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SAE MEDIA GROUP

SAE Media Group Proudly Presents the 13th Annual Conference...

PFS & INJECTABLE DRUG DEVICES

APRIL 27 - 29 2026

EAST COAST

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 13th Annual Pre-Filled Syringes and Injectable Drug Devices East Coast Conference, taking place from 27th to 29th April 2026.

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 injectable drug delivery field continues to evolve rapidly. Significant strides are being made in device technologies, including platform-based delivery systems, solutions for large-volume and highly viscous drug administration, and the integration of AI to support smarter development processes. There is a continued emphasis on usability, comfort, and adherence to enhance the patient experience. Progress is also being made in integrating sustainability practices into device development, from manufacturing to end use.

In addition to cutting-edge content, across the 3 days, the event will feature dedicated networking sessions and interactive roundtables, providing unparalleled opportunities to exchange ideas, build partnerships, and engage in meaningful discussions with industry leaders and peers.

This year's conference will not only showcase insightful 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 2026 Advisory Board

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

Bharat Arora,
Global Director, Product Quality,
Cell & Gene Therapies,
Vertex Pharmaceuticals

Subhi Saadeh,
Associate Director - MDCP QA
Gilead

Mark Howansky,
Vice President of Device Development and Commercialization,
Viridian Therapeutics

Sujit Basu,
Head of Pharmaceutical Development,
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Mark DeStefano,
Director, Combination Products and Device R&D,
Teva Pharmaceuticals

Tim Quigg,
Development Director,
Crux Product Design

Dany Doucet,
Director Early Engagement and Deviceability,
GSK

HIGHLIGHTS FOR 2026:

- **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 platform technology, and on-body injectors and autoinjectors for the delivery of large volumes and novel drug products.
- **Putting Sustainability into Practice:** Explore how leading pharmaceutical companies are integrating sustainability into device design, manufacturing, and lifecycle management.
- **Engage in Patient-centric Design:** Takeaway actionable insights for developing devices tailored to user populations.

Bringing Major Players Across Industry Together

Past Attendees Include...

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abbvie
ADVANEX
altimmune
ALMAC
Alnylam
AMERICAN REGENT
AMGEN
Apellis
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Arbutus BIOPHARMA
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What to Expect...

400+ ATTENDEES

40+ SPEAKERS

65+ BIG PHARMA AND BIOTECH COMPANIES IN ATTENDANCE

FREE FOR PHARMA AND BIOTECH TO ATTEND*

Focus day:

Explore the latest innovations shaping combination product design. This focus day covers essential considerations in device design and development, and offers the opportunity to engage in interactive roundtable discussions tackling critical challenges and sharing practical solutions.

Dedicated Afternoon Topic Streams:

Day One Stream A: Device Innovations for Large Volume and Novel Drug Product Delivery
Discover strategies for large-volume drug delivery and the latest advancements in device technology - including handheld, on-body, and near-body systems. Gain insights into patient tolerability, evolving regulatory frameworks, and emerging solutions for cell and gene therapies

Day One Stream B: Advancing Sustainability in the Injectable Device Industry
Gain insight into how industry stakeholders are embedding sustainability into injectable devices. Topics include device-specific initiatives and impact measurement, frameworks for evaluating take-back schemes, and approaches to integrating sustainability into quality systems - offering practical strategies for a more circular future.

Day Two Stream A: Primary Packaging: Ensuring Safe, Stable, and Biocompatible Combination Products
Explore key factors impacting product integrity and patient safety in combination products. Experts will discuss silicone aging in glass barrels, stability challenges in drug-device systems, and best practices for biocompatibility. The session also covers primary container design and material choices.

Day Two Stream B: Patient-Driven Device Design
Delve into solutions that truly meet patient needs by aligning device selection with user demographics and capabilities, integrating connectivity to enhance engagement and adherence, and ensuring intuitive, safe designs through rigorous usability evaluations.

