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SAE Media Group Proudly Present the 19th Annual...

PFS & INJECTABLE DRUG DEVICES

EUROPE

*Developing Combination Products and
Drug Delivery Devices of the Future*

12 - 14 January 2027 | Marriott Grosvenor Square, London, UK

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A Letter From Our Advisory Board

Dear Colleagues

As members of the advisory board, we're delighted to welcome you to SAE's 19th Annual PFS & Injectable Drug Devices Europe Conference, taking place from 12-14 January, 2027.

This year's event will once again bring together leading experts from across the injectable drug delivery and combination product landscape. The conference opens with a pre-conference focus day dedicated to the latest advances in device design, followed by two days of insightful plenary sessions and focused afternoon streams.

The field of injectable drug delivery continues to evolve rapidly, driven by the demands of an increasingly diverse and complex therapeutic pipeline. Emerging biologics,

high-viscosity formulations, and long-acting therapies are reshaping expectations for device performance, materials selection, and primary container systems.

These developments are prompting innovation across the board, requiring device solutions that can accommodate new formulation profiles while maintaining safety, usability, and reliability.

At the same time, there is growing emphasis on patient-centric design, large volume delivery, and the integration of sustainability throughout the device lifecycle - from manufacturing and materials to end-of-life recycling. These shifts demand a more holistic and collaborative development approach, one that balances patient

needs, technical feasibility, and the increasingly complex regulatory landscape. Early alignment between pharmaceutical and device teams is now essential to ensure compliance, streamline development, and accelerate time to market.

This year's agenda will explore these themes through real-world case studies, expert insights, and forward-looking discussions that address both current challenges and future opportunities.

We look forward to the insights and collaboration this must attend event will encourage next January.

Yours Sincerely,

SAE Media Group PFS & Injectable Drug Devices Europe Advisory Board



Khaudeja Bano,
Vice President - Global
Head of Device Quality,
Roche-Genentech



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Charles Potter,
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BRINGING MAJOR PLAYERS ACROSS INDUSTRY TOGETHER

Past Attendees Include...



FEATURED SPEAKERS INCLUDE:



Jehanzeb Ahmed,
Project Leader,
Device Engineering,
GSK



Andrew Chapman,
Senior Director,
AstraZeneca



Joanna Zhizhong Chen,
Senior Regulatory
Professional,
Novo Nordisk



Louise Coldrick,
Regulatory Affairs
Director,
Novartis



Shzeena Dad,
Associate Director,
Regulatory Affairs Device,
Ascendis Pharma A/S



Fletcher Dix,
Principal Process
Characterization &
Technology Engineer,
Regeneron



Marc Egen,
Head of Primary Packaging
& Process Development,
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Andreas Emmendoerffer,
Principal Regulatory
Program Director,
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Claire Everitt,
Engineering Team Lead,
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Claus Geiger,
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Polpharma



Jussi Haikarainen,
Director, Device
Development,
AbbVie



Mikkel Hansen,
Director, Circular Economy
– Corporate Environmental
Strategy,
Novo Nordisk



David Harrison,
Business Lead, Drug
Products and Devices,
UCB



Tony Haythornthwaite,
Associate Director,
Device Engineering,
GSK



Daniela Henle,
Scientist, Primary Packaging
Development,
Boehringer Ingelheim



Christopher Hill,
Director of Ecodesign,
Life Cycle Assessment,
GSK



Gareth Hilton,
Associate Director,
Device Quality,
AstraZeneca



Mario Hirth,
Director Global
Verification Testing,
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Steve Hoare,
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Director Regulatory
Affairs RA Device and
Combination Products,
Ascendis Pharma



Theresa Jeary,
Global Head,
Medicinal & Biologics Team,
BSI



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Torsten Kneuss,
Lead Pharma Devices &
Maastricht Quality,
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Rachel Koppelman,
Head of Device
Engineering,
Sandoz



Michael Kuehler,
Senior MD Expert,
Regulatory Affairs,
Bayer



Joanita Lamien,
Senior Human
Factors Engineer,
Regeneron



**Francisco Lupiáñez-
Villanueva,**
Technical Coordinator,
BEAMER Project



George Moore-Arthur,
Senior Global Regulatory
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Thomas Wejs Moller,
Senior RA Policy Director,
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Louise Place,
Head of Device Regulatory,
Global CMC Regulatory
Affairs,
GSK



Charles Potter,
Project and Technical
Leader,
Chiesi



Dr. Christian Proff,
Senior Verification Engineer,
Roche



Fatima Sanfourche,
Global Senior Director for
QA & RA Compliance,
Medical Devices, Combination
Products & eHealth,
Bayer



