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SAE MEDIA GROUP

SAE Media Group Proudly Presents the 3rd Annual...

WEARABLE INJECTORS AND CONNECTED DEVICES USA

SEPT 8-9 2025

Advancing innovation and fostering collaboration to advance the future of on-body drug delivery and connected healthcare solutions

Courtyard by Marriott Boston Downtown, Boston MA, USA

HIGHLIGHTS FOR 2025:

- **Engage** in the latest approaches for enhanced device design and development with case studies on on-body injector programs from Alexion, and a device connected submission from Eli Lilly
- **Engage** in strategies for tackling large-volume and high-viscosity delivery challenges with learnings from Biogen on leveraging platform technologies
- **Explore** how to enhance drug stability and delivery effectiveness with insights from Pfizer and Novartis on formulation optimization and the importance of strong collaboration to ensure reliable and efficient therapeutic outcomes
- **Delve** into how Big Pharma are leveraging digital tools to enhance user experience, engagement and adoption

CHAIR FOR 2025:

Paul Upham,
Global Head of Smart Devices,
Genentech/Roche

FEATURED 2025 SPEAKERS INCLUDE:

- **Anjana Wills,** Head of Device Combination Products and Software Quality, **AstraZeneca**
- **Mark Harycki,** Senior Director, Device Portfolio and Program Management, **Eli Lilly**
- **Lipa Shah,** Director Science and Technology, **Novartis**
- **Yvette Appleby,** Senior Manager, Digital Health & PMO, **Pfizer**
- **George Currier,** Senior Principal Scientist, **Bristol Myers Squibb**
- **Cheng Yang,** Digital Diagnostics Lead, Drug Product and Device Development, R&D, **Takeda**
- **Harry Jiang,** Device Engineering Lead, **Alexion Pharmaceuticals**

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Wearable Injectors and Connected Devices USA

Day One | Monday September 8 2025

LETTER FROM THE CHAIR:

Dear Colleagues,

As Chair of SAE's 3rd Annual Wearable Injectors and Connected Devices USA Conference, I am delighted to welcome you to this event in Boston on September 8-9, 2025.

This year, we bring together experts and industry leaders from the injectable drug delivery and digital health domains. Across the two-day agenda, we will examine advancements in on-body drug delivery technologies and the seamless integration of digital solutions into delivery devices—key areas driving the transformation of healthcare.

The agenda will feature diverse and engaging sessions, including deep dives into device technologies for large-volume drug delivery and discussions on how connected features and digital tools are impacting patient experience and adoption. We will emphasize the importance of user-centric design, sharing insights on embedding patient-centricity into development processes and best practices for optimizing workflows for wearable injectors. Through industry outlooks and real-world case studies, we aim to foster valuable opportunities for learning, collaboration, and benchmarking.

This event provides a unique platform for exchanging knowledge, inspiring innovation, and building connections to accelerate important progress in the field. I look forward to welcoming you to Boston this September for what is set to be an unmissable event!

Yours Sincerely,

Paul Upham,
Global Head of Smart Devices,
Genentech/Roche

08.00 **Registration & Coffee**

09.00 **Chair's Opening Remarks**
Paul Upham, Global Head of Smart Devices, **Genentech/Roche**

09.10 **OPENING ADDRESS**
Future Proofing Your Injectable Device Portfolios and Pipelines

- Outlining key considerations for the evolving ecosystem for injectable devices including, diagnostics, SaMD and digital therapeutics
- Exploring the global regulatory landscape evolutions for combination product reporting and recommendations
- Best practices for ensuring safety and quality, and taking a risk-based approach

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

ENHANCING DEVICE DESIGN AND DEVELOPMENT WITH PROGRAM INSIGHTS

09.50 **Developing Phase Appropriate Requirements for Combination Products**

- Understanding the impact of performance claims vs convenience features
- Phase appropriate design control considerations throughout the lifecycle
- User needs commensurate with lifecycle phase
- Opportunities to leverage industry knowledge and experience

Anjana Wills, Head of Device Combination Products and Software Quality, **AstraZeneca**
Michael Price, Associate Director, Human Factors, **AstraZeneca**