PFS & INJECTABLE DRUG DEVICES

EAST COAST

April 27 - 29, 2026

Featured Speakers Include:

Aditya Sukthankar, Associate Director – GRA Device Lead – Specialty Care (Devices and Combination products), **Sanofi**

Adrienne Fletcher, Director, Packaging and Device Strategy and Innovation, **Johnson and Johnson**

Alicia Douglas, Human Factors Lead, Principal Scientist, **Merck**

Amardeep Hoonjan, Director, Biological Research, Device R&D, **AbbVie**

Amin Sedighiamiri, Senior Director, Device Development & Technology, **Merck**

Amy Wise, Associate Director, RA Emerging Technologies, Combination Products, and Devices, **AbbVie**

Ashish Pokharel, Senior Device Engineer, R&D, **AstraZeneca**

Brittany Conrad, Human Factors Engineer, **Pfizer**

Christina Van Geen Hoven, Director and Portfolio Project Lead, **Pfizer**

David Vazquez, Senior Director, Medical Devices & Combination Products (MDCP) Technical Lead, **Pfizer**

Doug Bakan, Chief Technology Officer, **Kailera Therapeutics**

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

Edward Hatton, Director Quality Assurance, External Manufacturing, **Amneal Pharmaceuticals**

Ellie Rundell, Usability Leader, Global Design and Packaging Unit, **Sanofi**

Javad Eshraghi, Senior Advisor, Device, Delivery and Connected Solutions, **Eli Lilly**

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

Johanna Schoss, Principal Human Factors Engineer, **Biogen**

Gretchen Piwinski, Sr Manager Combination Product Development, **Regeneron**

Kevin Maloney, Senior Director, Biologics Drug Product Development, **Biogen**

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

Kinsuk Shah, Senior Advisor, Combination Product Steward, **Boehringer Ingelheim**

Roy Wang, Associate Director, Device Development & Manufacturing, **Viridian Therapeutics**

Lisa Ray, Executive Director; Portfolio and Operations, Delivery, Device & Connected Solutions, **Eli Lilly**

Mark DeStefano, Global Technology Innovation, Combination Products and Device Research & Development, **Teva**

Mark Howansky, Vice President of Device Development and Commercialization, **Viridian Therapeutics**

Mayumi Bowen, Senior Principal Engineer, **Genentech**

Merin Kalapurackal, Engineer, Device Development, **Bristol Myers Squibb**

Monica Swinney, Sr. Director & Head, Drug Delivery Innovation & New Product Planning, **Gilead Sciences**

Ning Yu, Vice President, Device and Combination Product Development, **Astria Therapeutics**

Prasad Peri, AVP Regulatory Affairs Connected Delivery, Devices and Digital Health, **Eli Lilly**

Sharmad Joshi, Senior Engineer II Device Development, **Alexion**

Shirish Ingawale, Director, Device & Combination Product Development, **Takeda**

Richard Braga, Device SRM/CDMO Lead, **Takeda**

Shruti Parikh, Director, Product Design, **Takeda**

Sriram Natarjaan, Sr. Manager, Product Quality Management, **Johnson & Johnson**

Subhi Saadeh, Associate Director – MDCP QA, **Gilead**

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

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

Senior Representative, **Immunovant**

PFS & INJECTABLE DRUG DEVICES

EAST COAST

April 27 - 29, 2026

Pre-Conference Focus Day

Advances in Combination Product Design and Development

Monday 27 April, 2026

08.00 **Registration & Coffee**

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

OPENING ADDRESS

09.00 **Keeping up with the Evolving Drug Delivery Landscape, Looking to the Future and Beyond**
- Exploring the foundation of combination products
- Reviewing the evolving landscape and advancements in drug delivery
- Highlighting non-traditional routes of administration

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

09.30 **Session Reserved for Sponsor**

10.00 **Quality by Design: Enhancing Safety, Efficacy & Manufacturability of Your Device**
- Reviewing the QbD framework and its impact on device development with real-world case study insights
- Embedding safety and performance early through structured design
- Streamlining manufacturing by aligning design and process controls

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

10.30 **Morning Networking Break**

11.00 **Digital twins for dual chamber prefilled syringe autoinjectors - faster decisions, fewer builds and predict performance more accurately**
- Why digital twins? Where it pays off?
- Case study on modelling for predicting performance of dual chamber PFS in an autoinjector - reduce builds and set specs
- Playbook for future programs