Theresa Scheuble,
R&D Director,
Drug Delivery Systems,
Johnson & Johnson



Chris Smith,
Director, Combination
Products & Devices,
Teva Pharmaceuticals



Rhian Standley,
Sustainability &
Ecodesign Steward,
GSK



Slobodan Stefanov,
Programme Director,
Cagrisema Device
Programme,
Novo Nordisk



Richard Wedge,
Associate Research Fellow,
Pfizer



Lucy Williams,
Clinical Statistician,
Pfizer



Simon Wilson,
Device Development Lead,
Pfizer



Dr Ying Wang,
Head of Device
Development Science,
Pfizer



Senior Representative,
BioPhorum



Senior Representative,
BioPhorum

WHAT TO EXPECT:

Bring together expertise from individuals across the combination product and injectable drug delivery field...

250+
ATTENDEES

50+
SPEAKERS

50+
BIG PHARMA
AND BIOTECH
COMPANIES IN
ATTENDANCE

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Focus Day: Advances in PFS Design for Enhanced Delivery

The 2027 conference will feature a dedicated focus day which will explore how innovation is shaping the future of drug delivery design. Throughout the day, speakers will examine novel approaches moving beyond standard industry practices, including the use of emerging technologies and new delivery concepts to optimise device performance and accelerate development.

Dedicated Afternoon Topic Streams:**Day One Stream A: Device Innovations for Large-Volume and Novel Drug Product Delivery**

Explore strategies and technologies for delivering large-volume and novel drug formulations, focusing on the challenges of enabling effective, patient-centered delivery solutions and advancing device design to meet evolving therapeutic needs.

Day One Stream B: Sustainability in Device Development

Discover practical strategies, innovations, and real-world case studies driving sustainable transformation across the injectable device lifecycle.

Day Two Stream A: Primary Drug Container Development and Biocompatibility

Explore approaches to developing robust primary container strategies that support safe and effective delivery, and needs of emerging drug modalities.

Day Two Stream B: Patient Centric Device Development

Explore how human factors engineering and patient insights are driving the development of the next generation of drug delivery devices.

**PFS & INJECTABLE
DRUG DEVICES**
NEWSLETTER

Your trusted monthly source
for news, updates and insights
in injectable drug delivery

ADVANCES IN PFS DESIGN FOR ENHANCED DELIVERY | FOCUS DAY | Tuesday 12 January 2027

08.00	Registration & Coffee
08.50	Chair's Opening Remarks Charles Potter, Project and Technical Leader, Chiesi
OPENING KEYNOTES	
09.00	Developing Successful Combination Products: Integrating Science, Engineering and Human Factors from Concept to Commercialisation  <ul style="list-style-type: none"> Aligning drug, device and human factors teams early to define product requirements, development strategy and regulatory expectations Understanding how formulation, dose volume, viscosity and delivery requirements influence device design, testing and validation throughout development Applying a holistic combination product approach, incorporating scientific justification, measurement strategies, manufacturing considerations and ISO 11608 requirements to support successful product launch and lifecycle management Dr Ying Wang , Head of Device Development Science, Pfizer
09.30	Session Reserved for Sponsor
REGULATORY UPDATES	
10.00	Why Regulatory Strategies Fail—and How to Win with Combination Product <ul style="list-style-type: none"> Common strategy pitfalls Align clinical, device, and CMC Winning globally: FDA, EU, and beyond Javad Jabbari , Director Regulatory Affairs RA Device and Combination Products, Ascendis Pharma
10.30	Morning Coffee
11.00	Article 117: Key Challenges, Updates and Lessons Learned <ul style="list-style-type: none"> Understanding evolving Notified Body expectations and recent regulatory guidance for Article 117 submissions Addressing common challenges around data readiness, technical documentation, and GSPR compliance Sharing practical strategies to streamline submissions, reduce delays, and improve approval predictability Shzeena Dad , Associate Director, Regulatory Affairs Device, Ascendis Pharma A/S Theresa Jeary , Global Head, Medicinal & Biologics Team, BSI
11.30	Session Reserved for Suttons Creek 

