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ADVANCES IN DEVICE DESIGN FOR ENHANCED DELIVERY
MAIN CONFERENCE | 14 - 15 JANUARY 2026

SAE MEDIA GROUP

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PFS & INJECTABLE DRUG DEVICES

13 - 15 JAN 2026

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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 18th Annual Pre-Filled Syringes and Injectable Drug Devices Conference, taking place from January 13–15, 2026.

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 Pre-Filled Syringes and Injectable Drug Devices Advisory Board

Mitali Aon,
VP and Global Head of Device Development,
Sanofi

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Vice President - Global Head of Device Quality,
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Business Lead, Drug Products and Devices,
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Pre-Filled Syringes and Injectable Drug Devices

13-15 January 2026

Featured Speakers Include:

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

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

Andrew Chapman,
Senior Director,
AstraZeneca

Richard Crowther,
Sr Manager Regulatory Affairs,
Amgen – plenary

Mario Hirth,
Director Global Verification Testing,
AbbVie

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

Matt Nicolas,
Device Engineering Associate Director,
GSK

Andreas Emmendoerffer,
Principal Regulatory Program Director,
Roche

Rachel Koppelman,
Head of Device Engineering,
Sandoz

Jussi Haikarainen,
Director, Device Development,
AbbVie

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

Anja Hartman,
Lead Auditor Medical Devices,
TUV SUD

Tony Haythornwaithe,
Device Engineering Associate Director,
GSK

Steve Hoare,
Deputy Director, Partnerships,
MHRA

Xavier Donnette,
Device Program Lead,
UCB

Javad Jabbari,
Director Regulatory Affairs, Medical devices and Combination Products,
Ascendis Pharma

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

Cedric Gysel,
Chief Changemaker,
Be Circular

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

Abby Lambretti,
Senior Scientist II,
AbbVie

Tiffany McIntire,
Device Team Leader,
Roche

Jacob Moberg Sandager,
Senior Circular Plastic Engineer,
Novo Nordisk

George Moore Arthur,
Senior Global Regulatory Professional,
Novo Nordisk

Simon Wilson,
Device Development Lead,
Pfizer

Tarja Nurmi,
Senior Expert, Extractables and Leachables,
Bayer

Kristine Berkenhoff, Head of Laboratory, Global Development CMC Biologicals,
Boehringer Ingelheim

Bérengère Paris,
Regulatory Affairs Specialist, RA Devices,
Novo Nordisk

Louise Place,
Director, Devices, Global CMC Regulatory Affairs,
GSK

Charles Potter,
Project and Technical Leader,
Chiesi

Farshad Ramazani,
Formulation Project Leader (Senior Expert Science and Technology),
Novartis

Soren Skov,
Senior Human Factors Engineer,
Roche

Courtney Soulsby,
Global Director, Healthcare and Life Sciences,
BSI

Sandra Einemann,
Customer Relationship Manager,
TUV SUD

Richard Wedge,
Associate Research Fellow,
Pfizer

Thomas Wejs Moeller,
Senior RA Policy Director,
Novo Nordisk

Chris Smith,
Director,
Teva Pharmaceuticals

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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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: Digital Health Tools and Connectivity for a Maximised User Experience
Gain insights into the use of digital tools and connectivity through real-world applications and clinical trial learnings, highlighting their role in improving patient care

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Pre-Conference Focus Day
Advances in PFS Design for Enhanced Delivery
Tuesday 13 January 2026

08.00 **Registration & Coffee**

08.50 **Chair's Opening Remarks**

Charles Potter,
Project Leader and Technical Leader,
Chiesi

OPENING ADDRESS:

09.00 **Regulatory expectations for the Development and Lifecycle of Drug-Device Combination Products**
- Key considerations in early-stage development of pre-filled syringes and combination products, including human factors, risk management, and EDDOs
- Strategies for aligning design control documentation with global regulatory expectations (EU MDR, NBoP, FDA, etc.)

