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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:

**Renato Ravanello,** Director, **Genentech**

## FEATURED EXPERTS:

**Dominick DeGrazio,** Early Device Project Engineering Lead, **GSK**

**Rebecca Engel,** Director, Regulatory CMC Strategy, **Pfizer, Inc.**

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

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

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

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

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

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

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

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**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
CARMOT THERAPEUTICS
Celanese
Clexio Biosciences
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CORNING
Jazz Pharmaceuticals
CREDENCE MEDSYSTEMS
CSL
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Dr.Reddy's
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Pfizer
Polyplastics
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REGENERON
Rx Bandz Built for health. Designed for life.
SHL MEDICAL
sagentia innovation
sanofi
SCHERDEL
SCHOTT glass made of ideas
schreiner MediPharm
SteriTek Expert Sterilization Services
SG Stevanato Group
Takeda
team technik PRODUCTION TECHNOLOGY
TERUMO PHARMACEUTICAL SOLUTIONS
teva
TÜV SÜD
UserWise a ClariMed company
VJ ELECTRONIX Process Control Solutions
VERTEX
WEIDMANN
WEISS-AUG GROUP MANUFACTURE SMARTER
West
ZEBRASCI
ZEON
Zwick Roell

## 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,

**Renato Ravanello,** Director, **Genentech**

| | | | |
|---|---|---|---|
| **09.00** | **Chair's opening remarks**<br>**Renato Ravanello,** Director, **Genentech** | | |
| **09.10** | **Opening Keynote Address: Strategic Combination Product Test Method Development and Validation**<br>• How have we seen industry adapting to meet evolving regulations through effective compliance strategies<br>• Current guidance for industry on postmarket safety reporting for combination products<br>• Case study examples for effective approaches to efficiently maintain global reporting compliance for combination products and injectable devices<br>• Looking to the future how can we expect the global regulatory landscape to evolve for combination product reporting and recommendation to be best prepared<br>**Leonel Vanegas,** Formerly Director, Medical Device and Combination Product Quality, **Formerly Alexion Pharmaceuticals** | | |
| **09.50** | **Panel Discussion: Optimizing patient experience and device development whilst meeting evolving regulatory requirements**<br>• Opportunities for technology innovation for enhanced subcutaneous administration and how to be prepared for new technologies<br>• Impact of evolving regulations on the device development process such as the newly released ISO11608 and FDA EDDO draft guid-ance and overcoming challenges to advance innovation<br>• Addressing unmet customer needs and challenges associated with existing technologies such as autoinjectors, with discussion of potential industry solutions for ensuring delivery of the whole dose<br>• What can industry do to ensure customer needs are met whilst also striking an effective balance between cost of goods and development stage requirements<br>***Moderator:*** **E Guan,** Head of Injection Systems, **Takeda**<br>***Panellists:*** **Dominick DeGrazio,** Early Device ProjectEngineering Lead, **GSK**<br>**Kinsuk Shah,** Sr. AD Combination Product Steward, **Boehringer Ingelheim** | | |
| **10.30** | **Morning break** | | |
| **11.00** | **Take your pick of two 40 minute roundtables** | | |
| | **1: Primary Perspective: Device Technologies for Novel Drug Products**<br>• Innovative device technologies to facilitate SC and IM delivery of novel drug products<br>• Technical challenges associated with novel drug product modalities that necessitate need for innovative device solutions<br>• Current state and opportunities to advance device technologies to support self-administration of novel drug products<br>**Dominick DeGrazio,** Early Device Project Engineering Lead, **GSK** | **3: Primary Perspective: As innovation in industry accelerates complex products are being designed and developed, how do members of the industry and various regulatory agencies keep up?**<br>• Exploring industry experiences<br>• Approaches for mitigating challenges<br>**Adrienne Fletcher,** Director Packaging and Device Innovation, **Johnson & Johnson Innovative Medicine** | **5: Accelerating PFS Development**<br>• Experiences in PFS development and learnings from challenges encountered<br>• Improving development efficiency for an accelerated product development<br>• Deliberate partner selection for optimizing time to market<br>**Ravi Kaushik, V**ice President, Patient Integrated Care Innovation Platform, **Takeda Pharmaceuticals** |
| | **2: Commercial Perspective: Device Technologies for Novel Drug Products**<br>• Innovative device technologies to facilitate SC and IM delivery of novel drug products<br>• Technical challenges associated with novel drug product modalities that necessitate need for innovative device solutions<br>• Current state and opportunities to advance device technologies to support self-administration of novel drug products<br>**Ingo Waschulewski,** Senior Sales Manager, **Gerresheimer** | **4: Commercial Perspective: As innovation in industry accelerates complex products are being designed and developed, how do members of the industry and various regulatory agencies keep up?**<br>• Exploring industry experiences<br>• Approaches for mitigating challenges<br>**Clare Beddoes,** Head of Drug Delivery, **Cambridge Design Partnership** | **6: Successfully integrating combination product development with wider drug product development**<br>• Collaboration across device and drug development to ensure speed to clinic<br>• Key factors to take into consideration<br>**Michael Song, Expert in Aseptic Filling, Combination Product and Packaging Development and Commercialization** |
| **12.30** | **Networking Lunch** | | |