FUTURE PERSPECTIVES ON DRUG DELIVERY

12.00	Panel Discussion: Future of Drug Delivery: What's Next in Drug Delivery and Device Design?  <ul style="list-style-type: none"> Exploring next-generation delivery technologies beyond traditional PFS Balancing innovation with cost, scalability, and real-world patient usability Understanding how digital and material advancements will shape the future of device design Moderator: Javad Jabbari , Director Regulatory Affairs RA Device and Combination Products, Ascendis Pharma Panellist: Claus Geiger , Independent Consultant, Formerly Sanofi Fletcher Dix , Principal Process Characterization & Technology Engineer, Regeneron David Harrison , Business Lead, Drug Products and Devices, UCB
12.45	Session Reserved for Sponsor
13.15	Networking Lunch
14.15	Improving Health Outcomes Through Patient-Centric Design: Expanding Beyond the Physiological – The BEAMER Approach <ul style="list-style-type: none"> Expanding the focus from purely physiological needs to a broader understanding of patient behaviours, motivations, and real-world challenges to improve adherence and health system efficiency Introducing the BEAMER / B-COMPASS model and how behavioural insights can be applied to design more effective, patient-centred solutions Demonstrating how shifting to human-centric design approaches can drive improved treatment adherence, better patient outcomes, and overall healthcare value Claire Everitt , Engineering Team Lead, Pfizer
14.45	Panel Discussion: Advancing Quality by Design and Design Controls in Device Development  <ul style="list-style-type: none"> How are organisations strengthening the link between QbD principles and design control processes? Best practices for improving collaboration, risk management, and development efficiency across teams Building a stronger foundation for innovation, regulatory readiness, and product quality in combination product development Panellists: Tony Haythornthwaite , Associate Director Device Engineering, GSK Jehanzeb Ahmed , Project Leader, Device Engineering, GSK
15.15	Afternoon Tea

15.45 Afternoon Roundtables

Roundtable 1: Integration of Quality by Design (QbD) and design controls in device development

- Current State of the Industry: The BioPharma sector is advancing in its use of QbD and design controls, but maturity levels vary widely - highlighting gaps in how CQAs, control strategies, and design inputs are interconnected across organizations
 - Why Integration Is Important: Stronger integration between QbD principles and design control is essential to reduce development friction, enable clearer alignment across cross-functional teams, and create a more consistent foundation for device-drug combination product quality
 - Benefits of Integration: A unified framework and shared training can streamline development, enhance risk management, and improve regulatory readiness - ultimately accelerating innovation while supporting sustainability and robust product performance
- Tony Haythornthwaite**
- , Associate Director Device Engineering, GSK
-
- Jehanzeb Ahmed**
- , Project Leader, Device Engineering, GSK

Roundtable 2: Platform-Based Drug Delivery Development – Opportunities, Challenges and Future Directions

- Sharing experiences and lessons learned from implementing platform-based device development strategies
 - Discussing how platform approaches can reduce development timelines, costs, and regulatory burden
 - Exploring the balance between standardisation, flexibility, and evolving patient and product requirements
- Senior Representative, BioPhorum**

Roundtable 3: Building Effective Collaboration Across Combination Product Development

- Integrating pharmaceutical sciences, device engineering sciences, manufacturing, regulatory and user perspectives to support informed cross-functional decision-making
 - Building effective collaboration models that translate patient and product requirements into successful combination product development and commercialisation strategies
 - Identifying opportunities to strengthen collaboration and decision-making as combination products become increasingly complex, data-driven and globally regulated
- Dr Ying Wang**
- , Head of Device Development Science, Pfizer

Roundtable 4: Sustainability and Lifecycle Responsibility

- Turning sustainability commitments into practical design and manufacturing decisions
 - Balancing regulatory requirements, cost pressures, and environmental targets
 - Aligning lifecycle thinking across materials, supply chain, and end-of-life solutions
- Rhian Standley**
- , Sustainability & Ecodesign Steward, GSK

17.15 Chair's Closing Remarks and Close of Focus Day
 Charles Potter, Project and Technical Leader, Chiesi

MAIN CONFERENCE | DAY 1 - MORNING PLENARY | Wednesday 13 January 2027

08.00 Registration & Networking

08.50 Chair's Opening Remarks

Fatima Sanfourche, Global Senior Director for QA & RA Compliance, Medical Devices, Combination Products & eHealth, **Bayer**

OPENING KEYNOTES

09.00 Building the Next Generation of Combination Products Through Platform Innovation



- Applying platform-based thinking to streamline device development across multiple therapies
- Enhancing collaboration between drug, device, and manufacturing teams throughout the product lifecycle

Jussi Haikarainen, Director, Device Development, **AbbVie**
Mario Hirth, Director Global Verification Testing, **AbbVie**

09.30 Session Reserved for MGS



10.00 Notified Body Opinions for a Legacy Products, How Hard Can They Be?

- Notified Body Opinions are now routine for new combination products, but are still relatively rare for legacy approved products.
- What are the potential challenges and pitfalls associated with seeking a NBOp for a legacy approved product?
- What best practices that may be applied to aid in a successful NBO process for a legacy product?

