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SAE MEDIA GROUP

SAE Media Group Proudly Presents the 7th Annual...

INJECTABLE DRUG DELIVERY CONFERENCE 2025

24 - 25 JUNE 2025

Navigating technical parenteral delivery challenges for advanced drug products

Hilton London Kensington, London, UK

Highlights FOR 2025:

- **ENGAGE** in discussions on the latest innovations within complex formulations including long acting and large volume injectables with leaders from **Novartis, Pfizer, and MedinCell.**
- **GAIN** insights from senior industry experts on combination product design considerations including primary packaging material choices and risk management strategies.
- **UNCOVER** the robust E&L and toxicology testing strategies being employed to minimize unwanted drug-device interactions through detailed case study presentations from **CSL Behring, Octapharma and Biophorum.**
- **DISCUSS** the future of sustainable material selection and device design with industry leaders from **GSK, UCB Pharma, Roche** and more, through an interactive panel discussion session.

Chairs for 2025:

Rachel Koppelman,
Head of Device Engineering,
Sandoz

Ryan Noble,
Associate Director Regulatory Affairs - CMC Devices,
GSK

Featured 2025 Speakers Include:

- **Clovis Pichon,** Head of Device Program Leadership, **UCB Pharma**
- **Joel Richard,** Chief Commercial Officer, **Enterome**
- **Nicola Bettini,** Senior Process Engineer - PTT Global dMSAT, **Roche**
- **Conor O'Neill,** Head of Packaging Development and Design, **GSK**
- **Simon J. Dell,** Senior Principal Scientist – Device Development Lead, Project Manager, **Pfizer R&D UK**
- **Klaus Boje,** Senior Scientist Primary Packaging Development, **Boehringer Ingelheim**
- **Alicja Sobantka,** Head of Corporate Material Qualification, **Octapharma**
- **Stephanie Greco,** Section Head in Formulation and Process **Development, Sanofi**
- **Chantal Pfaffen,** Scientist, Validation, **CSL Behring**
- **Fatima Bennai-Sanfourche,** Senior Director of QA & RA Compliance for Medical Devices and eHealth, **Bayer AG**
- **Sylvestre Grizot,** Research & Innovation Leader, **MedinCell**

www.injectable-drug-delivery.com

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Letter From the Chair's

Dear Colleagues,

It is with great pleasure that we invite you to the Injectable Drug Delivery conference, taking place on the 24 – 25th June 2025 in London.

The 7th annual conference brings together leading big pharma experts within the Injectable Drug Delivery space to discuss the technical challenges facing the sector. Detailed case study presentations will reveal the latest innovations within formulation strategies, primary packaging considerations, extractables & leachables and toxicological testing of injectable devices. While open panel discussions will uncover insights into sustainability considerations for material selection and regulatory updates specific to combination products.

This conference brings case studies from senior big pharma representatives alongside interactive and engaging panel discussions featuring mid-size pharma and biotech leaders. This is the perfect opportunity to benchmark your drug delivery programme and optimise the development of your injectable portfolio.

As chairs of this conference, we look forward to welcoming you to this must attend event in London this June.

Yours Sincerely,

Rachel Koppelman, Head of Device Engineering, **Sandoz**

Ryan Noble, Associate Director Regulatory Affairs - CMC Devices, **GSK**

08.00 **Registration & Coffee**

09.00 **Chair's Opening Remarks**
Rachel Koppelman, Head of Device Engineering, **Sandoz**

OPTIMIZING FORMULATION FOR ADVANCED DELIVERY

OPENING ADDRESS

09.10 **Novel immunomodulatory peptide formulations for improved therapeutic outcomes in immuno-oncology**
- Peptide-based Vaccines Strategies in Immuno-Oncology
- What Key Features of Liquid Formulations improve the Delivery and Efficacy of Peptide-based Vaccines
- Advantages and Challenges of Using Multiple Peptides: Progress in this area
- Drug Development Challenges up to the Clinic

Joel Richard, Chief Commercial Officer, **Enterome**

09.50 **Implications of fast, large volume delivery**
- Impact of large volume formulations with fast delivery rates on drug efficacy and safety
- 3D imaging methods for testing efficacy and risk in novel formulations
- Innovations within patient-device interactions

Simon J. Dell, Senior Principal Scientist – Device Development Lead, Project Manager, **Pfizer R&D UK**

10.30 **Morning Break**

11.00 **Enabling controlled and targeted delivery of long acting injectables**
- Medincell's BEPO technology
- Improving drug efficacy through use of long acting injectables
- Case studies on overcoming challenges within long-acting injectable formulations

Sylvestre Grizot, Research Director, **MedinCell**

PRIMARY PACKAGING: COMPATIBILTY AND CCI

11.40 **Compatibility studies for a pre-filled syringe: case studies from Boehringer Ingelheim**
- Comparison of commercially available PFS qualities
- Selection criteria and compatibility considerations
- Case study: How to deal with challenges

Klaus Boje, Senior Scientist Primary Packaging Development, **Boehringer Ingelheim**

12.20 **Networking Lunch**

13.20 **Packaging challenges in extreme cold temperatures - from secondary packing to container closure integrity**
- Comparison standard to cryo packaging conditions
- Labelling requirements - secondary packaging
- Handling
- Primary packaging - container closure integrity assurance

Christian Proff, Senior Verification Engineer, **Roche**
Elodie Hablot, Senior Packaging Engineer, **Roche**

COMBINATION PRODUCT DESIGN CONSIDERATIONS

14.00 **Session reserved for GSK**
Tony Haythornthwaite, Device Engineering Associate Director, **GSK**
Jehanzeb Ahmed, Project Leader, Device Development, **GSK**

