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SAE MEDIA GROUP

SAE Media Group Proudly Presents the Inaugural Roundtable Event...

PRE-FILLED SYRINGES CONNECT EAST COAST

SEPT 11 - 12 2024

The table is round, the ideas are infinite:
Focused roundtable networking for the PFS community

Courtyard by Marriott Boston Downtown, MA, USA

REASONS TO ATTEND:

ENGAGE in in-depth discussions with the injectable drug delivery community, helping advance device development strategies through the exchange of ideas and experiences.
At PFS Connect, there are no attendees, only participants!

GAIN access to 15+ roundtable discussions led by senior representatives from big pharma, biotech and device developers discussing industry's most pressing challenges.

HEAR the latest advances and innovations in device development from those at the forefront of industry through keynote presentations on topics such as wearable device development, optimising the patient experience, formulation considerations and more.

TAKE advantage of the unparalleled networking opportunities that will allow you to engage and collaborate with high level industry experts, giving you the key connections and takeaways needed to advance your device portfolio.

CHAIR FOR 2024:

Manuel Sanchez Felix, VP Drug Delivery Search & Evaluation, **Halozyme**

FEATURED EXPERTS:

Robert 'Joe' Mather, Vice President, Head of Digital Sciences and Head of Research, Development and Regulatory, **Pfizer**

Khaudeja Bano, Vice President, Combination Product Quality, **Amgen**

Soumen Das, Medical Device Qualification Lead & Associate Scientific Fellow, **Takeda**

Ram Halthore, Director of Engineering, **Merck**

E Guan, Head of Injection Systems, **Takeda**

Adrienne Fletcher, Director Packaging and Device Innovation, **Johnson & Johnson Innovative Medicine**

Kinsuk Shah, Sr. AD Combination Product Steward, **Boehringer Ingelheim**

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

Renato Ravanello, Senior Director, Device and Packaging Development, **Genentech**

www.pfsamericas-connect.com

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Bringing Major Players Across Industry Together

Past Attendees from the PFS East Coast portfolio include...

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altimmune
ALMAC
Alnylam
AMERICAN REGENT
AMGEN
Apellis
apiject
Arbutus BIOPHARMA
AstraZeneca
BD
BAUMANN MEDICAL
Biogen
bsi.
Bristol Myers Squibb
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DAY ONE | Wednesday September 11th, 2024

A letter from our Chair...

Dear Colleagues,

As chair of the conference, it is with great pleasure that I welcome you to SAE's inaugural Pre-Filled Syringes Connect East Coast Roundtable Event, taking place in Boston on the 11th and 12th of September 2024.

The event will bring together experts from the PFS community in an intimate, relaxed and engaging setting, fostering collaboration and idea exchange crucial for driving innovation in injectable drug delivery.

The agenda offers a series of roundtable discussions facilitated by industry experts sharing their invaluable expertise and experiences and will allow for deeper insights into industry challenges and emerging trends, enabling attendees to come away equipped with actionable knowledge to enhance device development initiatives. Roundtable discussions will be supported by a series of keynote presentations covering case studies and the latest developments in injectable device design and development.

As chair of this event, I look forward to welcoming you to this must-attend event this September!

Yours Sincerely,

Manuel Sanchez Felix
VP Drug Delivery Search & Evaluation, **Halozyme**

08.50	**Chair's opening remarks** **Manuel Sanchez Felix,** VP Drug Delivery Search & Evaluation, **Halozyme**			
09.00	**Opening Keynote Address: Post market safety reporting for combination products and injectable devices** •How have we seen industry adapting to meet evolving regulations through effective compliance strategies •Current guidance for industry on postmarket safety reporting for combination products •Case study examples for effective approaches to efficiently maintain global reporting compliance for combination products and injectable devices •Looking to the future how can we expect the global regulatory landscape to evolve for combination product reporting and recommendation to be best prepared **Khaudeja Bano,** Vice President, Combination Product Quality, **Amgen**			
09.30	**Session reserved for sponsor**			
10.00	**Pharmaceutical and Biotech Industry Perspectives on Optimizing Patient Experience and Treatment Adherence Through Subcutaneous Drug Delivery Design** • Busting myths around subcutaneous delivery • Overview of Subcutaneous Drug Development and Delivery Consortium • Review of a recent article on industry view of device features that optimize patient experience • Introduction to Enhanze and our new HVAI combination that enable <30 sec subcutaneous administration **Manuel Sanchez Felix,** VP Drug Delivery Search & Evaluation, **Halozyme**			
10.30	**Morning break**			
	Roundtable A: Technologies for Novel Drug Delivery	**Roundtable B: Advancing Manufacturing Capabilities**	**Roundtable C: Accelerating Industry Innovation**	**Roundtable D: Streamlining Device Development**
11.00	**Producing next generation technologies to facilitate the SC delivery of novel drug products** • How can industry accelerate development of novel technologies • Current and future opportunities for advancement and challenges to be overcome **Manuel Sanchez Felix,** VP Drug Delivery Search & Evaluation, **Halozyme**	**Overcoming manufacturing and scale up challenges for injectable drug delivery systems** • Importance of considering manufacturing in design - how do we build a bridge between manufacturing and design • Approaches and considerations for enabling scalability **Ram Halthore,** Director of Engineering, **Merck**	**As innovation in industry accelerates complex products are being designed and developed, how do members of the industry and various regulatory agencies keep up?** • Exploring industry experiences •Approaches for mitigating challenges **Khaudeja Bano,** Vice President, Combination Product Quality, **Amgen** **Adrienne Fletcher,** Director Packaging and Device Innovation, **Johnson & Johnson Innovative Medicine**	**Successful strategies for combination product risk management** •Ensuring aligned understanding • Drug vs device methodologies **Ning Yu,** Executive Director, Device and Combination Product Development, **Astria Therapeutics**
12.00	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**