Gareth Hilton, Associate Director, Device Quality, **AstraZeneca**

10.30 Morning Coffee

11.00 Risk Management Harmonisation: Lessons Learned and Pathways to Greater Consistency

- Examining study findings on common hazards, harms, and variations in risk scoring across the industry
- Driving more consistent submissions, predictable regulatory outcomes, and streamlined product development pathways

Richard Wedge, Associate Research Fellow, **Pfizer**

11.30 Session Reserved for SHL Medical



12.00 Panel Discussion: Embedding Sustainability into Device Development



- Integrating sustainability into design, regulatory strategy, and human factors, what's changing in practice
- Balancing environmental goals with usability, patient outcomes, and commercial viability
- Moving beyond siloed "green" initiatives to fully embedded, cross-functional development approaches

Moderator:

Cedric Gysel, Chief Changemaker, **Be Circular**

Panellists:

Thomas Wejs Moller, Senior RA Policy Director, **Novo Nordisk**

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

Charles Potter, Project and Technical Leader, **Chiesi**

Steve Hoare, Deputy Director, Partnerships, **MHRA**

12.45 Networking Lunch



MAIN CONFERENCE | DAY ONE | AFTERNOON STREAMS | Wednesday 13 January 2027

Stream A: Large Volume and Novel Drug Product Delivery

STREAM SPONSORED BY



14.00	Chair's Opening Remarks Mario Hirth, Director Global Verification Testing, AbbVie
14.10	Human Factors and Usability Challenges in Large-Volume Injection Devices <ul style="list-style-type: none"> Addressing the unique usability challenges associated with high-volume drug delivery Applying human factors testing to optimise device design, instructions for use (IFUs), and labelling Translating user insights into practical design solutions to support safe and effective product adoption Mark Kamensek , Associate Director, Human Factors & User Experience, Takeda
14.40	Session Reserved for Nemera
15.10	Advancements in Drug Delivery including new modalities for treating Bladder Cancer <ul style="list-style-type: none"> Explore Evolution of drug delivery, Review current advancements in traditional drug delivery routes Deeper dive into Targeted delivery with examples Detailed review of new modality for treating Bladder Cancer Theresa Scheuble , R&D Director, Drug Delivery Systems, Johnson & Johnson
15.40	Afternoon Tea
16.10	Device Development Strategy in Early Drug Development <ul style="list-style-type: none"> Device strategy must start early: Decisions on formulation, presentation, and delivery platform made before or during Phase 1 can significantly constrain future device options and commercialization pathways. Define a device selection point before Phase 1: Early alignment across formulation, device, clinical, and manufacturing teams reduces the risk of costly late-stage changes, additional studies, or reformulation. Integrated planning reduces risk: Proactively evaluating device constraints and using parallel cross-functional development improves predictability, accelerates development, and increases the likelihood of commercial success. Slobodan Stefanov , Programme Director, Cagrisema Device Programme, Novo Nordisk
16.40	Session Reserved for Credence MedSystems
17.10	Driving Novel Device Development Through Platform Innovation <ul style="list-style-type: none"> Applying platform approaches across pre-filled syringes, autoinjectors, and pen injectors to accelerate innovation Balancing common device architectures with the need for differentiated patient experiences Lessons learned from developing next-generation delivery systems across multiple product platforms Navigating updates to ICH guidance for drug-device combination product content and understanding the impact on future regulatory submissions Andreas Emmendoerfer , Principal Regulatory Program Director, Roche
17.40	Chair's Closing Remarks and Close of Day One Mario Hirth, Director Global Verification Testing, AbbVie

Stream B: Sustainability in Device Development

STREAM SPONSORED BY



14.00	Chair's Opening Remarks Steve Hoare, Deputy Director, Partnerships, MHRA
14.10	Driving Sustainability in Drug Delivery Devices: From Ambition to Action <ul style="list-style-type: none"> Embedding circular economy principles into the development, manufacture, and end-of-life management of drug delivery devices Balancing sustainability goals with patient needs, regulatory requirements, and product performance Exploring opportunities for collaboration across the value chain to reduce environmental impact and accelerate progress Mikkel Hansen , Director - Circular Economy - Corporate Environmental Strategy, Novo Nordisk
14.40	Session Reserved for Haselmeier
15.10	Reducing Carbon Impact Across the Patient Care Pathway: Advancing Sustainable Drug Delivery Development <ul style="list-style-type: none"> Measuring and reducing product carbon footprints through lifecycle assessment (LCA) and data-driven decision making Driving sustainability through material innovation, circularity initiatives, and responsible device design Improving patient outcomes and reducing healthcare burden through at-home administration and next-generation drug delivery devices Christopher Hill , Director of Ecodesign, Life Cycle Assessment, GSK
15.40	Afternoon Tea
16.10	Driving Sustainable Packaging Compliance: Preparing for the EU Packaging and Packaging Waste Regulation (PPWR) <ul style="list-style-type: none"> Understanding the impact of PPWR on pharmaceutical packaging design, materials selection, and lifecycle management Leveraging industry collaboration, baseline waste data, and shared toolkits to support effective compliance strategies Balancing packaging reduction, product protection, and patient needs while meeting evolving sustainability requirements across Europe Senior Representative , BioPhorum
16.40	Session Reserved for DCA Design
17.10	EFPIA Perspective on Article 117: Lessons Learned and the Road Ahead <ul style="list-style-type: none"> Reviewing key challenges and successes from five years of Article 117 implementation Exploring industry expectations for Notified Body opinions, timelines, and regulatory alignment Identifying opportunities to improve predictability, collaboration, and lifecycle management for integral drug-device combination products including emerging risk-based approaches Michael Kuehler , Senior MD Expert, regulatory affairs, Bayer
17.40	Chair's Closing Remarks and Close of Day One Steve Hoare, Deputy Director, Partnerships, MHRA

