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FOCUS DAY | APRIL 28, 2025

ADVANCES IN COMBINATION PRODUCT DESIGN AND DEVELOPMENT

MAIN CONFERENCE | APRIL 29 - 30, 2025

SAE MEDIA GROUP

SAE Media Group Proudly Presents the 12th Annual Conference...

PRE-FILLED SYRINGES AND INJECTABLE DRUG DEVICES EAST COAST

APRIL 28 - 30 2025

INNOVATIONS FOR THE COMBINATION PRODUCTS OF THE FUTURE

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A Letter From Our Advisory Board

Dear Colleagues

It is with great pleasure that we, as members of the advisory board, invite you to join us at SAE's 12th Annual Pre-Filled Syringes and Injectable Drug Devices East Coast Conference, taking place from 28th to 30th April 2025.

This year's conference will once again serve as a platform for experts across the combination product and injectable drug delivery landscape to connect, exchange ideas, and drive innovation. The event begins with an engaging pre-conference focus day, dedicated to the latest advances in combination product design and development. This is followed by a dynamic two-day main agenda, featuring keynote plenaries highlighting the most pressing trends and breakthroughs, followed by afternoon topic streams, offering deep dives into the field's most pivotal challenges and opportunities.

The injectable drug delivery field continues to evolve rapidly. Significant strides are being made in device technologies including smart devices, solutions for large-volume and highly viscous drug delivery, and innovations addressing unmet needs. There is a continued emphasis on usability, comfort, and adherence to enhance patient experiences. Progress is also being made in integrating eco-friendly practices into device development, from manufacturing to end use. This year's conference will not only showcase groundbreaking case studies and expert perspectives but also explore emerging trends and future opportunities, driving the next wave of innovation in our industry.

We look forward to welcoming you to this must-attend event this coming April.

Yours Sincerely,

SAE Media Group's 2025 Advisory Board

Theresa Scheuble,
Head of Design and Innovation,
Johnson & Johnson

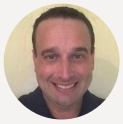
Bharat Arora,
Director, Global Combination Products Quality,
Moderna

Subhi Saadeh,
Sr. Manager – Device/ Combination Products,
Gilead

Ravi Kaushik,
Vice President, Global Head of Device/Digital Innovation & Product Strategy, PDT,
Takeda

Sujit Basu,
Head of Pharmaceutical Development,
Ionis

Nicholas Mandala,
VP Medical Devices & Combination Products Technology,
Pfizer



James Wabby,
Head Global Reg Affairs,
AbbVie

Mark DeStefano,
Director, Combination Products and Device R&D,
Teva Pharmaceuticals

Dany Doucet,
Director Early Engagement and Deviceability
GSK

HIGHLIGHTS FOR 2025:

- **Collaborate and Network With Industry Experts:** Engage with pharmaceutical, biotech, and device innovators over three dynamic days focused on advancing injectable drug delivery solutions.
- **Discover Cutting-Edge Drug Delivery Technologies:** Learn about the latest advancements in wearable injectors and autoinjectors for the delivery of large volumes and highly viscous drug products.
- **Navigate Regulatory Pathways with Confidence:** Gain insights from regulatory experts on combination product requirements including the newly released EDDO guidance and explore strategies for fostering innovation through collaboration.
- **Embrace Sustainability in Device Development:** Explore how leading pharmaceutical companies are integrating sustainability into device design, manufacturing, and lifecycle management.
- **Harness the Power of Digital Health:** Dive into the transformative potential of digital technologies to enhance patient outcomes, alongside practical strategies for implementation.
- **Optimize Primary Packaging Container Solutions:** Examine case studies addressing container innovation and strategies to align with novel drug modalities.

Bringing Major Players Across Industry Together

Past Attendees Include...

abbvie
ALEXION
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ALMAC
Alnylam
AMERICAN REGENT
AMGEN
Apellis
apiject
Arbutus BIOPHARMA
AstraZeneca
astria THERAPEUTICS
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What to Expect...