Javad Jabbari, Director Regulatory Affairs (RA) Device and Combination Products, **Ascendis Pharma**

09.30 **Building a Robust Device Control Strategy: From Concept to Quality Execution**
- Approaches for establishing a harmonised framework for device critical functions addressing all development stages to ensure consistency and reliability
- Integrating device strategy with quality by design (QbD) and leveraging QbD principles to embed quality into device development from the outset, improving risk management and regulatory readiness
- Applying the strategy in practice: Case Study demonstrating real-world implementation of a device control strategy, highlighting lessons learned and measurable outcomes
- Prioritising control points that impact patient safety, product performance, and regulatory compliance to drive meaningful quality assurance

Tony Hayhtornwaithe, Associate Director Device Engineering, **GSK**

10.00 **Session Reserved for Sponsor**

10.30 **Morning Coffee Break**

11.00 **Clinical Evaluation Plans and reports: Breaking silos and building bridges**
- Overview of the CEP and CER requirements
- Connecting ISO14971 requirements with the CEP and CER
- Harmonizing processes across Clinical and Device

Tiffany McIntire, Device Team Leader, **Roche**

11.30 **Session Reserved for Sponsor**

12.00 **Fireside Chat: Keeping Up with the Evolving Drug Delivery Landscape and Looking to the Future and Beyond**
- Exploring how patients will manage their own health by the end of 2025 (next 5 years) and its impact on drug delivery and device design, including self-injection device demand
- Streamlining interactions and promoting effective collaboration between teams across device and drug development, and commercial stage support

Moderator:
Javad Jabbari, Director Regulatory Affairs (RA) Device and Combination Products, **Ascendis Pharma**
Panellists:
David Harrison, Business Lead, Drug Products and Device, **UCB**
Theresa Jeary, Global Head, Medicinal & Biologics Team, **BSI**
Rachel Koppelman, Head of Device Engineering, **Sandoz**

12.30 **Networking Lunch**

13.30 **Five Years of MDR for Combination Products: Lessons, Timelines & Industry Expectations**
- Insights from five and a half years of MDR implementation and adaptation
- How evolving processes impact regulatory approval for combination products
- An update on Notified Bodies expectations from documentation and timeline refinements
- Industry Engagement: Timing Matters

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

14.00 **Session Reserved for Sponsor**

14.30 **EDDO in Focus: Progress, Perspectives, and Pathways Forward**
- How teams are aligning design outputs with EDDO definitions to meet regulatory expectations
- Integrating EDDOs across drug-device development to ensure consistent performance and quality
- Strategies for harmonising specifications and controls between stakeholders
- Anticipating international alignment and building scalable compliance frameworks

Bérengère Paris, Regulatory Affairs Specialist, RA Devices, **Novo Nordisk**

15.00 **Afternoon Networking Break**

15.30 ROUNDTABLE DISCUSSION SESSIONS

1 **Utilising AI in Injectable Device Development**
- Sharing experiences on how AI is being used to optimise design, testing, report writing and decision-making across device programmes

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

2 **Strategic Partnerships in Injectable Drug Delivery: Aligning External Networks**
- Exploring how pharma companies can build and sustain high-value partnerships with CMOs and device developers to support innovation, scalability, and performance
- Discussing strategies for aligning to ensure mutual value creation, operational excellence, and long-term collaboration

Leader: David Harrison, Business Lead, Drug Products and Device, **UCB**

3 **Driving Sustainability in Device Design**
- Practical strategies for reducing environmental impact across the device lifecyle - from materials to end of life
- Key trade-offs in sustainable design, including reusability, human factors, and the integration of electronics.