MAIN CONFERENCE | DAY 2 - MORNING PLENARY | Thursday 14 January 2027

08.00 Registration & Networking

08.50 Chair's Opening Remarks

Andrew Chapman, Senior Director, **AstraZeneca**

OPENING KEYNOTES

09.00 Bridging the Gap: Ensuring Lab-Based Device Verification Reflects Real-World Use in 2027

- Identifying where traditional lab-based and automated testing still fail to capture real-world user variability, edge cases, and human-driven failure modes
- Integrating human factors, risk management, and regulatory expectations into next-generation verification strategies to strengthen evidence packages
- Leveraging advanced simulation, digital tools, and user-informed test design to generate robust, regulator-ready data demonstrating real-world performance

Chris Smith, Director, Combination Products & Devices, **Teva Pharmaceuticals**

09.30 Session Reserved for Gold Sponsor

10.00 Advancing Innovation in Injectable Device Development

- Exploring key considerations for successful device development across the product lifecycle
- Balancing patient needs, usability, and technical requirements in device design
- Current and future priorities for Sandoz

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

10.30 Morning Coffee

AI IN DEVICE DEVELOPMENT

11.00 Applying AI in Medical Device Development – Opportunities, Regulations, and Practical Lessons

- Where AI Creates Value in Design and Development
- From Chatbots to Intelligent Systems: AI Deployment Models
- Regulatory and Quality Expectations for AI in Regulated Environments
- Lessons Learned from Early AI Adoption
- The Future of AI in Device Development: Opportunities and Challenges

Torsten Kneuss, Lead Pharma Devices & Maastricht Quality, **Bayer**

11.30 Session Reserved for Gold Sponsor

12.00 Panel Discussion: AI in PFS & Injectable Drug Devices: From Concept to Patient Impact

- Where AI is already making a difference in device design, manufacturing, and quality
- Practical use cases for AI across the PFS lifecycle, and where the limits still are
- Keeping innovation patient centric: improving usability, safety, and outcomes while adopting AI

Moderator:

Andrew Chapman, Senior Director, **AstraZeneca**

Panellists:

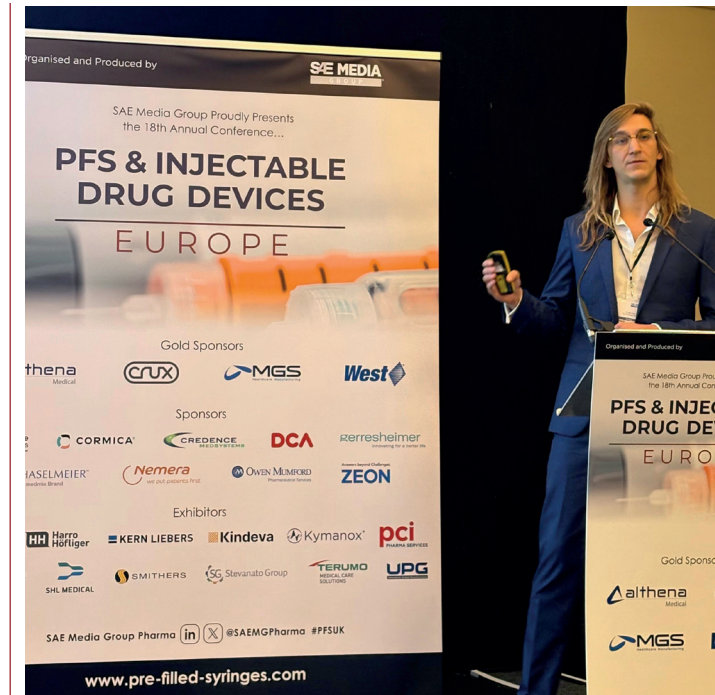
Fletcher Dix, Principal Process Characterization & Technology Engineer, **Regeneron**