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

250+ ATTENDEES

40+ SPEAKERS

50+ BIG PHARMA AND BIOTECH COMPANIES IN ATTENDANCE

FREE FOR PHARMA AND BIOTECH TO ATTEND*

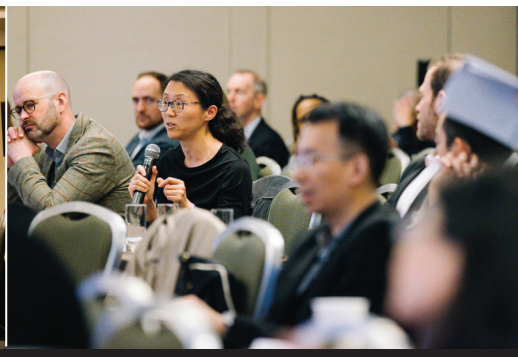
Dedicated Afternoon Topic Streams:

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, including advancements in on-body injectors and the challenges of enabling effective, patient-centered delivery solutions

Day One Stream B: Advancing Sustainability in the Injectable Device Industry
Explore strategies, innovations, and case studies driving the adoption of sustainable practices across the medical device lifecycle, focusing on reducing environmental impact while maintaining quality and patient-centricity

Day Two Stream A: Primary Packaging and Building Successful Supplier Relationships
Explore strategies for developing a comprehensive primary container strategy that meets the demands of new drug modalities while fostering effective supplier partnerships to drive innovation, ensure quality and efficiency in the injectable drug device industry

Day Two Stream B: Digital Health Technologies and Connected Devices: Use Cases and Clinical Trials
Discover the transformative potential of digital health technologies and connected devices through real-world use cases and insights from clinical trials, highlighting their role in advancing patient care and device innovation



Featured Speakers Include:

Lisa Ray,
Executive Director Program Management – Delivery, Device & Connected Solutions, **Eli Lilly**

Kinsuk Shah,
Senior Combination Product Steward,
Boehringer Ingelheim

Mark DeStefano,
Director, Combination Products and Device R&D,
Teva Pharmaceuticals

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

Duncan Paterson,
Senior Director of Device Development,
AstraZeneca

Martin McLoughlin,
Vice President, Device and Delivery Technologies,
Apogee Therapeutics

Ajit Dsouza,
Executive Director Device Development,
Eli Lilly

Alie Jahangir,
Head of Quality, Device and Combination Products,
Biogen

Gretchen Piwinski,
Sr Manager Combination Product Development,
Regeneron

Subhi Saadeh,
Sr. Manager – Device/ Combination Products External Quality Operations,
Gilead

David Vazquez,
Head SaMD Legal Manufacturing,
Pfizer

Joyce Zhao,
Director, Combination Product Development,
Takeda

Theresa Scheuble,
Head of Design and Innovation,
Johnson & Johnson

Amardeep Hoonjan,
Director Device R&D Lead, Biocompatibility Group,
AbbVie

Fletcher Dix,
Sr. Process Characterization and Technology Engineer,
Regeneron

Bharat Arora,
Director, Global Quality,
Moderna

Matt Marber,
Senior Usability Engineer,
Novo Nordisk

Megan Heft,
Director, Device Development,
AstraZeneca

Ravi Kaushik,
Vice President, Global Head of Device/Digital Innovation & Product Strategy, PDT,
Takeda

Aditya Nair,
Packaging Engineer,
Pfizer

Nick Mandala,
VP Medical Devices and Combination Products Technology,
Pfizer

Alan Stevens,
Global Head, Complex Devices and Drug Delivery Systems,
AbbVie

Sujit Basu,
Vice President & Head, Pharmaceutical Development,
Ionis

Nolan Dow,
Combination Product Development Engineer,
Pfizer

Ellie Younger,
Assoc Principal Device Engineer,
AstraZeneca

Sarah Fairfield,
Associate Director, RA Device and Combination Products (Digital Device and Software), **AbbVie**

Soumen Das,
Delivery System Qualification Lead,
Takeda

Ning Yu,
Executive Director, Device and Combination Product Development,
Astria Therapeutics

Dany Doucet,
Director Early Engagement and Deviceability
GSK

Jayne Gavrity,
Senior Device Engineer,
AstraZeneca

Joanita Lamien,
Sr. Human Factors Engineer,
Regeneron

Daniel Davenport,
Associate Director Early Engagement and Deviceability,
GSK

Guangli Hu,
Director, Device Development & Technology,
Merck

Jia Huang,
Associate Director, Regulatory Digital Health,
Merck

Yvette Appleby,
Senior Manager Project Management,
Pfizer

Jamie Tsung,
Head of DP Formulation, CMC,
Alnylam Pharmaceuticals

and more...

