**

09.50 **Embedding sustainability into medical device product life cycle**
- Barriers of waste
- Enveloping circular economy into design
- Global impacts to social and economic

Martin Townsend, Global Head of Sustainability and Circle Economy, **BSI Group**

10.30 **Morning Coffee**

11.00 **Driving Sustainability: New Materials and Product End of Life Solutions for Pharmaceutical Delivery Systems**
- Creating a Roadmap to enable circularity
- Design for Sustainability
- Product end of life solutions

Cedric Gysel, Manager, Healthcare Solutions Design, **Johnson & Johnson**

11.40 **An overview of sustainability and recycling on devices**
- The current landscape and industry movement towards sustainable practices
- Examples of current approaches and steps to introduce recycling to the device delivery industry
- Challenges and barriers in recycling for drug delivery devices
- An outlook to the coming years of sustainability in pharma and recycling for drug delivery devices

Sriman Banerjee, Head of Packaging Development & CDE, **Takeda**

12.20 **Networking Lunch**

13.20 **Can you recycle an insulin pen?**
- What are the current challenges in re-purposing parenteral drug delivery devices?
- Overcoming the challenge of automatically sorting discarded plastic device components
- Looking forward, scale up solutions
- Case Study: Launching a take-back pilot

Niels Otterstrøm Jensen, Associate Director - Corporate Environmental Strategy, **Novo Nordisk**

14.00 **Taking a sustainable approach for parenteral delivery device development**
- An overview of GSK's roadmap to reduce environmental impact
- Insights into sustainable approaches to class I medical devices and packaging
- Initial approaches to optimising device development practices for a reduced environmental footprint
- Challenges in sustainable device development and looking forward

Stephen Chamberlain, Director, Device Engineering, **GSK**
Conor O'Neill, Head of Packaging Development, **GSK**

14.40 **Case Study: An insight into Chiesi's UK take-back pilot**
- Understanding current challenges in inhaler disposal and sustainability
- An exploration into Chiesi's pilot scheme for efficient inhaler recycling
- Key takeaways from the pilot and assessing user feedback
- Looking to the future, how can the learnings from this pilot be applied to enhancing sustainability throughout the drug delivery device industry

Harriet Lewis, Head of Public Affairs, Market Access and Public Affairs, **Chiesi Ltd.**

15.20 **Afternoon Tea**

15.50 **A sustainable future for R&D, manufacturing, and operations in the life sciences**
- The scope of the laboratory sustainability movement and possibly entry points
- Sustainability considerations and touch-points for development operations and R&D
- The benefits of going green – cost savings, reduced environmental impact, case studies
- How to transform sustainability engagement at your organization – teams, discussions, behavior change

Christina Greever, Sustainability Program Manager, **My Green Lab**

PANEL DISCUSSION

16.30 **Strategizing sustainability in pharma**
- Assessing the industry landscape – how is environmental sustainability already being integrated in pharma development?
- How can the medical device industry adapt to help solve the growing plastic challenge?
- Keeping the patient in mind – ensuring sustainable design changes are safe and user friendly
- Thinking long-term: Approaches to become a fully circular company

Panel Moderator:
Cedric Gysel, Manager, Healthcare Solutions Design, **Johnson & Johnson**
Panelists:
Sriman Banerjee, Head of Packaging Development & CDE, **Takeda**
Martin Townsend, Global Head of Sustainability and Circle Economy, **BSI Group**
Fiona Adshead, Chair, **Sustainable Healthcare Coalition**

17.10 **Chair's Closing Remarks and Close of Focus Day**

Pre-Filled Syringes & Injectable Drug Devices

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Harro Höfliger specializes in the development of customer-oriented process and production solutions for pharmaceutical, medical device applications and consumer products. Our core expertise with innovative machine platforms is in packaging machines, customized turnkey system solutions for product assembly, processing of web materials, as well as dosing and inhalation technology. The portfolio of upscalable test machines and modules, as well as technology platforms to meet your precise requirements, comes from many years of experience in targeted research and development. Therefore, Harro Höfliger covers all phases of your project from the laboratory to high efficiency production. **www.hoefliger.com**

Nemera As a world-leading drug delivery device solutions provider, our purpose of putting patients first enables us to design and manufacture devices that maximize treatment efficacy. We are a holistic partner and help our customers succeed in the sprint to market of their combination products. From early device strategy to state-of-the-art manufacturing, we're committed to the highest quality standards. Agile and open-minded, we work with our customers as colleagues. Together, we go the extra mile to fulfill our mission. Nemera leverages decades of experience in the parenteral device segment from full development to pure contract manufacturing, through customized solutions. **www.nemera.net**

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Pre-Filled Syringes and Injectable Drug Devices

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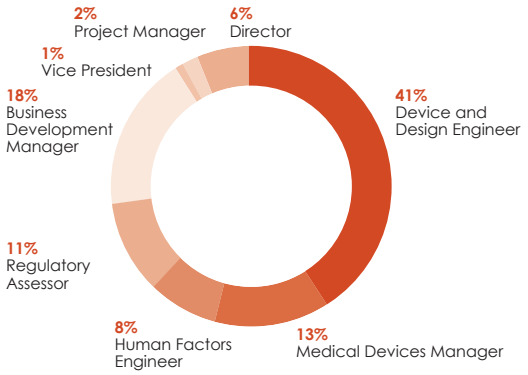

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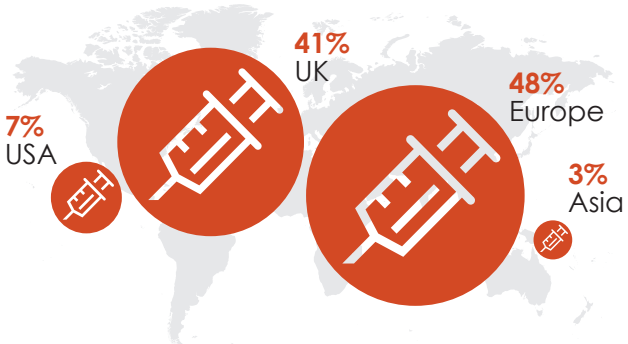

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18th - 19th October 2021,
Virtual Conference,
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Medical Wearables for Biosensors NEW FOR 2021
25th - 26th October 2021,
Virtual Conference,
All Timings Eastern Daylight Time (EDT)

Transdermal and Microneedle Delivery NEW FOR 2022
24th - 25th January 2022,
London, UK

Pre-Filled Syringes East Coast
25th - 26th April 2022,
Boston, MA, USA

Register online at www.pre-filled-syringes.com

PRE-FILLED SYRINGES AND INJECTABLE DRUG DEVICES 2022

Conference: Wednesday 12th & Thursday 13th January 2022 **Focus Day:** Tuesday 11th January 2022
Venue to be confirmed, London, UK

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☐ **Credit Card** ☐ Visa ☐ MasterCard ☐ American Express

SMi Group will apply surcharges to commercial cards
Please tick here ☐ if the card provided is not a commercial card

Card No: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐
Valid From ☐☐/☐☐ Expiry Date ☐☐/☐☐
CVV Number ☐☐☐ 3 digit security on reverse of card, 4 digits for AMEX card

Cardholder's Name:

Signature: **Date:**

I agree to be bound by SMi's Terms and Conditions of Booking.

Card Billing Address (If different from above):

VAT

VAT at 20% is charged on the attendance fees for all delegates. VAT is also charged on Document portal and literature distribution for all UK customers and for those EU Customers not supplying a registration number for their own country here.

If you have any further queries please call the Events Team on tel +44 (0) 870 9090 711 or you can email them at events@smi-online.co.uk