Ashish Pokharel, Senior Device Engineer, R&D, **AstraZeneca**

11.30 **Session Reserved for Cambridge Design Partnership**

12.00 **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
- Benefi ts of Integration: A unifi ed framework and shared training can streamline development, enhance risk management, and improve regulatory readiness - ultimately accelerating innovation while supporting sustainability and robust product performance

Moderator: David Vazquez, Senior Director, Medical Devices & Combination Products (MDCP) Technical Lead, **Pfizer**
Panellists:
Chuck Ventura, CEO, **Ventura Solutions**
Shirish Ingawale, Director, Device & Combination Product Development, **Takeda**
Khaudeja Bano, Vice President - Global Head of Device Quality, **Roche-Genentech**
Gretchen Piwinski, Sr Manager Combination Product Development, **Regeneron**

12.30 **Networking Lunch**

13.30 **Navigating ISO 10993: Biocompatibility Requirements for Combination Products**
- Understanding the latest ISO 10993 updates and their implications for device components in combination products
- What manufacturers must do to remain compliant under the revised biocompatibility framework
- Designing for the Future: How upcoming product designs should integrate biocompatibility considerations early in development
- Practical Insights: Lessons from real-world projects where teams ensured biocompatibility alignment before launch

Amardeep Hoonjan, Director, Biological Research, Device R&D, **AbbVie**

14.00 **Session Reserved for Stevanato Group**

14.30 **Strategic Approaches in Brain-Targeted Drug Delivery: Overcoming Barriers and Fostering Collaborative Innovation**
- Addressing obstacles and innovative solutions for navigating the blood-brain barrier
- Rethinking conventional methods of drug delivery for neurological disorders
- Regulatory frameworks and phase-appropriate approaches for brain-targeted delivery systems

Mayumi Bowen, Senior Principal Engineer, **Genentech**

15.00 **DMS: Graveyard, or Treasure Trove? Rethinking the Lifecycle of Usability Data**
- Exploring how usability insights from formative and validation studies often get buried in DMS archives, despite their potential value across similar combination products
- Discuss how adopting a platform mindset - structuring studies, datasheets, and reports with consideration towards future use - and emerging AI tools could help surface patterns, reduce redundancy, and make usability data a strategic asset rather than a regulatory artifact
- Goal is to spark conversation around long-term insight mining

Ellie Rundell, Usability Leader, Global Design and Packaging Unit, **Sanofi**

15.30 **Afternoon Networking Break**

16.00 **Roundtable Discussion Sessions**

ROUNDTABLE 1:

Beyond "connectivity": Practical Digital Innovations that Improve Self-Injection Experience
- Define value in digital for patients. What matters most: Reduce errors, improve adherence or streamline onboarding?
- "Simple wins" in the development lifecycle: Low-friction digital features for combination products that scale

Leader: Amin Sedighiamiri, Senior Director, Device Development and Technology, **Merck**

ROUNDTABLE 2:

Optimizing External Collaboration in Injectable Drug Delivery
- How pharma companies can build strategic partnerships with CDMOs and device developers to streamline product development, drive innovation, and enable scalability
- Strategies to harmonize goals and operations, fostering resilient, high-performance collaborations that deliver sustainable value

Leader: Richard Braga, Device SRM/CDMO Lead, **Takeda**

ROUNDTABLE 3:

Building a Robust Combination Product Ecosystem
- Design Controls and Program Optionality: How do regulatory, quality, and design control requirements shape early decisions and documentation strategies?
- Integrating Human Factors, Design Controls, and Aggressive Timelines: What proven approaches ensure usability and reliability while meeting accelerated development schedules?