Pre-Conference Focus Day
Advances in Combination Product Design and Development
Monday April 28, 2025

08.15 **Registration & Coffee**

09.00 **Co-Chair's Opening Remarks**
Alan Stevens, Global Head, Complex Devices and Drug Delivery Systems, **AbbVie** *Co-Chair to be confirmed*

OPENING ADDRESS

09.10 **Streamlining Collaboration in Drug/Device Combination Product Development**
- Exploring bespoke vs. platform approaches: designing devices for specific drugs or using adaptable platform devices for broader applications
- Key considerations and strategies for a successful transition from IV to subcutaneous administration
- Enhancing cross-functional communication to improve collaboration between drug and device R&D teams, ensuring alignment and streamlining device development

Ajit D'Souza, Executive Director, Drug Delivery & Devices, **Eli Lilly**

09.40 **Session Reserved for Haselmeier**

10.30 **Morning Networking Break**

11.00 **From Concept to Lifecycle in Combination Product Development: Synergies between drug product and device development**
- Establishing awareness of drug product and device development
- Navigating challenges at Clinical and Lifecycle product stages
- Structural approach to drive collaboration from the beginning
- Identify the collaboration areas and integration plans
- Understand "Fit for Purpose" development process

Bharat Arora, Director, Global Combination Products Quality, **Moderna**

11.40 **The Power of Independent Review for De-risking Products**
- Definition of independent review/due diligence
- Benefits of independent review, for example:
- Evidencing a robust product
- Identifying opportunities for improvement
- Capitalizing on opportunities for improvement (e.g., improving device offering)
- Organizing and leveraging data for future developments

Frances Pencliffe, Consultant Healthcare Devices Engineer, **Cambridge Design Partnership**
Greg Moakes, EVP, New Business Development, **LTS Device Technologies**

12.20 **Navigating Essential Drug Delivery Outputs (EDDO) in Combination Product Development**
- Examining the Clarity and Direction in EDDO Guidance
- Addressing regulatory challenges related to EDDO integration

Alan Stevens, Global Head, Complex Devices and Drug Delivery Systems, **AbbVie**

13.00 **Networking Lunch**

14.00 **Combination Product Risk Management: Understanding and Drug vs Device Methodologies**
- Integrating distinct drug and device risk management methodologies to ensure regulatory compliance and patient safety
- Practical tools and strategies for cross-functional collaboration to manage risks throughout the product lifecycle

Ning Yu, Executive Director, Device and Combination Product Development, **Astria Therapeutics**

14.40 **Session Reserved for Sponsor**

15.20 **Successful Human Factors Integration During Device Development: Best Techniques to Integrate Human Factors Early and Successfully Implement Recommendations from Human Factors Findings in Device Design**
- Best approaches to successfully integrate Human Factors early on in device development process
- Contributing effectively to device iterative design through human factors/usability studies
- Identify key steps to successfully implement recommendations from Human factors formative studies in device development

Joanita Lamien, Sr. Human Factors Engineer, **Regeneron**

16.00 **Afternoon Networking Break**

16.30 **Roundtable Discussion Sessions**

ROUNDTABLE 1:

Producing New Technologies for the Future: Getting Ahead of the Curve and Gaining Stakeholder Buy In
- Anticipating future needs and strategies to stay ahead of technology demands in injectable drug devices
- Building consensus with best practices for gaining stakeholder alignment and fostering collaboration to support innovation

Mark DeStefano, Director, Combination Products and Device R&D, **Teva Pharmaceuticals**

ROUNDTABLE 2:

Utilizing In Silico Technologies in Development Programs: Integration, Uses and More
- Exploring how in Silico technology can streamline product design, development, lifecycle management, testing, and optimization processes for injectable devices
- Discussion of practical In Silico technology use cases for accelerating development timelines and improving product efficacy

Joyce Zhao, Director, Combination Product Development, **Takeda**

ROUNDTABLE 3:

Effectively Taking a Platform Approach: Implications, Technicalities and Regulations
- Benefits and challenges of leveraging platform technologies for multiple drug-device combinations and when it this approach appropriate
- Addressing compliance and design considerations when implementing a platform strategy.

