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SAE Media Group Proudly Presents the 5th Annual...

Injectable Drug Delivery

Enhancing parenteral drug delivery with improved device and drug synergy

8 - 9 MAY 2024

Hilton London Kensington, London, UK

Highlights for 2024

- **Evaluate** how devices can be co-developed alongside drug products to foster a collaborative approach to improve **biocompatibility** and effective **toxicological testing**
- **Expand** on risk management strategies for streamlined connected parenteral devices development
- **Learn** through focused presentations tailored to a technical device development and primary packaging audience, exploring vial material and **primary component selection** and standardisation of **primary container formats**
- **Benefit** from a **sustainable device materials** keynote, offering comprehensive perspectives on sustainable device designs, policy requirements and real world examples for correct material disposal
- **Learn** how major device developers are **streamlining product development** and CMC practices for effective compliance throughout and post-NDA/MAA approval as well as MDCG experiences on Article 117 challenges

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Chair for 2024:

Fatima Bennai-Sanfourche, Senior Director of QA & RA Compliance for Medical Devices and eHealth, **Bayer AG**

Featured 2024 speakers include:

- **Julian Dixon**, Senior Director, Biopharmaceutical Development - Human Factors, **AstraZeneca**
- **Selenge Erdenechimeg**, Combination Products Regulatory Specialist, **Novo Nordisk**
- **Ryan Noble**, Associate Director, Devices, **GSK**
- **Simon Wilson**, Device Development Lead, Devices Centre of Excellence, **Pfizer**
- **Cinzia Rotella**, Project Leader, Global Device Packaging Unity (GDPU), **Sanofi**
- **Soumen Das**, Associate Scientific Fellow, **Takeda**
- **Cedric Gysel**, Manager, Sustainable Innovation & Circular Economy Solutions at the Office of Sustainability, **Johnson & Johnson**

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Injectable Drug Delivery

Day One | Wednesday 8th May 2024

www.injectable-drug-delivery.com

Dear Colleagues,

It is with great pleasure that we invite you to the Injectable Drug Delivery conference, taking place on the 8th – 9th May 2024 in London.

SAE's 2024 Injectable Drug Delivery conference brings together a big pharma led speaker line-up providing technical updates on the relationship between drug product formulation and device primary packaging, with considerations for formulation strategies, extractables & leachables and toxicological testing of injectable devices as well as insights into life cycle management and connected parenteral devices.

This conference brings case studies from senior big pharma representatives providing an opportunity to discuss formulation considerations in depth for parenteral packaging, this is the perfect opportunity to benchmark your drug delivery programme and optimise the development of your injectable portfolio.

As the chair of this conference, we look forward to welcoming you to this must attend event in London this May.

Yours Sincerely,

Fatima Bennai-Sanfourche
Senior Director of QA & RA Compliance for Medical Devices and eHealth
Bayer AG

08.00 **Registration & Coffee**

09.00 **Chair's Opening Remarks**
Fatima Bennai-Sanfourche, Senior Director of QA & RA Compliance for Medical Devices and eHealth, **Bayer AG**

USER DRIVEN PLATFORM DEVELOPMENT FOR PARENTERAL DELIVERY

Opening Address

09.10 **What should combination product human factors engineering (CP HFE) look like in 2034?**

- Are we still on a learning curve or have we reached a knowledge plateau?
- Our business is one of platforms. How will the reuse of existing drug delivery platforms – and the creation of new ones - be reflected in CP HFE?
- In what ways will we be more truly patient-centric?

Julian Dixon, Senior Director, Biopharmaceutical Development - Human Factors, **AstraZeneca**

9.50 **Platform Drug-Delivery Devices: Regulatory Considerations**

- Definition of platform for drug-delivery - devices
- Set realistic expectation of "Device Platform" approach
- Approaches to develop these platforms

Selenge Erdenechimeg, Combination Products Regulatory Specialist, **Novo Nordisk**

10.30 **Morning break**

BIOCOMPATIBILITY AND TOXICOLOGY TESTING

11.00 **Empirical and digital tools for plunger stoppers characterization**

- The presentation describes the approach used to characterize and discriminate different plunger stoppers
- The characterization was performed by using empirical tests – standards & ad-hoc methods – and model digital twins
- The approach was used to build a guideline for stopper selection inside Sanofi

Cinzia Rotella, Project Leader, Global Device Packaging Unity (GDPU), **Sanofi**

11.40 **Evaluation of Extractables and Leachables for Pre-filled Syringes**

- Introduction: why do we need to care about E&L?
- How to perform an E & L investigation?
- Principles of a Toxicological Risk Assessment on E & L

Clemens Guenther, Senior Expert Nonclinical Safety, **Bayer AG**

12.20 **Networking lunch**

LIFECYCLE MANAGEMENT

13.20 **Change management and CMC best practices for streamlined injectable device development**

- The latest updates in European regulatory guidance and MDR
- CMC guidance in approaching the injectable combination product development and change management lifecycle
- Assessing interpretations across device and pharma landscapes, how can we control for differences across health authorities, notified bodies and industry
- Projections and opportunities for improved alignment in change management across drug-device development teams