Mr Torsten Kneuss, Lead Pharma Devices & Maastricht Quality, **Bayer**

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

Louise Coldrick, Regulatory Affairs Director, **Novartis**

12.45 Networking Lunch



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Contact **Alessandra De Maria**,
Marketing Manager
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MAIN CONFERENCE | DAY TWO | AFTERNOON STREAMS | Thursday 14 January 2027

Stream A: Primary Drug Container Development and Biocompatibility

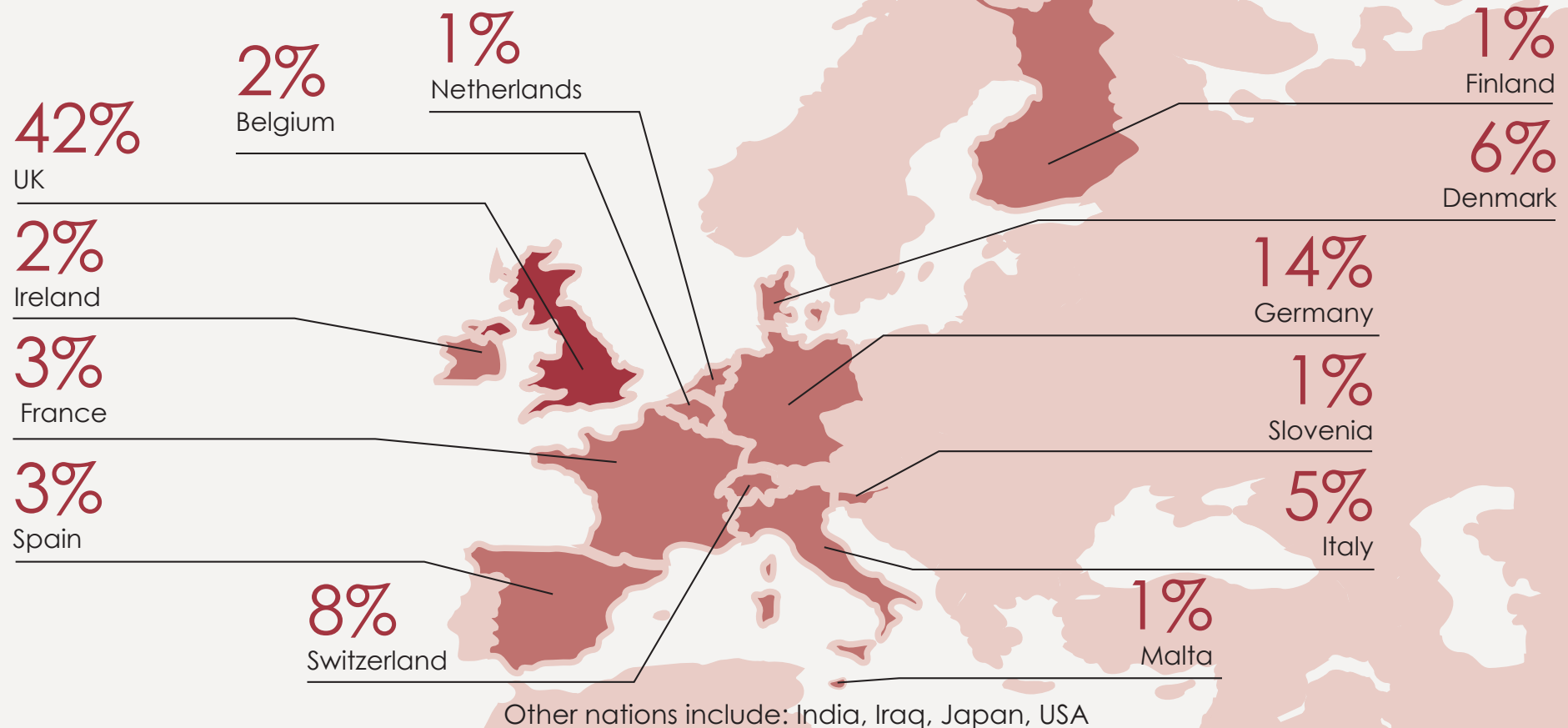
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Innovating for a better life