David Vázquez, Sr Director of Digital & Device Technical Operations, **Pfizer**

ROUNDTABLE 4:

Optimizing Formulation Strategies for Combination Drug Products for Seamless Integration
- Key considerations in tailoring drug formulations for optimal compatibility with delivery systems
- Navigating CMC complexities to ensure robust development and regulatory compliance

Jamie Tsung, Head of DP Formulation, CMC, **Alnylam Pharmaceuticals**

18.00 **Chair's Closing Remarks and End of Focus Day**

Main Conference Day 1
Morning Plenary
Tuesday April 29, 2025

07.30 **Registration & Coffee**

08.20 **Chair's Opening Remarks**
Nicholas Mandala, VP Medical Devices & Combination Products Technology, **Pfizer**

OPENING ADDRESS

08.30 **Power of AI for Accelerating Combination Product Development from a Submission and Clinical Standpoint**
- Leveraging AI in design controls and GMP operations
- Future opportunities for utilising AI and computer simulation, starting from modelling device performance to bioavailability and extension into running full in silico trials

Nicholas Mandala, VP Medical Devices & Combination Products Technology, **Pfizer**

08.55 **Considerations for phase-appropriate drug-device combination (DDC) product development**
- Introduction to approaches and key factors affecting development strategy
- When is the best time to introduce a device into clinical studies?
- Strategies and examples of bridging to a DDC product
- Stakeholders alignment across the organization

Daniel Davenport, Associate Director Early Engagement and Deviceability, **GSK**

09.20 **Session Reserved for Crux Product Design**

09.45 **Introductory Short Presentation: An Update: The Evolving Drug Delivery Device Landscape**
Theresa Scheuble, Head of Design and Innovation, **Johnson & Johnson**

09.55 **Advisory Board 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 and its impact on drug delivery and device design, including self-injection device demand
- Evaluating AI's effectiveness in healthcare and its real-world applications in drug discovery, delivery and patient care
- Approaches for mapping device needs and patient preferences for emerging injectable therapies touching on the rise of the GLP-1 market
- Identifying key drivers of successful partnerships in pharma, devices, and digital health, and forecasting future trends in healthcare, keeping sustainability in mind

Confirmed Advisory Board Members:
Theresa Scheuble, Head of Design and Innovation, **Johnson & Johnson**
Bharat Arora, Director, Global Combination Products Quality, **Moderna**
Subhi Saadeh, Sr. Manager – Device/Combination Products, **Gilead**
Ravi Kaushik, Vice President, Global Head of Device/Digital Innovation & Product Strategy, PDT, **Takeda**
Sujit Basu, Vice President & Head, Pharmaceutical Development, **Ionis**
Nicholas Mandala, VP Medical Devices & Combination Products Technology, **Pfizer**
Dany Doucet, Director Early Engagement and Deviceability, **GSK**

10.20 **Session Reserved for Instron**

10.45 **Morning Networking Break**

11.20 **Quality by Design: Enhancing Safety, Efficacy and Manufacturability of your Injection Device**
- Introduction to the quality by design framework
- How to maximise product safety and efficacy
- Insight into improving development efficiency and aligning design controls
- Ensuring labelling and IFUs are patient centric

Subhi Saadeh, Sr. Manager – Device/ Combination Products External Quality Operations, **Gilead**

11.50 **Navigating the Drug Delivery Device Development process**
- Why it is so important to have a customer centric approach in order to develop a new medical device
- Which advantage in having a full turnkey service
- Two case studies: why being fast and fl exible add value to the customer

Alfredo Ricci, CEO, Althena Medical

12.15 **Device Submission Acceleration Using Platform Strategy**
- Share acceleration levers utilized to conduct multiple human factors studies, execute a clinical study and accelerate a device submission
- Includes details related to leveraging an existing device platform strategy while balancing other portfolio priorities
- Includes key learnings toward replication of this strategy across other device programs

Lisa Ray, Executive Director Program Management – Delivery, Device & Connected Solutions, **Eli Lilly**

12.45 **The Vendor Perspective: Approaching Challenges That Can Derail Combination Product Development**
- The Situation: Review of the common pain points experienced in BioPharma / Device Supplier partnerships and the resulting delays, setbacks and resource drains
- Suppler-Driven Solutions: OEM and CMO strategies for stronger alignment, collaboration, and impact
- BioPharma-Driven Solutions: Best practices for planning/ budgeting, cross-functional alignment, vendor management, regulatory strategy, QMS set up, and postmarket systems