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

4 **Navigating EDDO Guidance**
- Examining the Clarity and Direction in EDDO Guidance
- Addressing challenges related to EDDO integration

Leader: Javad Jabbari, Director Regulatory Affairs (RA) Device and Combination Products, **Ascendis Pharma**

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

Main Conference Day 1
Morning Plenary
Wednesday 14 January 2026

07.30 Registration & Coffee

08.10 **Chair's Opening Remarks**

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

OPTIMISING DEVICE SELECTION AND DEVELOPMENT

08.20 **OPENING ADDRESS:**
Integrated Combination Product Development Strategies
- Introduction to combination product delivery systems and related development challenges
- Streamlining combination product development by leveraging platform approaches
- Successful combination product development by program management excellence

Mario Hirth, Director Global Verification Testing, **AbbVie**
Jussi Haikarainen, Director, Device Development, **AbbVie**
Abby Lambretti, Senior Scientist II, **AbbVie**

09.00 **Collaborative Pathways to Bespoke Medical Device Innovation**
- Outlining Sandoz's approach to optimising off-the-shelf medical devices through collaboration with medical device developers
- Aligning device functionality with drug characteristics to enhance delivery, safety, and patient experience
- Unlocking speed, flexibility, and innovation through integrated cross-functional partnerships
- Case studies highlighting key challenges, breakthroughs, and measurable impact from collaborative device development

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

09.30 **Session Reserved for Gold Sponsor**
Crux Product Design

REGULATORY UPDATE PART 1

10.00 **Updates in Regulatory CMC for Injectable Combination Products**
- Aligning global expectations: FDA, EMA, and ISO convergence on device-drug interface requirements
- Addressing sustainability in CMC: integrating recyclability, responsible material sourcing, and environmental impact into development strategy
- Integrating human factors and usability data into CMC submissions for device-led therapies
- Strengthening lifecycle CMC readiness: change management, post-approval variations, and digital traceability

Louise Place, Director, Devices, Global CMC Regulatory Affairs, **GSK**

10.30 Morning Networking Break

DEVELOPMENTS IN SUSTAINABILITY

11.00 **Rethinking Sustainability: Designing Meaningful Change in Injectable Drug Delivery Systems**
- Sharing insights on the 'Pack of the Future' initiative, grounded in research of current industry practices and environmental impact
- Exploring how platform designs contribute to inertia in device innovation - and where opportunities for disruption lie
- Reviewing strategies for embedding sustainability into earlystage design and development
- Highlighting how broader industry awareness and collaboration can accelerate meaningful change in combination product sustainability

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

11.30 **Session Reserved for Gold Sponsor**
Althena Medical

12.00 **PANEL DISCUSSION:**
Advancing Sustainability from Concept to Execution in Medical Device Development
- Practical insights and tools to equip teams with actionable guidance for integrating sustainable practices and materials into development workflows
- Managing and reviewing trade-offs between usability, performance, cost, and environmental impact
- Building circular business models and potential strategies for reshaping industry operations to prioritise reuse and longevity
- Moving beyond collection and disassembly to integrating recovered materials back into production

Panel Moderator:
Steve Hoare, Deputy Director, Partnerships, **MHRA**
Panellists:
Thomas Wejs Moeller, Director Global Regulatory Affairs, **Novo Nordisk**
Charles Potter, Project Leader and Technical Leader, **Chiesi**
Cedric Gysel, Chief Changemaker, **Be Circular**
Conor O'Neill, Head of Packaging Development and Design, **GSK**
Charlie Dean, Head of Sustainable Medical Technology, **Cambridge Consultants Ltd**

12.30 **Session Reserved for Gold Sponsor**
MGS

REGULATORY UPDATE PART 2

13.00 **Applying Regulatory Reliance Pathways for Drug-Device Combinations**
- Overview on global harmonization efforts for drug device combinations
- WHO Regulatory Reliance Pathways
- Concrete example on how these Regulatory Reliance Pathways were applied for two combination products

Andreas Emmendoerffer, Principal Regulatory Program Director, **Roche**

13.30 Networking Lunch

Main Conference Day 1
Afternoon Streams
Wednesday 14 January 2026

Stream A: Large Volume and Novel Drug Product Delivery

STREAM SPONSORED BY Nemera we put patients first · CREDENCE MEDSYSTEMS

14.30 **Chair's Opening Remarks**

Mario Hirth,
Director Global Verification Testing,
AbbVie

14.40 **Bridging the Gap: Ensuring Lab-Based Device Verification captures Real-World Performance**
- Why automated lab tests may overlook critical user-driven failure modes and real-world variability
- Integrating human factors and risk management to strengthen verification strategies and outcomes
- Approaches for simulating user behaviour and variability within controlled test programs
- Building robust, regulator-ready evidence that demonstrates device safety and performance in the user's hands