10.30 **Morning Coffee**

11.00 **Overview of a Device Connected Submission**

- Background: Overview of the medical device development process, focusing on mechanical and electronic integration
- Key to success: Collaborating with suppliers for seamless integration through clear communication, early expectation-setting, and adherence to quality and timelines
- Platform strategies: Optimizing and streamlining future device-connected submissions and commercial supply for efficiency and scalability

Mark Harycki, Senior Director, Device Portfolio and Program Management, **Eli Lilly**

11.40 **Innovations in On-Body Injector Development: Lessons from Two Large Volume Delivery Device Case Studies**

- Outlining design strategies for on-body injectors with insights from two projects, including challenges, user-centric design, and integration with drug formulation and primary packaging
- Delving into lessons learned in adhesive performance and user interface development from the programs
- Key hurdles in gaining regulatory approval, and scaling manufacturing for market launch

Harry Jiang, Device Engineering Lead, **Alexion Pharmaceuticals**

12.20 **Patient Acceptance in Large Volume Drug Delivery**

- Understanding patient preferences in large volume drug delivery and reviewing key factors influencing patient acceptance, including comfort, convenience, and perceived ease of use
- Outlining key usability considerations such as user interaction, training needs, and patient burden, and optimizing device selection and design based on this
- Leveraging usability testing and risk assessment to enhance patient confidence and adherence
- Strategies to ensure patients can self-administer large-volume drugs safely and effectively including labelling and training

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

13.00 **Networking Lunch**

TECHNICAL STRATEGIES FOR DELIVERY OF LARGE VOLUMES AND HIGH VISCOSITIES

14.00 **Advancing Subcutaneous Delivery: A High Viscosity and High-Volume Platform Technology Approach**

- Examine design strategies and considerations to enable efficient delivery of high-volume, high-viscosity drugs through subcutaneous administration
- Assess patient tolerance and user acceptability of high-volume injectables, focusing on improving comfort and adherence
- Provide an overview of current challenges faced by wearable devices in delivering larger volumes and strategies to optimize subcutaneous delivery systems for enhanced patient experience
- Discuss emerging trends and innovations shaping the future of high-volume subcutaneous drug delivery

Cindy Tritton, Project Lead, Senior Engineer III, Technical Development, **Biogen**

14.40 **Key Performance and Quality Considerations for Wearable Injector Development**

- Overview of the latest applicable standards and regulations impacting wearable injector development
- Insights into design verification challenges and learnings to implement
- High-viscosity formulation challenges
- Human Factors and User preferences

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

15.20 **Afternoon Networking Break**

15.50 **Design Space Considerations and Highly Accelerated Stress Screening (HASS) for Combination Products**

- Understanding the design space and its potential variations for device evaluation and selection
- Applying Highly Accelerated Stress Screening (HASS) to rapidly gather insights with a limited quantity of devices
- Leveraging learnings from HASS testing to promote focused and productive early engagement during a development program

George Currier, Senior Principal Scientist, **Bristol Myers Squibb**

KEY DRUG PRODUCT AND FORMULATION CONSIDERATIONS

16.30 **Optimising Formulation for High Concentration, High Volume Drug Development and Delivery**

- Examining current paradigms in subcutaneous drug delivery for these products
- Applying a biophysical perspective to drug development
- Navigating formulation challenges and opportunities in high concentration subcutaneous injection, highlighting key focus areas

Deep Bhattacharya, Principal Scientist Formulation and Process Development – Biotherapeutics, **Pfizer**

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

Wearable Injectors and Connected Devices USA

Day Two | Tuesday September 9 2025

08.30 **Registration & Coffee**

09.00 **Chair's Opening Remarks**
Paul Upham, Global Head of Smart Devices, **Genentech/Roche**

FOSTERING SUSTAINABLE AND COLLABORATIVE TECHNOLOGY INNOVATION

09.10 **OPENING ADDRESS**
Understanding the Sustainability Impacts of Connected Devices and Wearable Injectors