Craig Voellmicke, Director of Sales, **Suttons Creek**

13.10 **Advancing Approaches to Combination Product Test Method Development and Validation**
- Applying statistical techniques and ISO11040 standards for robust method validation in pre-filled syringes and combination products
- Integrating a device vs. drug quality risk management process to enhance the lifecycle approach for combination products
- Identifying critical variables, setting test limits, and establishing acceptance criteria to ensure effective test method validation
- Leveraging data science and understanding manufacturing processes, including special considerations for destructive testing, to optimize combination product testing

Gretchen Piwinski, Senior Manager, Combination Products, **Regeneron**

13.40 **Networking Lunch**

Main Conference Day 1
Afternoon Streams
Tuesday April 29, 2025

Stream A: Device Innovations for Large Volume and Novel Drug Product Delivery

STREAM SPONSORED BY EdgeOne medical

14.50 **Chair's Opening Remarks**
Mark DeStefano, Director, Combination Products and Device R&D, **Teva Pharmaceuticals**

15.00 **Innovation for Drug Delivery Devices: What's Needed and What's Next?**
- Fostering Innovation: Key steps the industry must take to drive research and development for cutting-edge drug delivery devices
- Learning from Experience: Lessons from past device successes and challenges to inform future advancements and strengthen the case for newer developments
- Pharma's Perspective: what are we looking for in drug delivery devices such as autoinjectors and wearables

Martin McLoughlin, Vice President, Device and Delivery Technologies, **Apogee Therapeutics**

15.30 **Session Reserved for Edgeone Medical** EdgeOne medical

16.00 **ELVIS - Evaluation of Large Volume Injection Study in Human Subjects**
- Rising drug dose volumes have led to the adoption of large-volume injection devices, with several recent drug approvals including these devices
- Understanding patient perspective of these large volume injections: A 30-subject study was conducted to assess pain levels and user preferences across different injection volumes, speeds, and device types
- Findings highlight key considerations in indications utilizing large drug volumes. Key findings are centred around the following:
- Where does injection pain come from and does the device type influence injection pain?
- What are the effects of injection site location on the pain experienced during an injection?
- What injection/device preference would user have after experiencing various injections?

Mark DeStefano, Director, Combination Products and Device R&D, **Teva Pharmaceuticals**

16.30 **Afternoon Networking Break**

17.00 **Dual Sourcing Prefilled Syringe Device Development**
- Approach to maintaining syringe barrel subassembly supply for high viscosity monoclonal antibodies
- Effective device and drug product development partnership
- Dual sourcing regulatory considerations for drug product and device stability and comparability
- Efficient design control dual sourcing considerations

Nolan Dow, Combination Product Development Engineer, **Pfizer**

17.30 **Session Reserved for Sponsor**

18.00 **Navigating the Evaluation of Dual Chamber Devices**
- Navigating the current landscape and limitations
- Design considerations on function and usability
- Integration of the primary container and the delivery system
- Manufacturing considerations

Jayne Gavrity, Senior Device Engineer, **AstraZeneca**

18.30 **Drug Product Development for Complex Nucleic Acid Molecules: Formulation Considerations for Switching from Vial to PFS**
- Overview of siRNA Platform for Drug Delivery
- Key Considerations in Drug Product Development
- Case Study: Formulation Development of siRNA – Transition from Vial to PFS

Jamie Tsung, Head of DP Formulation, CMC, **Alnylam Pharmaceuticals**

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

Stream B: Advancing Sustainability in the Injectable Device Industry

STREAM SPONSORED BY CREDENCE MEDSYSTEMS

14.50 **Chair's Opening Remarks:**
Duncan Paterson, Senior Director of Device Development, **AstraZeneca**

15.00 **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

Duncan Paterson, Senior Director of Device Development, **AstraZeneca**

15.30 **Solving Challenges Related to Sustainability and Other Emerging Trends in Injectable Drug Delivery**
- Sustainability: An opportunity rather than an obligation
- Avoiding a compromise between sustainability and cost of ownership
- Incorporating sustainability into innovative device design
- Let's not forget about the social side of sustainability

Mark Hassett, Vice President of Business Development, **Credence MedSystems** CREDENCE MEDSYSTEMS

16.00 **Adopting EcoDesign for Packaging and Device Development**
- Barriers to implementing sustainable practices in injectables devices and their associated packaging
- The mega trends that are likely to influence future injectable devices
- Sustainability hot spots for injectable devices and how ecodesign principles, aligned to the waste hierarchy, could be leveraged to overcome them
- Case study on GSK's approach: developing sustainable future-facing packaging and injectable devices