Leader: Mark Howansky, VP, Device Development & Commercialization, **Viridian Therapeutics**

ROUNDTABLE 4:

Platform Solutions in BioPharma Device Development: Opportunities and Challenges
- From Practice to Strategy: Key lessons from case studies and the operational, sustainability, and portfolio level value of platform driven approaches
- Future Outlook: Industry collaborations, evolving guidance, AI integration, and supplier perspectives shaping next-generation platforms

Leader: Shirish Ingawale, Director, Device & Combination Product Development, **Takeda**

17.30 **Chair's Closing Remarks and End of Focus Day**
Kinsuk Shah, Senior Advisor, Combination Product Steward, **Boehringer Ingelheim**

Main Conference Day 1

Morning Plenary

Tuesday 28 April, 2026

07.30 **Registration & Coffee**

08.00 **Chair's Opening Remarks**

Mark DeStefano, Global Technology Innovation, Combination Products and Device Research & Development, **Teva**

OPENING ADDRESS

08.05 **Strategic Foresight in Drug Delivery: Planning for Innovation, Scale, and Patient Impact**

- Bridging early planning with long-term device strategy with insights into how upstream planning decisions shape downstream success in platform selection, lifecycle management, and patient outcomes
- Aligning innovation with commercial and clinical realities with strategies Gilead utilizes for balancing cutting-edge delivery formats with scalability, regulatory readiness, and therapeutic relevance
- Leveraging cross-functional insights to future-proof development with practical approaches for integrating R&D, regulatory, and supply chain perspectives to de-risk device innovation
- Translating market signals into actionable platform strategy: exploring how real-world data and unmet needs inform device design choices and portfolio prioritization

Monica Swinney, Sr. Director & Head, Drug Delivery Innovation & New Product Planning, **Gilead Sciences**

08.35 **Advancing Use of Platforms for Development and Regulatory Submissions**

- Principles for developing the platform
- Modular device concept platform
- Bridging and reuse of platform concept

Amy Wise, Associate Director, RA Emerging Technologies, Combination Products, and Devices, **AbbVie**

09.00 **Session Reserved for Lead Sponsor**
Crux Product Design

09.30 **Leading the Next Wave of Obesity Treatments**

- Overview of Kailera's mission, therapeutic focus, and approach to obesity treatment
- Pipeline Highlights: Summary of key assets and clinical progress
- Exploring why GLP-1 and related mechanisms are pivotal for improving outcomes in obesity and metabolic disease
- Impact on Patient Population: Addressing unmet needs and long-term benefits of innovative drug therapies for weight management

Doug Bakan, Chief Technology Officer, **Kailera Therapeutics**

10.00 **Session Reserved for Gold Sponsor**
Suttons Creek

10.30 **Morning Networking Break**

11.00 **Fireside Chat: Driving Innovation: Gaining Stakeholder Alignment for Emerging and Existing Technologies**

- Engaging Stakeholders Effectively: Strategies to secure cross-functional alignment and leadership support for innovation initiatives
- Technology Scouting Challenges: Common pitfalls when establishing structured processes for identifying and evaluating emerging technologies
- Building Proactive Organizational Frameworks: Implementing a sustainable, scalable approach for technology adoption

Moderator:
Subhi Saadeh, Associate Director - MDCP QA, **Gilead**
Panellists:
Senior Representative, Crux Product Design
Theresa Scheuble, Director R&D Drug Delivery Systems, **Johnson & Johnson**
Mark DeStefano, Global Technology Innovation, Combination Products and Device Research & Development, **Teva**
Sujit Basu, Head of Pharmaceutical Development, **Ionis**
Mark Howansky, Vice President of Device Development and Commercialization, **Viridian Therapeutics**
Senior Representative, Kindeva

11.30 **Session Reserved for Gold Sponsor**
Instron

12.00 **Industry perspectives on delivery device circularity**

- Opportunities and challenges with injection device take-back and recycling
- Current state of the industry with injection device circularity
- Future outlook for circularity for injection devices

Duncan Paterson, Senior Director of Device Development, **AstraZeneca, Representing the Subcutaneous Drug Development & Delivery Consortium**

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

13.00 **Human Factors in the Post Market Space**

- Strategies for enabling lifecycle decisions based on usability and safety
- Bringing learnings from post market into development – Platform approach