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

15.10 **Session Reserved for Nemera** Nemera we put patients first

15.40 **Meeting Evolving Patient and Market Needs vs Regulatory Requirements**
- Aligning device design with patient and indication-specific needs and drawing upon this to design the right clinical studies
- Navigating development complexities with device partners: Overcoming regulatory hurdles, technical documentation gaps, and global component shortages through early, transparent collaboration
- Ensuring drug product compatibility, ergonomic design, and essential performance alignment while embedding sustainability and recyclability
- Future-Proofing for Emerging Therapies: Anticipating next-generation requirements, administration routes, and volume delivery to meet the demands of diverse therapeutic pipelines

Xavier Donnette, Device Program Lead, **UCB**

16.10 **Afternoon Networking Break**

16.40 **Designing patient-centric long-acting injectable formulations**
- Challenges associated with long-acting injectable formulations
- Innovations within injectable formulation focusing on volume and viscosity
- Insight into long acting injectable development: from small to large scale manufacture

Farshad Ramazani, Formulation Project Leader (Senior Expert Science and Technology), **Novartis**

17.10 **Session Reserved for Credence MedSystems** CREDENCE MEDSYSTEMS

17.40 **Autoinjectors for High-Volume Delivery: Integrating Human and Technical Needs**
- The growing need for autoinjectors to accommodate larger volumes while ensuring ease of use and patient comfort
- Balancing technical and human needs for delivery time optimization for high-volume delivery
- Highlighting strategies to ensure usability and safety in high-volume autoinjector platforms

Soren Skov, Senior Human Factors Engineer, **Roche**

18.10 **Chair's Closing Remarks and Closing of Day One**

Stream B: Sustainability in Device Development

STREAM SPONSORED BY HASELMEIER A medmix Brand · OWEN MUMFORD Pharmaceutical Services

14.30 **Co-Chair's Opening Remarks:**

Steve Hoare,
Deputy Director, Partnerships,
MHRA

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

14.40 **Creating a Circular Loop in Healthcare: Recycling Used Prefilled Pens into New Devices**
- Sustainability – Environmental benefits of collecting and recycling devices
- Collection and Sorting – ReMed: How Novo Nordisk is collecting and sorting our takeback devices today
- Quality – Ensuring product integrity with recycled materials
- Traceability – Maintaining control over materials in production

Jacob Moberg Sandager, Senior Circular Plastic Engineer, **Novo Nordisk**

15.10 **Session Reserved for Haselmeier** HASELMEIER A medmix Brand

15.40 **Navigating Global Compliance and Sustainability Mandates for pharmaceuticals company : Strategies for Aligning with Evolving Regulations and Regional Variations**
- Understanding Global Compliance
- Sustainability Mandates in the Pharmaceutical Industry
- Compliance Challenges
- Strategies for Aligning with Evolving Regulations
- Integrating Sustainability into Regulatory Planning
- Future Outlook

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

16.10 **Afternoon Networking Break**

16.40 **Consensus standards to drive scaled circularity for medical device industry**
- Overall market and public perceptions on circularity of medical devices and need for trust (based on recent research with Cambridge Unv)
- Standards subcommittee and links with European advisory group on med dev sustainability
- UK Design for Life programme – role of standards and regulation

Courtney Soulsby, Global Director, Healthcare and Life Sciences, **BSI**

17.10 **Session Reserved for Owen Mumford** OWEN MUMFORD Pharmaceutical Services

17.40 **Circular Solutions for a Greener Future**
- Strategies for embedding eco-friendly solutions in device design and manufacturing
- Implementing closed-loop systems to minimise waste and maximise resource efficiency
- Innovating business models for circular devices by transforming packaging and intermediate materials to extend product life cycles
- Global Expansion of Circular Initiatives: Lessons from Janssen's Circular Device program and its impact on pharmaceutical sustainability