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

16.30 **Afternoon Networking Break**

17.00 **Addressing Usability Considerations for Sustainable Devices**
- Transitioning from single-use injection devices to more durable, metal-based alternatives for long-term sustainability
- Influence of user preferences on more eco-friendly solutions on device development and design choices
- Balancing sustainability and usability - key considerations for maintaining ease of use while adopting more sustainable materials and practices in drug delivery devices

Matt Marber, Senior Usability Engineer, **Novo Nordisk**

17.30 **Session Reserved for Sponsor**

18.00 **Determining areas for Improvement During Product Lifecyle**
- An updated review on environmental challenges and opportunities for the biopharmaceutical sector, from design to end-of-life management
- Review of lifecycle assessment tools and approaches
- Successfully implementing life cycle assessment data into device & packaging design

Confirmed Senior Representative, BioPhorum

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

Main Conference Day 2
Morning Plenary
Wednesday April 30, 2025

08.00 **Registration & Coffee**

08.50 **Chair's Opening Remarks**
Kinsuk Shah, Senior Advisor Combination Products, **Boehringer Ingelheim**

OPENING ADDRESS

09.00 **From Drug Development to Successful Combination Product**
- Aligning drug development with evolving therapeutic delivery needs for combination products
- Key criteria for selecting the right partners to support early-stage development through commercialization
- Case study on the journey from concept to approval, highlighting regulatory, design, and testing insights for combination products

Sujit Basu, Vice President & Head, Pharmaceutical Development, **Ionis**

09.30 **Driving Patient Centricity in Biosimilars Development and Device Strategies**
- Exploring the latest advancements in biosimilar development and implications for device requirements, including customisation for complex therapies
- Case studies: challenges and experiences in biosimilar device development, regulatory hurdles and patient centric design
- Strategies for adapting device platforms to accommodate a diverse portfolio of biosimilars, improving scalability and time to market

Kinsuk Shah, Senior Advisor Combination Products, **Boehringer Ingelheim**

10.00 **Session Reserved for Gerresheimer**

gerresheimer
innovating for a better life

10.30 **Morning Networking Break**

11.00 **Innovative Approaches in Biopharmaceutical Formulation and Delivery: Enhancing Safety, Performance, and Stability**
- Robust Primary Container System Selection: Investigation of needle clogging & coring in elastomeric needle shields of pre-filled syringes using advanced imaging techniques, material characterization, and predicative modelling to inform effective mitigation strategies
- Advanced Characterization Techniques: Utilizing imaging and analytical models, studies on plunger movement, siliconization, and protein formulation stability provide critical insights for optimizing pre-filled syringe performance and drug delivery
- Optimizing Injectability Through Innovation: Analysis of high-concentration suspensions and the factors influencing needle clogging, providing insights into formulation and device design to enhance injectability and ensure accurate drug delivery

Guangli Hu, Director, Device Development & Technology, **Merck**

11.30 **Overcoming challenges and avoiding pitfalls of PFS Labeling**
- Considerations for successful PFS label design
- Material, ink, varnish, and adhesive selection
- Achieving the best user experience
- Specialty packaging designs
- Manufacturing considerations
- Dual Frequency RFID/NFC advantages
- Case studies

Paul Reyland, Director of Sales, **CCL Healthcare**

CCL

12.00 **Considerations for early technology evaluation for injection devices**
- Patient-centric evaluation: incorporating early human factors evaluations to inform use case boundaries
- Technical approaches to maximize characterization when drug product is scarce or unknown
- Balancing use, technical, and manufacturing trade-offs in technology selection

Megan Heft, Director, Device Development, **AstraZeneca**

12.30 **Helping Licence Holders, CDMOs and Suppliers Speak the Same Language: Aligning Risk Assessments for Streamlined Submissions**
- Licence holders, suppliers and CDMOs often have different ratings and take approaches to the same hazards when conducting risk assessments
- This also applies to the terminology used, often referring to the same hazards in different ways, all of which can result in unnecessary over testing in mitigation, and lead to delays and further requests for clarification following submissions
- BioPhorum's Risk Management team is creating a library of common hazards and harms
- This will help to streamline and harmonize ratings across sponsors, CDMOs, suppliers, helping to make submissions across the industry more consistent and with more predictable results