- Analysing the environmental footprint of connected devices and wearable injectors, focusing on materials, manufacturing processes, and end-of-life considerations
- Exploring opportunities to reduce waste through sustainable design and recycling initiatives in the production of drug delivery devices
- Reviewing the impact of connected devices in promoting sustainability through data collection, remote monitoring, and optimising patient outcomes while reducing healthcare system burdens
- Addressing regulatory challenges and industry efforts to align wearable injectors with global sustainability goals and environmentally responsible practices

Paul Upham, Global Head of Smart Devices, **Genentech/Roche**

09.50 **Designing a product with Delivery and Device in Mind: Strategies for Early Phase Development**

- Integrating drug product and device strategies early in development
- Fostering strong collaboration between formulators, device engineers, and chemists and utilising this to optimise pipeline timelines and outcomes
- Leveraging knowledge on preclinical and clinical dosing
- Incorporating expertise from pharmacokinetics and toxicology to enhance safety and efficacy

Lipa Shah, Director Science and Technology, **Novartis**

10.30 **Morning Coffee**

11.00 **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 Principal Engineer, **AstraZeneca**

11.40 **Advancing Platform Development for Combination Products**

- Exploring the challenges and opportunities in developing products that integrate drugs, devices, and biological components
- How standardized platforms can streamline development processes, reduce costs, and ensure compliance across diverse combination products
- Reviewing the regulatory landscape and how platform approaches can address global requirements for safety, efficacy, and quality
- Discussing emerging tools and technologies that are driving innovation in the development and lifecycle management of combination products

Confirmed Senior Representative, BioPhorum

12.20 **Networking Lunch**

UTILIZING DIGITAL HEALTH TOOLS FOR AN OPTIMIZED PATIENT EXPERIENCE

13.20 **Integrating SaMD in Patient-Centric Digital Health**

- Overview of the role of Software as a Medical Device (SaMD) in advancing digital health solutions
- Highlighting the importance of digital health literacy in empowering patients to understand and utilize their healthcare data
- Examining the application of data from both patient and care provider perspectives, focusing on enhancing care delivery and outcomes
- Address barriers and enablers for the adoption of digital health tools, emphasizing strategies to foster patient and provider engagement

Yvette Appleby, Senior Manager, Digital Health & PMO, **Pfizer**

14.00 **PANEL DISCUSSION:**
Digital Health from Clinic to Commercialization: Navigating the steps to success

- Leveraging digital solutions to personalize patient experiences, improve adherence, and increase retention, all for better outcomes
- Navigating regulatory and market access challenges: key considerations for compliance, reimbursement strategies, and aligning digital health with evolving regulatory landscapes
- Best practices for ensuring a seamless transition from clinical development to market launch, maximizing adoption, and demonstrating value to stakeholders

Panel Moderator:
Paul Upham, Global Head of Smart Devices, **Genentech/Roche**
Panellists:
Ravi Kaushik, Vice President, Patient Integrated Care Innovation Platform, **Takeda**
Jia Huang, Associate Director, **Merck**
Cheng Yang, Digital Diagnostics Lead, Drug Product and Device Development, R&D, **Takeda**
Mark Harycki, Senior Director, Device Portfolio and Program Management, **Eli Lilly**

14.40 **Afternoon Networking Break**

15.10 **Advancing Digital Diagnostics as Medical Devices – From Modality to Implementation**

- Exploring how digital diagnostics enhance the functionality of medical devices, enabling real-time monitoring and improved patient outcomes
- Insight into innovations in digital diagnostic and medical device integration, focusing on seamless data exchange and user-centric design
- Future Trends in Digital Health: Highlight emerging technologies and strategies shaping the future of digital diagnostics, emphasizing their role in transforming healthcare delivery

Cheng Yang, Digital Diagnostics Lead, Drug Product and Device Development, R&D, **Takeda**

15.50 **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 PDRUS: Impact on connected devices and related systems