DAY ONE | Wednesday September 11th, 2024

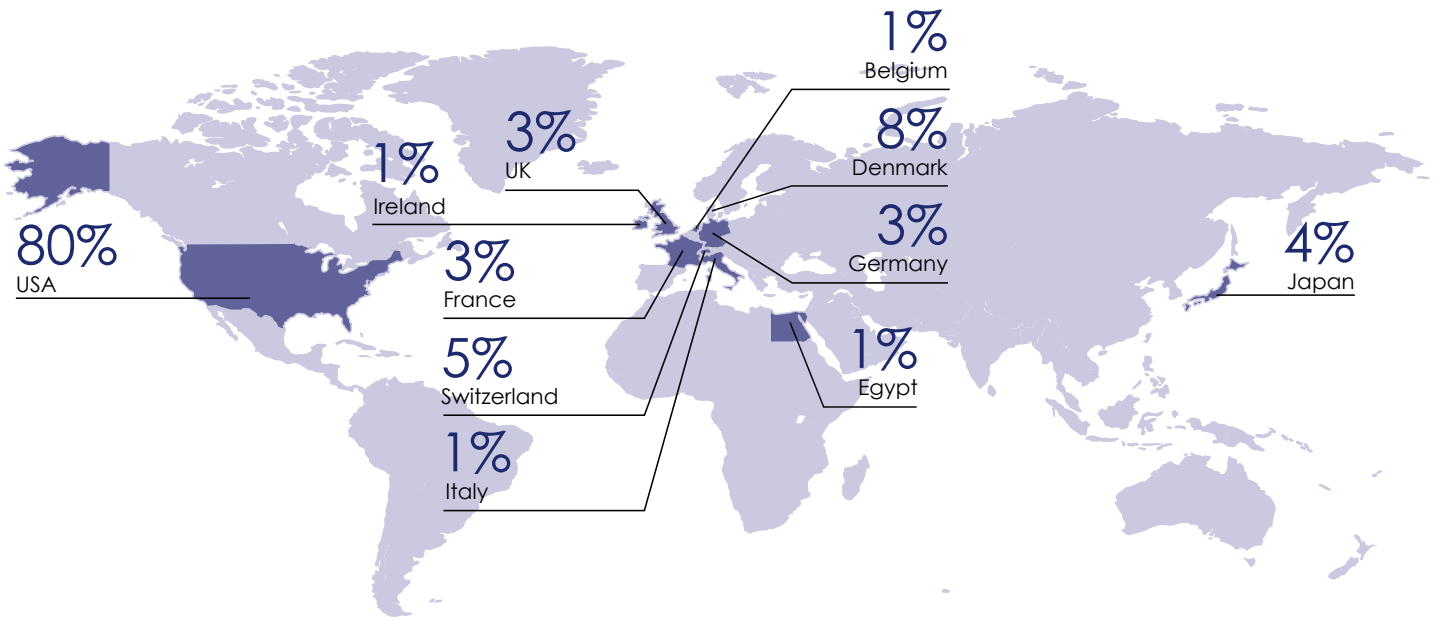
13.00	**Networking Lunch**			
	Roundtable E: Digital Health Technologies and Connected Devices	**Roundtable F: Navigating Regulatory Updates**	**Roundtable G: Assessing Human Factors Requirements**	**Roundtable H: Device Platform Approaches**
14.00	**Utilizing digital health technologies and connected devices in clinical trials** • Utilising qualified novel digital endpoints and strategies for expanding decentralized trial capabilities normalising remote monitoring in clinical trails • Impact of changing regulatory landscape post pandemic and approach to clinical trials • Making these technologies impactful in clinical trials and financially viable for post market real world evidence studies **Robert 'Joe' Mather,** Vice President, Head of Digital Sciences and Head of Research, Development and Regulatory, **Pfizer** **Sarah Fairfield,** Associate Director, RA Device and Combination Products Digital Device and Software, **AbbVie**	**Defining an effective biocompatibility strategy for clinical/regulatory success** • Lifecyle considerations • Risk assessments • Experiences with successful submissions **Soumen Das,** Medical Device Qualification Lead & Associate Scientific Fellow, **Takeda**	**Addressing critical human factors considerations through the connected product life cycle** • Reviewing key considerations from early-stage development to post-market monitoring **Leya Bergquist,** Associate Director of Human Factor, **UserWise ClariMed** **Ravi Kaushik,** Vice President, Patient Integrated Care Innovation Platform, **Takeda Pharmaceuticals**	**Effectively taking a platform approach** •Implications •Technicalities • Regulatory perspectives **Kinsuk Shah,** Sr. AD Combination Product Steward, **Boehringer Ingelheim**
15.00	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**
16.00	**Afternoon Break**			
16.30	**Maximising Patient Centricity in PFS Design** • Defining accessible patient centric design • Executing human factors and usability studies to understand patient needs and preference and successfully implementing this in PFS design • Strategies and factors to consider for balancing requirements (e.g. technical, commercial, user needs) • Case studies and trends in patient centricity **Shruti Parikh,** Director, Product Design, **Takeda**			
17.00	**Session Reserved for Sponsor**			
17.30	**Technical Considerations for the Development of a Biologic from a Frozen Vial to a Liquid Pre-filled Pen** • The presentation will highlight the development history of a biologic going from a single-dose frozen vial to a multi-dose liquid pre-filled pen. • Topics covered will include: - Formulation selection - Manufacturing considerations - Approaches for the development of a pre-filled pen presentation **Fawziya Ali,** Senior Scientist, **Pfizer**			
18.00	**Session Reserved for Sponsor**			
18.30	**Closing Remarks**			