Confirmed Senior Representative, BioPhorum

13.00 **Hidden but Vital: The Importance of Biocompatibility for Patient Safety**
- What is biocompatibility and why is it important for combination product safety
- The evolution of biocompatibility standards
- Where should biocompatibility be considered in combination product development
- Impact of biocompatibility on final product

Amardeep Hoonjan, Director Device R&D Lead, Biocompatibility Group, **AbbVie**

13.30 **Networking Lunch**

Main Conference Day 2
Afternoon Streams
Wednesday April 30, 2025

Stream A: Primary Packaging and Building Successful Supplier Relationships

STREAM SPONSORED BY MITSUBISHI GAS CHEMICAL / ZEON

14.30 **Chair's Opening Remarks**
Soumen Das, Delivery System Qaulification Lead, **Takeda**

14.40 **Developing a comprehensive primary container strategy for new modality programs**
- Assessing growth of new modalities (such as siRNA or AAV) and implications for primary containers including the need for deep cold storage
- Delving into the use and role of polymers in development
- Best practices for ensuring regulations are successfully met to ensure a safe end product
- Considering fill-finish and transportation in earlier stages of development while aligning with the CMO processes

Fletcher Dix, Sr. Process Characterization and Technology Engineer, **Regeneron**

15.10 **Oxycapt Vial & Syringe: High Gas Barrier Container for Biologics and Cell & Gene Therapy Products Sorted with Dry Ice or LN2**
- Overview of OXYCAPT Vial & Syringe
- Oxygen & Carbon Dioxide Barrier
- Break Resistance at Dry Ice & Liquid Nitrogen Storage
- CCIT at Dry Ice & Liquid Nitrogen Storage
- Carbon Dioxide Barrier & pH Shift after Freezing & Thawing Process

Masashi Miura, Researcher,
Mitsubishi Gas Chemical Company, Inc

15.40 **Exploring the Non-linear Friction Effects in a Pre-filled Syringe System**
- The interface between the syringe and stopper is most crucial for functional performance of the prefilled syringe system and the value in gaining a deeper understanding of this system will be presented
- A prefilled syringe system features a tribological contact mechanism between the glass wall and stopper that results in friction and deformation which ultimately govern the functional aspects such as break loose and extrusion forces
- The various nonlinear friction effects in a syringe stopper interface such as stick-slip, presliding, stiction are discussed
- Existing models relevant to nonlinear friction effects are introduced with a demonstration on how these models may be implemented for the syringe seal. Understanding of these models can prove to be a crucial step towards modelling of the dynamic forces in a PFS which can further aid in predicting functionality and saving experimental resources

Aditya Nair, Packaging Engineer, **Pfizer**

16.10 **Afternoon Networking Break**

16.40 **Collaboration with Commercial Suppliers: Relations and Lifecyle Management**
- Best practices for setting up an effective quality agreement
- Implications on validation and verification
- Dealing with changes from suppliers

Ellie Younger, Associate Principle Engineer, **AstraZeneca**

17.10 **Session reserved for Zeon** ZEON

17.40 **Navigating Recent Updates and Preparing for Future Standards in Biocompatibility**
- Recent updates and regulatory expectations for biocompatibility testing in injectable drug devices
- Recent experiences and lessons learned from implementing biocompatibility assessments under evolving guidelines
- Forecasting the new biocompatibility standards for 2025: anticipated changes and their implications for device design and compliance

Soumen Das, Delivery System Qaulification Lead, **Takeda**

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

Stream B: Digital Health Technologies and Connected Devices: Use Cases and Clinical Trials

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14.30 **Chair's Opening Remarks:**
Sujit Basu, Vice President & Head, Pharmaceutical Development, **Ionis**

14.40 **Opening Panel Discussion:**
Connectivity, Usability and Necessity: Creating A Balance
- When should we involve software in a device, and when should we not? Considering use settings and factors such as treatment regularity, sensors and adherence
- How do we make these technologies impactful in clinical trials and financially viable for post market real world evidence studies
- Software and app development as a part of the device development process – when should it be integrated and how?
- How do we manage the risk of software being outdated when the device hits the market?