Alicia Douglas, Human Factors Lead, Principal Scientist, **Merck**

13.30 **Networking Lunch**

Main Conference Day 1
Afternoon Streams
Tuesday 28 April, 2026

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

STREAM SPONSORED BY CREDENCE MEDSYSTEMS, EdgeOne medical

14.30 **Chair's Opening Remarks**
Amin Sedighiamiri, Senior Director, Device Development & Technology, **Merck**

14.40 **STREAM OPENING PANEL DISCUSSION: Large Volume Delivery Devices: Handheld, On Body, or Near Body delivery systems?**
- Decision frameworks and trade-offs as biologics move to higher volumes and at-home administration
- Clinical and patient factors that drive platform choice: dose frequency, injection duration, tolerability, etc
- Where each platform is winning today and why

Panel Moderator: Amin Sedighiamiri, Senior Director, Device Development and Technology, **Merck**

Panellists:
Mark DeStefano, Global Technology Innovation, Combination Products and Device Research & Development, **Teva**
Alicia Douglas, Human Factors Lead, Principal Scientist, **Merck**

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

15.40 **Combination Product Development from the Biologics Formulation and Fill-Finish Perspective**
- What good looks like for a combination product protein formulation
- High-dose/high-volume products; what are the challenges?
- Value of integrating CMC Development across Drug Substance, Drug Product, and Device

Kevin Maloney, Senior Director, Biologics Drug Product Development, **Biogen**

16.10 **Afternoon Networking Break**

16.40 **Global Device Regulatory Submission Strategies for On-body Delivery Systems**
- Key considerations when working with internal and external partners for developing effective collaborations for successful regulatory submissions
- Clinical Applications Considerations
  - Pilot Coordinated Assessment Process - European Commission – Overview and Learnings
  - Clinical study documentation strategies for global harmonization of regulatory submissions
- Marketing Applications – Navigating Pharma and Device partner regulatory submission pathways

Aditya Sukthankar, Associate Director – GRA Device Lead – Specialty Care (Devices and Combination products), **Sanofi**

17.10 **Session Reserved for EdgeOne Medical** EdgeOne medical

17.40 **Challenges in Development of Large Volume Delivery Device**
- Drug and device landscape
- Partnership between drug and device developers
- Design controls, risk management

Roy Wang, Associate Director, Device Development & Manufacturing, **Viridian Therapeutics**

18.10 **Chair's Closing Remarks and End of Day One**
Amin Sedighiamiri, Senior Director, Device Development & Technology, **Merck**

Stream B: Advancing Sustainability in the Injectable Device Industry

STREAM SPONSORED BY HASELMEIER A medmix Brand

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

14.40 **Sustainability Initiatives for Injectable Devices**
- Discuss why sustainability matters
- Share vision and key objectives
- Share device specific initiatives and global perspective
- Discuss how to measure impact and next steps

Lisa Ray, Executive Director; Portfolio and Operations, Delivery, Device & Connected Solutions, **Eli Lilly**

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

15.40 **PANEL DISCUSSION: Putting Sustainability into Practice in Combination Product Development**
- Sharing experiences with development programs and submissions
- Reviewing recent initiatives that integrate sustainability principles into the design and development of combination products, with a focus on long-term environmental impact
- Addressing key challenges including including technical, regulatory, and cultural that hinder the adoption of circular economy and sustainability models in injectable drug delivery

Panel Moderator:
Shruti Parikh, Director, Product Design, **Takeda**
Panellists:
Lisa Ray, Executive Director; Portfolio and Operations, Delivery, Device & Connected Solutions, **Eli Lilly**
Duncan Paterson, Senior Director of Device Development, **AstraZeneca**

16.10 **Afternoon Networking Break**

16.40 **Framework for evaluating takeback schemes**
- Review of current state of disposal options
- Comparing impacts of disposal methods
- Case study on value of take back scheme

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

17.10 **Session Reserved for Sponsor**

17.40 **Integrating Sustainability into Quality Systems and Life Cycle Management**
- Incorporating sustainable design principles into combination product development while maintaining regulatory compliance
- Developing risk management frameworks that integrate sustainability objectives alongside quality and safety requirements
- Discussing how post-market surveillance processes can monitor environmental impact throughout the product lifecycle to drive continuous improvement