14.00	Chair's Opening Remarks Marc Egen , Head of Primary Packaging & Process Development, Boehringer Ingelheim
14.10	Combined Experimental and Computational Approach to Analyze Strain on Vials During Freezing <ul style="list-style-type: none"> Frozen drug product storage can induce mechanical strain on glass vials, potentially causing vial breakage A combined methodological approach – experimental strain gauge measurements and finite element analysis, was developed to systematically characterize strain formation during freezing Key influencing factors (formulation composition, vial type, process parameters) were identified and effective strain-mitigating strategies derived Daniela Henle , Scientist, Primary Packaging Development, Boehringer Ingelheim GmbH & Co. KG
14.40	Session Reserved for Gerresheimer 
15.10	Next-Generation CCIT: Robust Helium Leak Testing via ICH Q14 Principles <ul style="list-style-type: none"> ICH Q14 Enhanced Validation Pathway: Establishes a comprehensive, deterministic validation pathway for quantitative helium leak detection by using multivariate Design of Experiments (DoE) to map a Method Operable Design Region (MODR). Modular Microcapillary Positive Controls: Introduces highly adaptable, modular positive controls to systematically evaluate precision, specificity, and the limit of quantitation (LoQ). Correction of Statistical Assumptions: Identifies distinct data heteroscedasticity across the test range, invalidating traditional homoscedastic Gage R&R models and establishing relative standard deviation (RSD) as the necessary metric for precision validity. Dr. Christian Proff , Senior Verification Engineer, Roche
15.40	Afternoon Tea
16.10	Navigating Regulatory Change for PFS and Injectable Devices in the EU and UK <ul style="list-style-type: none"> Key regulatory developments impacting combination products and device-led submissions Interpreting evolving EU and UK requirements across the product lifecycle Practical considerations for manufacturers during a period of regulatory transition Louise Place , Head of Device Regulatory, Global CMC Regulatory Affairs, GSK
16.40	Session Reserved for Sponsor
17.10	EDDOs for SDD/mPFS and Control Strategy <ul style="list-style-type: none"> Identifying and defining critical device performance parameters for single-dose devices or manual pre-filled syringes Linking elemental device design outputs to verification, risk management, and control strategy across development and manufacturing Ensuring consistent product quality and performance through robust control Joanna Zhizhong Chen , Senior Regulatory Professional, Novo Nordisk
17.40	Chair's Closing Remarks and Close of Day Two Marc Egen , Head of Primary Packaging & Process Development, Boehringer Ingelheim

Stream B: Patient Centric Device Development

14.00	Chair's Opening Remarks Simon Wilson , Device Development Lead, Pfizer
14.10	Human Factors as a Critical Strategic Asset: Leveraging prior Pre-filled Syringes Human Factors Data to accelerate Safe and Effective Drug Delivery <ul style="list-style-type: none"> Leveraging Decades of Human Factors Knowledge by Understanding the Enduring Nature of Prefilled Syringe User Interactions Moving Beyond Individual Studies: Leveraging Platform Human Factors Data and Use-Related Risk Knowledge from Established PFS Systems to Support Regulatory Confidence and Smarter Development Decisions Building a Future-State Human Factors Strategy: Harnessing Historical PFS Data While Applying a Risk-Based Framework to Ensure Every New Drug-Device Combination Remains Safe, Effective, and Patient-Centric Joanita Lamien , Senior Human Factors Engineer, Regeneron
14.40	Session Reserved for Sponsor
15.10	Patient-Centric Device Development: Designing Drug Delivery Solutions Around Real Patient Needs <ul style="list-style-type: none"> Understanding patient needs and translating user insights into device and packaging design decisions Improving usability, adherence, and accessibility through human-centred development approaches Lessons learned from developing patient-friendly injectable devices and packaging solutions across diverse patient populations Cornelia Hain , Device and Packaging Lead, Polpharma
15.40	Afternoon Tea
16.10	Validating Patient Behaviour Insights to Improve Adherence Outcomes <ul style="list-style-type: none"> Technical deep dive into the BEAMER behavioural model and segmentation of patient groups based on needs and adherence drivers Results from EU and global pilot studies, including validation of adherence prediction and targeted support approaches Designing patient-centric solutions to improve usability, outcomes, and value in healthcare systems Lucy Williams , Clinical Statistician, Pfizer Francisco Lupiáñez-Villanueva , Technical Coordinator, BEAMER Project
16.40	Session Reserved for Sponsor
17.10	Utilisation of Digital Endpoints in Injectable Drug Device Development <ul style="list-style-type: none"> How digital endpoints and connected device data can generate objective insights into patient adherence, treatment outcomes, and device performance Integrating digital endpoint strategies into device development programmes to support evidence generation and patient-centric product design Mr George Moore-Arthur , Senior Global Regulatory Professional, Novo Nordisk
17.40	Chair's Closing Remarks and Close of Day Two Simon Wilson , Device Development Lead, Pfizer