Panel Moderator:
Ravi Kaushik, Vice President, Global Head of Device/Digital Innovation & Product Strategy, PDT, **Takeda**

Panellists:
Martin McLoughlin, Vice President, Device and Delivery Technologies, **Apogee Therapeutics**
Sarah Fairfield, Associate Director, RA Device and Combination Products, **AbbVie**
Sriman Banerjee, Head of Packaging Development & CDE, **Takeda**
Jia Huang, Associate Director, Regulatory Digital Health, **Merck**

15.10 **Session Reserved for Schreiner MediPharm** schreiner MediPharm

15.40 **Navigating the Digital Frontier: The Role of Software as a Medical Device (SaMD)**
- Exploring the scope of SaMDs and applications in digital health
- Key compliance challenges, global frameworks, and best practices
- Real-world use cases and developing connected ecosystems
- Future Trends: Ethical considerations, patient safety, and the next wave of SaMD technologies

Yvette Appleby, Senior Manager Project Management, **Pfizer**

16.10 **Afternoon Networking Break**

16.40 **Best Strategies for Ensuring your Connected Ecosystem is Secure**
- Reviewing guidance and insight into FDA expectations
- Exploring requirements for manufacturers of cyber devices and related systems
- Assessing data implications on patient safety
- Maximising adoption of new technologies by designing devices for the long term as well as adaptive cybersecurity and safe patient access

Sarah Fairfield, Associate Director, RA Device and Combination Products, **AbbVie**

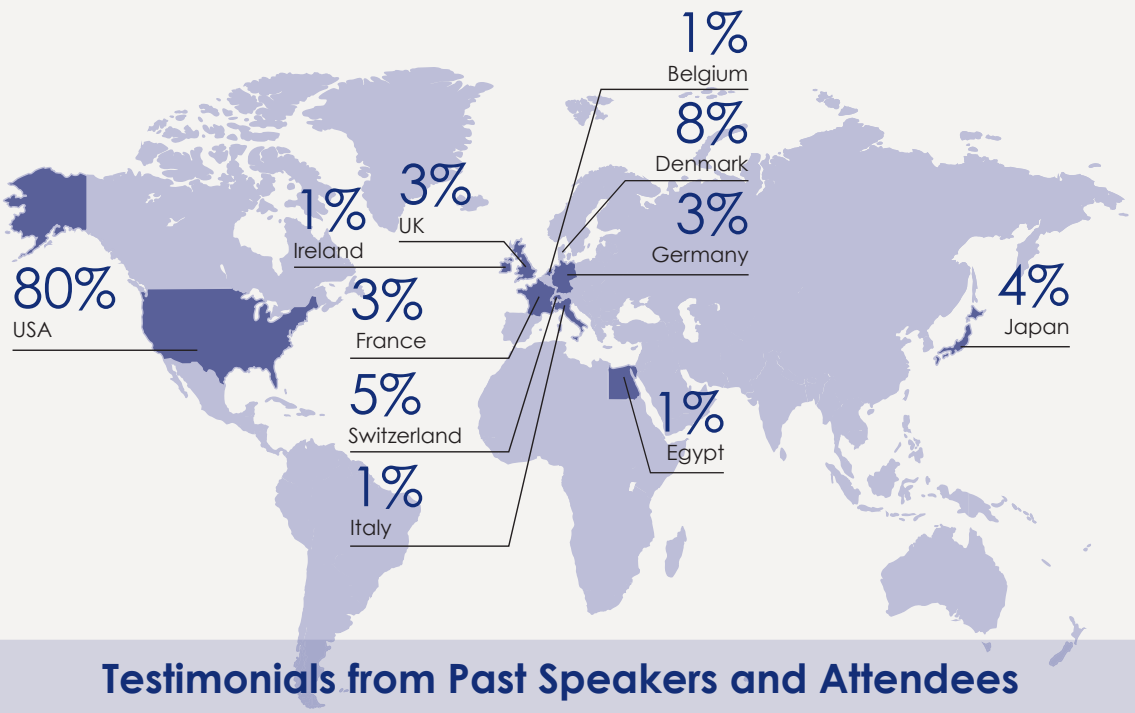
17.10 **Reserved Sponsor session**

17.40 **Digital Health Evolution: Trends in Connected Medical Devices**
- Exploring the latest advancements in connected drug delivery devices, including real-time monitoring and data integration
- Examining how connected devices are enhancing patient adherence, experience, and outcomes but also enhancing clinical trials
- Understanding the evolving requirements for digital health technologies, focusing on compliance and data security
- Future outlook on the integration of AI, machine learning, and IoT to drive the next generation of connected injectable devices

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

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

Audience Breakdown



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