Sriram Natarjaan, Sr. Manager, Product Quality Management, **Johnson & Johnson**

18.10 **Chair's Closing Remarks and End of Day One**
Duncan Paterson, Senior Director of Device Development, **AstraZeneca**

Main Conference Day 2
Morning Plenary
Wednesday 29 April, 2026

07.45 **Registration & Coffee**

08.20 **Chair's Opening Remarks**
Subhi Saadeh, Associate Director - MDCP QA, **Gilead**

OPENING ADDRESS

08.30 **Balancing Platform Innovation with Patient-Centric Drug Delivery**
- Exploring how platform-based delivery systems can adapt to both rare and prevalent disease conditions
- Ensuring that product design remains responsive to diverse patient needs across therapeutic areas
- Balancing scalability with customization to meet contrasting demands effectively
- Aligning platform capabilities with real-world outcomes to optimize impact and accessibility

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

09.00 **Session Reserved for Gold Sponsor SHL Medical**

SHL MEDICAL

09.30 **Rethinking Device Substitutability: Human Factors Innovation for Generics & Biosimilars**
- Challenging the Status Quo: Why replicating reference devices may perpetuate usability flaws and hinder innovation
- Human Factors Reimagined: How traditional usability testing and validation methods offer a more effective path than CUHF studies
- Real-World Study Insights: Evidence from substitutable device testing showing safe, effective use without added training or errors
- Path to Patient-Centric Design: Leveraging risk-based human factors to accelerate access to affordable, user-friendly therapies

Mark DeStefano, Director, Global Technology Innovation, Combination Product and Device R&D, **Teva**

10.00 **Session Reserved for Gold Sponsor Gerresheimer**

gerresheimer
innovating for a better life

10.30 **Morning Networking Break**

11.00 **Global Perspectives on Subcutaneous Injection: Patient Needs and Barriers Across Three Markets**
- Present findings from recent survey-based patient research conducted across three global market regions
- Identify key subcutaneous injection factors that drive patient preferences and barriers to adoption and adherence
- Provide insights into drivers for patient preferences and acceptance of product sustainability and take-back offerings
- Share implications for product development and use of conjoint analysis to evaluate "what if" scenarios to understand how changes in features and key injection factors would alter patient preferences

Adrienne Fletcher, Director, Packaging and Device Strategy and Innovation, **Johnson and Johnson**
Johanna Schoss, Principal Human Factors Engineer, **Biogen**

11.30 **Session Reserved for CCL**

CCL

12.00 **Navigating the Complexities of mRNA PFS Scale-up: Development, Timelines and Supply**
- Navigating development of PFS format selection for mRNA drug products
- Aligning device strategy with clinical and commercial timelines
- Sourcing and capacity planning challenges

Christina Van Geen Hoven, Director and Portfolio Project Lead, **Pfizer**

12.30 **Session Reserved for Gold Sponsor West Pharma**

West

13.00 **Closing the Loop: Smarter Complaint Handling for Auto-Injector Combination Products**
- Integrating Drug and Device Data Streams: Complaint investigations must go beyond isolated failure reports - combining mechanical, formulation, and human factors data to reveal the true failure story
- Predictive Insights Through Trend Analysis: Moving from reactive tracking to proactive signal detection - using complaint trend analytics to predict emerging failure modes before they trigger recalls or field actions
- Human Factors and Root Cause Rigor: Shifting investigations from "user error" to "use error" - applying human factors engineering to identify systemic design or labelling contributors often missed in device complaint reviews
- The Quality-Regulatory Continuum: Strengthening the feedback loop linking complaint handling to CAPA, risk management, and post-market surveillance - aligning with both FDA 21 CFR 4 and EU MDR Article 83 expectations

Edward Hatton, Director Quality Assurance, External Manufacturing, **Amneal Pharmaceuticals**

13.30 **Networking Lunch**

Testimonials from Past Speakers and Attendees

"Very impressive agenda and excellent presentations!"
- HEAD OF INJECTION SYSTEMS, TAKEDA

"The SAE PFS events are always really great and informative conferences"
- DIRECTOR, DEVICE DEVELOPMENT, GILEAD