Ryan Noble, Associate Director, Devices, **GSK**

14.00 **Session reserved for Apiject** apiject™

14.30 **Afternoon break**

15.00 **Container Closure Integrity of OXYCAPT Vial at Deep Cold Storage**

- Container Closure Integrity of OXYCAPT Vial at Deep Cold Storage
- Overview of OXYCAPT Vial
- Oxygen & Carbon Dioxide Barrier
- Break Resistance at -80 & -180°C
- CCIT at -80°C
- Comparison of CCIT among OXYCAPT, Glass and COP

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Hiroki Hasegawa, Assistant Research Manager, **Mitsubishi Gas Chemical Company, Inc.**

15.30 **MediPhorum: Presenting a working tool for Device Design Changes [form, fit, function] to Drug Delivery Devices Post-Launch**

- An interactive document to support technical engineers in parallel to regulatory teams
- MediPhorum Membership has developed a US based 'decision tree' tool which combines several guidance / frameworks and provides further user-guidance and case-studies across seven categories of design change, including key lists of considerations/evaluation for assessing if a design change is needed, and provides a library of justifications / evidence supporting why / why not

Victoria Ludlow, Program Manager, **MediPhorum**

16.10 **Chair's Closing Remarks and Close of Day One**

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www.mgc.co.jp/eng/products/abd/oxycapt.html

08.30 **Registration & Coffee**

09.00 **Chair's Opening Remarks**

Fatima Bennai-Sanfourche, Senior Director of QA & RA Compliance for Medical Devices and eHealth, **Bayer AG**

PRIMARY CONTAINER CONSIDERATIONS FOR INJECTABLE DELIVERY SYSTEMS

Opening Address

09.10 **CCI compliance challenges after (recent) regulatory updates**

- USP<1207> and EU Annex 1
- Expectations for pharmaceutical packaging development and lifecycle management
- Details available from thorough packaging development which supports compliance to regulatory requirements
- Typical examples we will shed light on selected aspects of individual packaging solutions

Christian Proff, Senior Verification Engineer, Global Device and Packaging Development, **F. Hoffman-La Roche**

09.50 **Selection of a new primary component: an interdisciplinary approach**

- Understanding the importance of primary packing from the perspective of drug development
- Optimising the process development approach can reduce lead times into manufacturing
- Standardisation of primary container formats
- Engagement of manufacturing and device development functions

Soumen Das, Associate Scientific Fellow, **Takeda**

10.30 **Morning break**

11.00 **Notified Body Opinion Considerations for Post-Authorization Changes**

- What constitutes a non-substantial change?
- What is the threshold for requiring an updated Notified Body Opinion?
- What are the main challenges?

Berna Kosekaya, Regulatory Professional, RA CMC & Devices / RA Device, **Novo Nordisk**

11.40 **Primary Packaging Supplier Selection and Portfolio Management**

- Selection panel, fit for purpose
- Deep dive into some important materials properties
- Packaging portfolio management

Marc Egen, **Head of Primary Packaging & Process Development, Boehringer Ingelheim**

12.20 **Networking lunch**

STRATEGIES FOR EFFECTIVE CONNECTED INJECTABLE DEVICE DEVELOPMENT

13.20 **Risk Management Process for Connected Drug-Devices Combination product**

- Introduction: The future of patient care
- Impact of the EU MDR on connected drug-device risk management process
- Cybersecurity
- Usability engineering/Human Factors (HF)
- Benefit-risk assessment of connected drug-device combination product

Fatima Bennai-Sanfourche, Senior Director of QA & RA Compliance for Medical Devices and eHealth, **Bayer AG**

14.00 **Ensuring Patient Safety through Interoperability and Cybersecurity in Connected Drug Delivery Solutions**

- Interoperable devices and changing landscapes
- Cybersecurity risks and threats
- Regulatory requirements for cybersecurity in medical devices

George Moore-Arthur, Senior Global Regulatory Professional, RA Digital Health & IVD, **Novo Nordisk**

14.40 **Afternoon break**

15.10 **Strategies to manage partner relations for collaborative, user-centric development teams**

- Challenging the old school supplier-customer relationship: why complex projects require dynamic collaboration
- Managing effective relationship building with suppliers as well as supplier sub-contractors to advance innovation
- Working frameworks for improved synergy to ensure streamlined development of optimal user-centric devices
- Looking forward: Toolkit for effective external stakeholder management for parenteral devices of the future

Simon Wilson, Device Development Lead, Devices Centre of Excellence, **Pfizer**

CLOSING KEYNOTE: DELVING INTO THE FUTURE OF SUSTAINABLE DEVICE DEVELOPMENT

15.50 **Maximising pharmaceutical development of novel injectable delivzry technologies through sustainable approaches**

- Designing for the future with sustainable device designs and partial reusability
- Where does the industry need to collaborate on policy to enable circular supply chains
- Implementing end of life procedures for device disassembly and correct material disposal
- Looking to the future, what does the industry need to focus on for further sustainable approaches to device development

Cedric Gysel, Manager, Sustainable Innovation & Circular Economy Solutions at the Office of Sustainability, **Johnson & Johnson**

16.30 **Chair's Closing Remarks and Close of Day Two**

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INJECTABLE DRUG DELIVERY 2024

Location: Hilton London Kensington, London, UK Conference: 8-9 May 2024

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