DAY TWO | Thursday September 12th, 2024

08.50	**Chairs opening remarks** **Manuel Sanchez Felix,** VP Drug Delivery Search & Evaluation, **Halozyme**			
09.00	**Opening Keynote Address: Developing wearable injection devices: Facilitating effective drug delivery** • Insight into developing user centric devices for effective delivery of novel therapeutic products: sustained release, large volume • Optimising the therapeutic effect of injection devices: considering dose accuracy and injection related infection • Case study on wearable device development • Successful strategies for producing and commercialising of a portfolio of device and combination products **Renato Ravanello,** Director, **Genentech**			
09.30	**Session reserved for sponsor**			
10.00	**Suitability of human factors studies for patient centricity** • Bullet points to be confirmed **Senior Industry Representative to be announced**			
10.30	**Morning Break**			
	Roundtable A: **Technologies for Novel Drug Delivery**	**Roundtable B:** **Advancing Manufacturing Capabilities**	**Roundtable C:** **Accelerating Industry Innovation**	**Roundtable D:** **Streamlining Device Development**
11.00	**On-body delivery device technical and regulatory challenges** • Best practices to implement in development to work towards gaining regulatory approval • Overcoming device technology challenges **Renato Ravanello,** Senior Director, Device and Packaging Development, **Genentech**	**Quality by Design: Enhancing Safety, Efficacy and Manufacturability of your PFS** • Reviewing the quality by design framework • Maximising product safety and efficacy **Senior Industry Representative to be announced**	**Successfully integrating combination product development with wider drug product development** • Collaboration across device and drug development to ensure speed to clinic • Key factors to take into consideration **Michael Song, Expert in Aseptic Filling, Combination Product and Packaging Development and Commercialization**	**Accelerating PFS Development** • Experiences in PFS development and learnings from challenges encountered • Improving development efficiency for an accelerated product development • Deliberate partner selection for optimizing time to market **Lawton Laurence,** Head of Device & Combination Product Development, **Apellis**
12.00	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**
13.00	**Networking Lunch**			
	Roundtable E: **Digital Health Technologies and Connected Devices**	**Roundatble F:** **Navigating Regulatory Updates**	**Roundtable G:** **Assessing Human Factors Requirements**	**Roundtable H:** **Device Platform Approaches**
14.00	**Digital Health Technologies and Connected Devices** • Cybersecurity risks surrounding medical devices and role of global regualtors in reducing these risks • Guidance on implementing regulations and steps to be taken to protect patients **Senior Regulatory Representative to be Announced**	**Impact of ISO 11608-1 2022 version: industry's response and pain points** • Discussing industry's response • Current pain points and overcoming these **E Guan,** Head of Injection Systems, **Takeda**	**Reserved for Commerical Perspective**	**Reserved for Commerical Perspective**
15.00	**Closing Remarks and Early Finish**			

Audience breakdown

Geo breakdown of the PFS East Coast Portfolio



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PRE-FILLED SYRINGES EAST COAST CONNECT

Conference: Sept 11-12, 2024 | Courtyard by Marriott Boston Downtown, MA, USA

SAE MEDIA GROUP

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Our Reference	P-453

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- ☐ **Book by 28th June to receive $200 off the conference price**
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I would like to attend: (Please tick as appropriate)	Price
Big Pharma and Biotech Representatives	**FREE***

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I cannot attend but would like to Purchase access to the following Document Portal	Price	
☐ Access to the conference documentation on the Document Portal	**£699.00**	**+ VAT**

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