"A packed agenda and an extremely informative event."
- VP MEDICAL DEVICE AND COMBINATION PRODUCT TECHNOLOGY, PFIZER

Main Conference Day 2
Afternoon Streams
Wednesday April 29, 2026

Stream A: Primary Packaging: Ensuring Safe, Stable, and Biocompatible Combination Products

STREAM SPONSORED BY MITSUBISHI GAS CHEMICAL / ZEON

14.30 Chair's Opening Remarks
Ning Yu, Vice President, Device and Combination Product Development, **Astria Therapeutics**

14.40 Silicone Aging in Glass Barrels – Risks and Mitigation Strategies
- Mechanisms of silicone degradation and its impact on drug-device compatibility
- Analytical methods for monitoring silicone aging and migration over time
- Design and formulation strategies to mitigate risks in long-term storage and use

Ning Yu, Vice President, Device and Combination Product Development, **Astria Therapeutics**

15.10 Session Reserved for Zeon

15.40 Accelerating Device Integration for Safe, Stable Combination Products
- Driving early device planning aligned with clinical and commercial expectations to shorten timelines from selection to IND submission
- Ensuring cross-functional coordination on development strategies, including DV, shipping studies, and E/L HF assessments
- Streamlining design transfer by onboarding manufacturing CMOs with robust audits, assembly line qualification, and risk-based control strategies

Senior Representative, Immunovant

16.10 Afternoon Networking Break

16.40 Stability Considerations for Combination Products
- Impact of temperature selections for stability
- Impact of drug product through accelerated stability on functional performance of device
- Case study and next steps

Sharmad Joshi, Senior Engineer II Device Development, **Alexion**

17.10 Session Reserved for Mitsubishi Gas Chemical

17.40 Closing Panel Discussion: Challenges and Opportunities in Biocompatibility for Combination Products
- Complexity of Evaluation:
  Combination drug-device products require rigorous biocompatibility assessments, aligning with global standards and cross-organizational collaboration. BioPhorum's position paper outlines these challenges
- Stakeholder Alignment:
  Evolving regulations make internal and external alignment difficult. Biopharma must optimize use of supplier data; BioPhorum is developing a collaborative supplier checklist
- Data Standardization
  Industry is moving toward reusable, platformable data to reduce redundant testing. Harmonizing global standards and defining use cases are key. BioPhorum is reviewing case studies and next steps

18.10 Chair's Closing Remarks and Close of Conference
Ning Yu, Vice President, Device and Combination Product Development, **Astria Therapeutics**

Stream B: Patient-Driven Device Design

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14.30 Chair's Opening Remarks
Shirish Ingawale, Director, Device & Combination Product Development, **Takeda**

14.40 Transitioning from Drug to Device and Incorporating Connectivity
- Addressing evolving cybersecurity expectations and challenges in connected drug delivery systems
- Insights into basics of interacting with the FDA and pre-market regulations for medical devices
- Connected Solutions and PDURS: Impact on connected devices and related systems

Prasad Peri, AVP Regulatory Affairs Connected Delivery, Devices and Digital Health, **Eli Lilly**

15.10 Session Reserved for Scheiner Medical

15.40 Patient-Driven, Targeted Enhancements That Elevate the User Experience
- Bullet points to be confirmed

Javad Eshraghi, Senior Advisor, Device, Delivery and Connected Solutions, **Eli Lilly**

16.10 Afternoon Networking Break

16.40 Choosing the right prefilled syringe design for your intended user population
- Identify user characteristics that may influence the user interface
- Understanding the market landscape for your proposed product
- Putting it together: The path to approval