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

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

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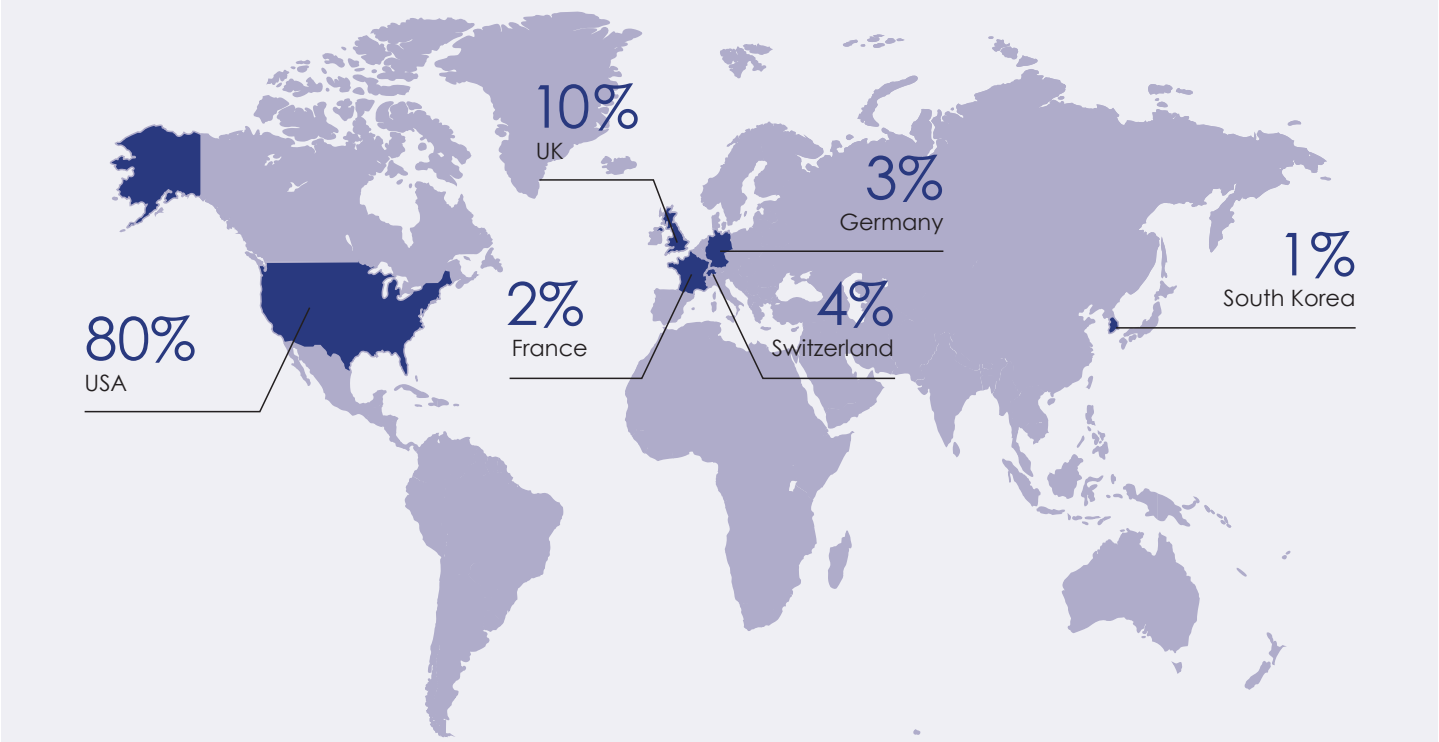

Portfolio Testimonials from Past Speakers and Attendees

"It has been an amazing conference – all of the presentations have been so interesting"

JOHNSON & JOHNSON

"The Wearable Injectors conference has gotten off to an interesting and informative start. Appreciative of the opportunity to show how using a risk-based approach can keep development programs on track and moving forward to help more patients."

BIOGEN

"Thanks for organizing a wonderful conference. It has been a great opportunity to connect with other like-minded individuals in the space"

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WEARABLE INJECTORS AND CONNECTED DEVICES USA

Monday September 8 & Tuesday September 9 2025, Courtyard by Marriott Boston Downtown, Boston, MA, USA

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