14.40 **User-centric device design incorporating risk management strategies**
- Ensuring appropriate balance of risk vs benefit for medical devices in development
- Understanding the importance of biocompatibility, E&L and patient safety during device design
- Impacts of the EU MDR on risk management processes for combination products

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

15.20 **Afternoon Break**

15.50 **From Fill to Finish: Optimizing Filling Parameters to Improve Lyophilized Cake Appearance and Minimize Rejects**
- Description of visual defects related to splashing and dripping effects during filling
- How to avoid these undesired filling events by playing on critical parameters: filling flow-rate, height of the filling needle, suck-back parameter

Stephanie Greco, Section Head in Formulation and Process Development, **Sanofi**

16.30 **Panel discussion: Combination product design - challenges associated with drug-device co-development**
- Discussing the latest industry findings regarding drug-device co-development challenges
- Mid-size pharma and biotech perspectives on the biggest challenges they face during combination product design and development
- What solutions exist to overcome formulation challenges relating to novel and complex parenterally delivered modalities including biologics, peptides and cell and gene therapies

Moderator:
Rachel Koppelman, Head of Device Engineering, **Sandoz**
Panellists:
Joel Richard, Chief Commercial Officer, **Enterome**
Alicja Sobantka, Head of Corporate Material Qualification, **Octapharma**
Soroosh Bagheriasl, Phorum Director - Drug Delivery, **BioPhorum**

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

08.30 **Registration & Coffee**

09.00 **Chair's Opening Remarks**
Ryan Noble, Associate Director Regulatory Affairs - CMC Devices, **GSK**

OPENING ADDRESS

09.10 **The role of collaboration in delivering bespoke medical devices for novel drug products**
- Sandoz's approach to optimizing off-the-shelf medical devices through collaboration with medical device developers
- Strategies for design and optimization of medical devices for novel drug products to ensure efficacy
- Challenges and learnings: case studies on collaborative design of bespoke medical devices for novel drug products

Rachel Koppelman, Head of Device Engineering, **Sandoz**

BIOCOMPATIBILITY AND TOXICOLOGY TESTING

09.50 **Toxicological and product quality concerns during E&L testing of Injectable Drug Devices**
- Risks assessments and toxicological testing strategies for injectable drug products
- E&L safety assessments for novel immunotherapeutic preparations
- Dealing with unexpected occurrences during manufacturing of combination products in the context of patient risk
- Preparing for the upcoming ICH Q3E quality guidelines, due to come into effect in 2026

Kai Zwingenberger, formerly Medical Director Global Quality, **CSL Behring**
Chantal Pfaffen, Scientist, Validation, **CSL Behring**

10.30 **Morning Break**

11.00 **Technical challenges and considerations for E&L testing of advanced modality injectable drug products**
- Developing analytical tools for protein-reactive extractables and leachable risk assessments
- Challenges relating to emerging technologies within E&L
- Technical advancements within the E&L field

Alicja Sobantka, Head of Corporate Material Qualification, **Octapharma**

11.40 **Biocompatibility Challenges and considerations for Drug Delivery Devices**
- Biological Safety Risk assessments
- Leveraging supplier data
- ISO vs USP what is the expectation
- Component/device classification and categorization for Biological safety risk assessment
- Internal training to reduce the burden of testing

Senior Biophorum representative

12.20 **Networking Lunch**

THE FUTURE OF SUSTAINABLE DEVICE DEVELOPMENT

13.20 **Implementing device sustainability frameworks in line with regulatory variation expectations**
- Assessing the impacts of updated EU variation and other regulations on injectable device sustainability initiatives
- Considering different aspects of sustainability with respect to both existing and new injectable products
- Opportunities for improved alignment in change management across drug-device development teams

Ryan Noble, Associate Director Regulatory Affairs - CMC Devices, **GSK**

14.00 **Industrialization of Combination Products; a final assembly perspective**
- General considerations
- Important device features aimed to Design for Manufacturing/ Design for Assembly
- Supply chain
- Sustainability

Nicola Bettini, Senior Process Engineer - PTT Global dMSAT, **Roche**

14.40 **Adoption of sustainability practices within subcutaneous drug delivery: Industry Insights**
- Overview of an industry benchmarking survey to understand industry sustainability trends
- Insights into the current state of adoption and prioritization of sustainability practices within the industry
- Highlighting key barriers to implementation and opportunity areas for impactful change
- Benchmarking insights and opportunities for sustainability best practices and collaboration

Conor O'Neill, Head of Packaging Development and Design, **GSK**

15.20 **Afternoon Break**

15.50 **Towards a more sustainable future – sustainability initiatives within combination product design and development**
- Discussing recent sustainability initiatives within combination product design
- Major blockers to sustainability and circular economy within the injectable drug delivery sector
- Addressing the reasons for industry hesitation to use of recycled materials within drug delivery devices
- Novel and alternative methods to improve sustainability of combination products

Moderator:
Marion Briggs, Circular Economy Expert, and Member, **Alliance to Zero**
Panellists:
Clovis Pichon, Head of Device Program Leadership, **UCB Pharma**
Conor O'Neill, Head of Packaging Development and Design, **GSK**
Ryan Noble, Associate Director Regulatory Affairs - CMC Devices, **GSK**

REGULATORY HOT TAKES

16.30 **A notified body perspective on biologics-based drug-device combinations**
- Notified body opinion requirements relating to drug-device combination products in a changing environment
- Advice and best practices for development of biologics-based drugs and drug-device combinations
- Current regulatory and lifecycle management challenges

Estefania Dos Anjos, Senior Product Specialist, **TUV SUD***

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

* Subject to final confirmation

Injectable Drug Delivery

Conference: 24 - 25 June 2025
Hilton London Kensington, London, UK

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