Brittany Conrad, Human Factors Engineer, **Pfizer**

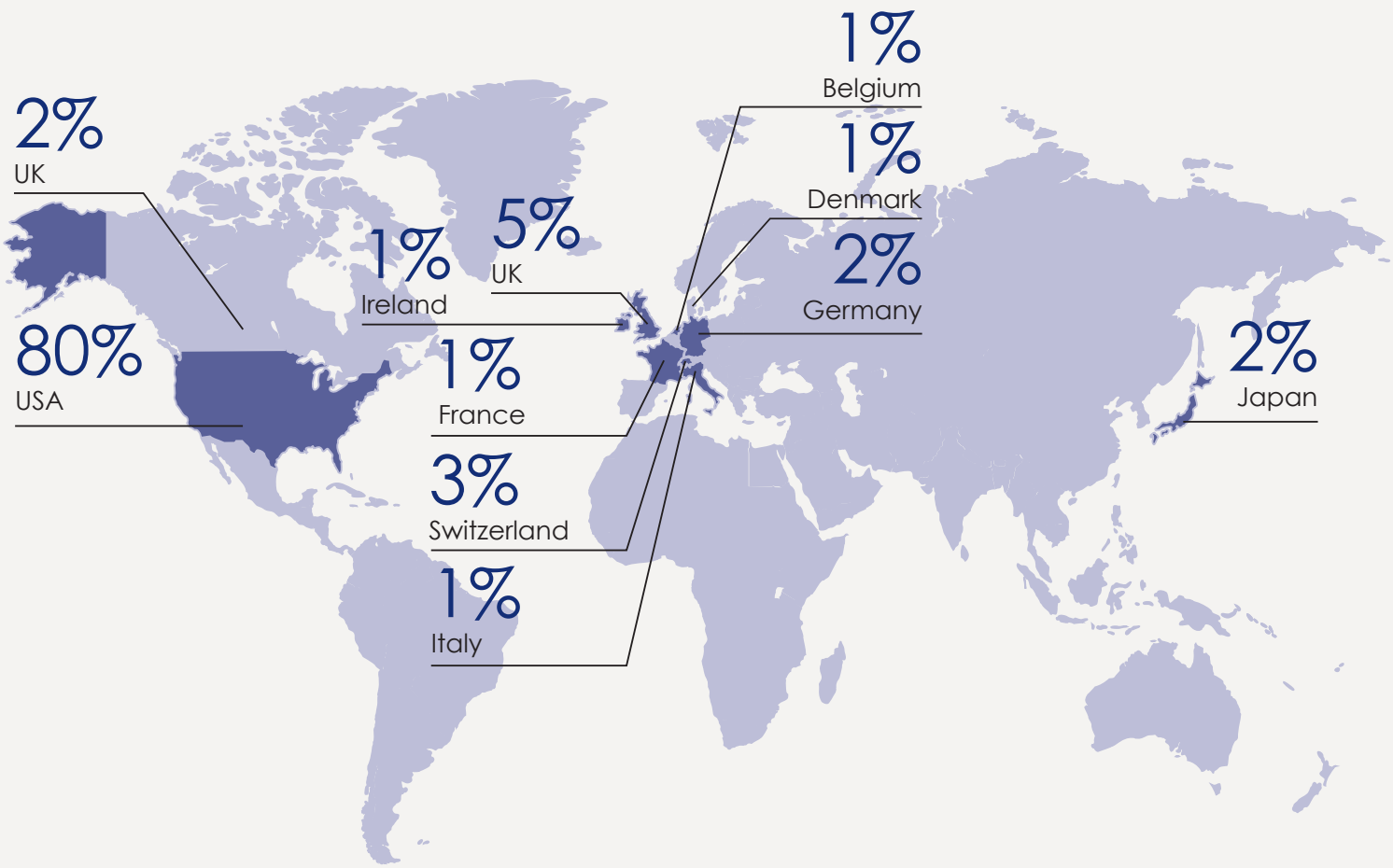
17.10 Session Reserved for Sponsor

17.40 Evaluating Usability of a Safety Syringe Device for Pediatric Indications for Clinical Readiness
- Human Factors and regulatory requirements for clinical readiness (what is required for IND)
- Case Study: Pediatric Patient SSD (risk management, IFU development, etc)
- Utilization of study results and feedback from users for clinical readiness

Merin Kalapurackal, Engineer, Device Development, **Bristol Myers Squibb**

18.10 Chair's Closing Remarks and Close of Conference
Shirish Ingawale, Director, Device & Combination Product Development, **Takeda**

Audience Breakdown



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