AUDIENCE BREAKDOWN



Hear from Past Speakers and Attendees

“The event was a great kick-off to the new year, offering excellent inspiration and valuable exchanges throughout all days.”
Bayer

“Interesting insights and valuable contacts. Good platform to contribute in problem solving process.”
Bachmann Forming AG

“PFS & Injectable Drug Devices Europe 2026 was an outstanding event, with high quality presentations and insightful discussions across the themes of platform technologies, combination product regulation, connectivity and AI and sustainability. It was also an excellent opportunity for meaningful networking. Highly recommended.”
BSI

“It was, again, a very good opportunity to meet with colleagues in the industry and exchange on most recent developments.”
Boehringer Ingelheim

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- Quality content and a proven track-record in delivering the best and most up-to-date content
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SHL Medical is a pioneering leader in self-injection solutions, such as autoinjectors. Driven by our purpose of "enabling patients' independence", we partner with leading pharma and biotech companies to develop self-injection systems and digital solutions that enhance patients' treatment experience and quality of life. Our customers benefit from our proven track record and scalable, global manufacturing excellence, with locations in Switzerland, USA, Sweden, and Taiwan. By focusing on innovation, we challenge the status quo and shape the future of state-of-the-art drug delivery. We cover the entire drug delivery value chain, providing piece of mind through our end-to-end services, from design, development, to final assembly, labeling, and packaging. www.shl-medical.com

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DCA offer comprehensive design, development and analysis solutions for the medical devices industry. Our multidisciplinary team offers an integrated, evidence based service focused on helping our clients achieve success through great product design. With a wealth of experience in developing leading injection devices for global markets, DCA's work includes: variable dose pen injectors, single and multi-fixed dose injectors, disposable and reusable products, autoinjectors, wearable patch injectors, large volume injectors, connected and electro-mechanical devices. Our portfolio encompasses mass-market injectors that are manufactured in multi-billions, as well as lower volume devices targeting specific user populations and regional market needs. Alongside device design, we provide comprehensive support for industrialisation/production and create innovative instructions and product packaging solutions. Since 2000 our team have created over 1,700 granted patents for our clients. In the last 10 years we have received over 100 major design awards and supported our clients to launch more than 100 new products. We can provide expert support for device strategy, usability, due diligence, connectivity, mechanical engineering, electronics, medical device software, industrial design, UX/UI development, prototyping, industrialisation/production support, packaging and instruction design. We are certified to ISO13485 and work to ISO14971, IEC62304 and IEC62366. www.dca-design.com



Gerresheimer is an innovative systems and solutions provider and a global partner for the pharma, biotech and cosmetic industries. The company offers a comprehensive portfolio of pharmaceutical primary packaging, drug delivery systems and digital solutions. Gerresheimer ensures that medicines reach patients safely and can be administered reliably. With around 12,000 employees and 35 production sites in 16 countries in Europe, America and Asia, Gerresheimer has a global presence and produces locally for the regional markets with a focus on the pharma industry. www.gerresheimer.com



Haselmeier, the drug delivery device business of medmix, designs, develops and manufactures advanced drug delivery systems such as pen injection systems and autoinjectors. Patient comfort and customers' needs are always at the heart of the company's practices. With its broad portfolio of technologies and services, Haselmeier delivers user-friendly injection systems that enable patients to self-administer their medication reliably and accurately. Haselmeier is known for its excellent and long-standing track record in providing these innovative drug delivery devices based on its proprietary IP business model. The company collaborates closely with its customers in the pharmaceutical and biopharmaceutical industries. Medmix, with its precision injection molding capabilities and expertise in liquid micro-dosing plus financial strength and global footprint, helps Haselmeier accelerate innovation in healthcare. With more than 100 years of expertise in the development and manufacture of drug delivery devices, our global footprint, nearly 250 distinguished and motivated experts, more than 200 patents granted, and numerous patents pending, Haselmeier remains committed to developing innovative solutions that support our customers and help improve the health of millions of people worldwide. haselmeier.com/en



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. www.nemera.net



Suttons Creek is pharma's device team. Any company adopting combination product technology needs an experienced combination products team working alongside their drug team, including specialists in areas like quality, regulatory, vendor selection and management, systems engineering, risk management, clinical development, and commercialization. Suttons Creek has over 650 years of combined experience and 120+ combination product projects under its belt, with a talent pool of subject matter experts that specialize in all aspects of combination product development from strategic planning through device development to launch and postmarket activities. We can be any or all things combination product to a client, consulting hour by hour or engaging in strategic partnerships to achieve milestones, lift roadblocks, fill knowledge gaps, and drive program success. www.suttonscreek.com

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