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

18.10 **Chair's Closing Remarks and Closing of Day One**

Main Conference Day 2
Morning Plenary
Thursday 15 January 2026

08.00 Registration & Coffee

08.50 Chair's Opening Remarks

Andrew Chapman, Senior Director, **AstraZeneca**

OPTIMISING DEVICE SELECTION AND DEVELOPMENT PROCESSES

09.00 OPENING ADDRESS:
The Impact of Device Selection on Injectable Drug Approval
- Understanding the influence of device selection on clinical and commercial approval pathways
- Addressing regulatory complexities and timeline implications when pairing drugs with standalone delivery systems
- Key steps for streamlined approval with practical approaches to navigating MDR requirements and minimising delays in clinical trials
- Recommendations on reducing regulatory burdens and improving efficiency in injectable device development

Richard Crowther, Snr Manager Regulatory Affairs, **Amgen**

09.30 **Risk Management: Between - and even within - companies, common hazards and harms can be scored in different ways, leading to confusion, questions and delays to new drug approvals**
- Developing a library of common hazards and harms will help to streamline (harmonize) ratings across sponsors, CDMOs, suppliers
- Submissions will 'de-risked' - with more consistent with more predictable results
- Applying common approaches to common, drug-agnostic hazards and harms showcases an industry that is coordinated and consistent, and willing to work together
- Aligning with suppliers further demonstrates the end-to-end value in reducing redundancies, building efficiencies, and getting valuable medicines to patients

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

10.00 Session Reserved for Gold Sponsor
West Pharmaceutical Services

10.30 Morning Networking Break

11.00 **Current Landscape: Maturity of platform solutions in BioPharma device development - opportunities, challenges, and industry alignment**
- Lessons from Practice: Case studies highlighting successes, pitfalls, and common barriers to implementation
- Strategic Value: Operational, sustainability, and portfolio-level benefits of adopting a platform-driven approach
- Future Outlook: Industry collaborations, evolving guidance, AI's role, and supplier perspectives shaping the next generation of platform development

Matt Nicolas, Device Engineering Associate Director, **GSK**

11.30 PANEL DISCUSSION:
Optimising Drug-Device Combination Product Development with AI
- Leveraging AI to streamline and speed up drug-device combination product development
- Securing and Integrating AI: strategies for safely incorporating AI technologies into healthcare systems
- Measures for ensuring patient safety and ethical AI application
- Future Outlook: Predictions on AI-driven advancements and regulatory trends in drug-device development

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

Panellists:
Andrew Chapman, Senior Director, **AstraZeneca**
Matt Nicolas, Device Engineering Associate Director, **GSK**

ARTICLE 117 BEST PRACTICES

12.00 **Bridging the gaps: regulatory challenges and best practice around data availability at the time of Art. 117 NBOp Vs MAA**
- As industry continues to gain experience in the Art. 117 process, a number of challenges and unknowns around the availability of data at the time of submission persist. This presentation intends to outline some of these challenges and propose best practices for industry to navigate them, such as:
- EMA guidance and requirements for NBOp and CTD device content
- Stability data and shelf-life: device component, drug-agnostic and drug-device combination product data
- PV, pre-PV, clinical: representativeness of materials and processes used in support of GSPRs compliance

Juan Martin Carriquiry, Director RA Medical Devices & Combination Products, **Novartis**

12.30 **Article 117 in Practice: Optimising Submissions for Drug-Device Combination Products**
- Best practices and recommendations on how to prepare compliant documentation
- Reviewing common pitfalls in Article 117 submissions and how to avoid delays in the review process
- Clarifying expectations for General Safety and Performance Requirements (GSPRs) and how they align with the device's intended use in the DDC
- Practical strategies to streamline collaboration between pharma and device developers for faster, more predictable approvals

Anja Hartman, Lead Auditor / Product Specialist, **TUV SUD**
Sandra Einemann, Customer Relationship Manager, **TUV SUD**

13.00 Networking Lunch

Main Conference Day 2
Afternoon Streams
Thursday 15 January 2026

Stream A: Primary Drug Container Development and Biocompatibility

STREAM SPONSORED BY CORMICA ZEON

14.00 **Chair's Opening Remarks**

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

14.10 **Air transport simulation study of Pre-Filled Syringes**
- Definition of sterility barrier of container closure systems
- Methods to assess plunger stopper movement under vacuum conditions
- Case study: air transport simulation of PFS

Kristine Berkenhoff, Head of Laboratory, Global Development CMC Biologicals, **Boehringer Ingelheim**

14.40 **Advanced Plastics Solutions for Next-Generation Therapeutic Delivery Systems**
- Advances in drug delivery are increasingly focused on improving patient adherence and enabling decentralized administration Shelf-stable formulations and patient-operated delivery devices allow dosing to occur outside the hospital setting, introducing stricter design requirements for primary packaging and device materials
- Key performance criteria include extended drug stability, container closure integrity during transport and cold storage, and assurance of patient safety during self-administration
- Cyclic Olefin Polymer (COP) has emerged as a high-performance material capable of meeting these demands
- Here we will discuss important critical material properties of COP such as impact strength at cold temperatures, sterilization compatibility, oxygen permeability, purity and inertness to protein binding that should be strongly considered when designing next generation drug delivery systems

Alison Skelley, Chief Science Officer, **Zeon Specialty Material Inc.**

15.10 **Strategic Pathways for Combination Products in a Shifting Regulatory Landscape**
- Global regulatory updates on combination products
- Understanding combination products in EU: Definitions and frameworks
- Challenges and strategic pathways for regulatory professionals

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

15.40 **Afternoon Networking Break**

16.10 **Maximising Safety and Efficiency in E/L Strategy**
- Designing robust Extractables and Leachables studies that meet regulatory expectations while supporting platform device strategies
- Understanding how product-specific characteristics influence the analytical evaluation threshold and guide risk-based decision-making
- Reviewing study results and exposure calculations to ensure accurate, product-relevant safety assessments
- Translating toxicological evaluations data into actionable insights that support safe, efficient product approvals

Tarja Nurmi, Senior Expert, Extractables & Leachables, **Bayer**

16.40 **Session Reserved for Sponsor Cormica** CORMICA

17.10 **ISO 10993-1:2025 — Identified Challenges and Impact on New and Legacy Combination Products**
- The impact of the standard on legacy combination products
- Changes in Categorization and what it means for Combination products
- How to navigate the Integration of ISO 14971 principles
- Overall impact of the standard- The good the bad and the ugly

Senior Representative, BioPhorum

17.40 **Chair's Closing Remarks and Closing of Day Two**

Stream B: Digital Tools and Connectivity for a Maximised User Experience

STREAM SPONSORED BY DCA gerresheimer

14.00 **Chair's Opening Remarks:**

Simon Wilson, Device Development Lead, **Pfizer**

14.10 **Designing Connected Devices That Patients Actually Want**
- Highlighting how the pharmaceutical industry must evolve to meet patient expectations in a digitally connected world
- Demonstrating the value of co-creating with patients to design experiences that drive adherence, satisfaction, and trust
- Exploring what makes a connected experience truly great - beyond just building an app
- Offering a fresh perspective on product design, drawing unexpected inspiration from other industries

Simon Wilson, Device Development Lead, **Pfizer**

14.40 **Session Reserved for Gerresheimer** gerresheimer

15.10 **Personalised Health in Practice: Digital Innovation in Injectable Drug Delivery**
- Examining developments in the use of digital technologies in optimising injectable therapies through personalised, data-driven treatment approaches
- Discussing strategies for navigating global regulatory submissions for digital health-enabled medical devices, with a focus on compliance and market access
- Highlighting case studies showcasing successful integration of digital ecosystems across the injectable device lifecycle

George Moore-Arthur, Senior Global Regulatory Professional, **Novo Nordisk**

15.40 **Afternoon Networking Break**

16.10 **Connected Autoinjector Development: Empowering Patients and Driving Better Clinical Outcomes**
- Key challenges and pitfalls encountered during development and key takeaways for future development
- Purpose-driven connectivity: How to determine when connectivity adds real value, and when it doesn't—anchored in measurable patient outcomes
- Ensuring digital features enhance adherence, engagement, and clinical results without overcomplicating the user experience

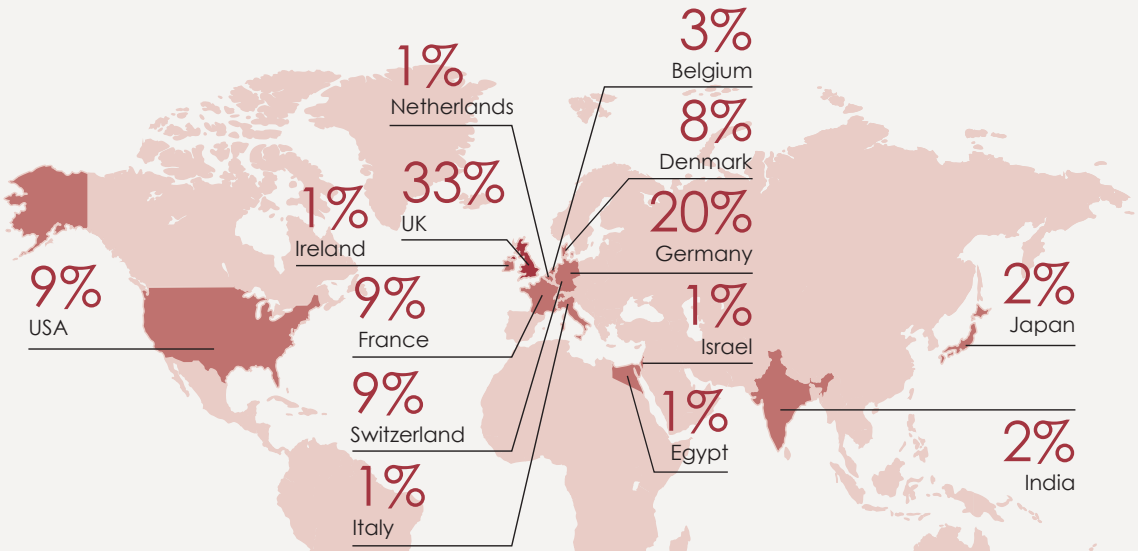
Senior Representative, To be confirmed

16.40 **Session Reserved for DCA Design** DCA

17.10 **Stream Closing Panel: Connecting the Dots: Unlocking the Full Potential of Digital Tools in Injectable Platforms**
- Reflecting on key themes from the stream—ranging from device connectivity to data-driven user support—and how they collectively shape the future of patient experience
- Challenges and opportunities in aligning digital tools across platforms, ecosystems, and stakeholders for seamless user journeys
- Exploring emerging trends, unmet needs, and collaborative pathways to accelerate development in the field

17.40 **Chair's Closing Remarks and Closing of Day Two**

Audience Breakdown



Hear from Past Speakers and Attendees

"Excellent opportunity to meet with colleagues and share the latest developments and a real sanity check where your peers are on e.g. the sustainability agenda."
Head of Takeback Program, Novo Nordisk

"Besides all the interesting conversations with speakers and participants, I enjoyed the exchange of experience between different companies, with notified bodies and the manufacturers of the drug delivery systems /technologies. The conference was also an occasion for exploring with all the actors the new technologies, innovative strategies in the design process and approaches to ensure safe and efficient product development."
Senior Director, Bayer

"A well-structured agenda that has matched greatly the needs of a well-identified target group within the life science community, which created a unique kind of 'family atmosphere' thus fostering information sharing and productive discussions."
Global Medical Device Leder, Sanofi

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