## DAY ONE | Wednesday September 11th, 2024

**13.30** — Take your pick of two 40 minute roundtables

**1: 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

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

**2: Defining an effective biocompatibility strategy for clinical/regulatory success**
- Lifecyle considerations
- Risk assessments
- Experiences with successful submissions

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

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

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

**3: 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, **ClariMed**

**Ravi Kaushik,** Vice President, Patient Integrated Care Innovation Platform, **Takeda Pharmaceuticals**

**4: Effectively taking a platform approach**
- Implications
- Technicalities
- Regulatory perspectives

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

**5: 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**

**15.00** — **Afternoon Break**

**15.30** — **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**

**16.10** — **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**

**16.50** — **Closing Remarks**

## DAY TWO | Thursday September 12th, 2024

| | |
|---|---|
| **09.00** | **Chairs opening remarks**<br>**Renato Ravanello,** Director, **Genentech** |
| **09.10** | **Opening Keynote Address: Developing wearable injection devices: Facilitating effective drug delivery**<br>• Insight into developing user centric devices for effective delivery of novel therapeutic products: sustained release, large volume<br>• Optimising the therapeutic effect of injection devices: considering dose accuracy and injection related infection<br>• Case study on wearable device development<br>• Successful strategies for producing and commercialising of a portfolio of device and combination products<br><br>**Renato Ravanello,** Director, **Genentech** |
| **09.50** | **Notified Body Opinion (NBO): Submissions and Evolving Trends**<br>• Preparedness is Key<br>• Aligning Submission Structure with EU MDR<br>• Submission Experience: Expectations are Evolving<br><br>**Rebecca Engel,** Director, Regulatory CMC Strategy, **Pfizer, Inc.** |
| **10.30** | **Morning Break** |
| **11.00** | **Take your pick of two 40 minute roundtables** |

**1: Primary Perspective: 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**

**3: Primary Persepctive: Ensuring medical devices are cybersecure in an evolving environment**
• 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

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

**5: 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**

**2: Commerical Perspective: On-body delivery device technical and regulatory challenges**
• Best practices to implement in developmentto work towards gaining regulatory approval
• Overcoming device technology challenges

**Hans Jensen,** Business Development Leader, **Cambridge Design Partnership**

**4: Commercial Perspective: Ensuring medical devices are cybersecure in an evolving environment**
• 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

**Ingo Waschulewski,** Senior Sales Manager, **Gerresheimer**

| | |
|---|---|
| **12.30** | **Closing Remarks and Networking Lunch** |
| **13.30** | **Early Finish** |

### Sponsored by:

**Gerresheimer** is the innovative system and solution provider and global partner for the pharma and biotech industry. The company offers a comprehensive portfolio of pharmaceutical containment solutions, drug delivery systems and medical devices as well as solutions for the health and cosmetics industry.

The product range includes digital solutions for therapy support, medication pumps, syringes, pens, auto-injectors and inhalers as well as vials, ampoules, tablet containers, dropper bottles, other bottles and more. Gerresheimer ensures the safe delivery and administration of drugs to the patient. With 36 production sites in 16 countries in Europe, America and Asia, Gerresheimer has a global presence and produces locally for the regional markets.

With over 11,000 employees, the company generated revenues of around €1.82bn in 2022. Gerresheimer AG is listed in the MDAX on the Frankfurt Stock Exchange (ISIN: DE000A0LD6E6)

www.gerresheimer.com

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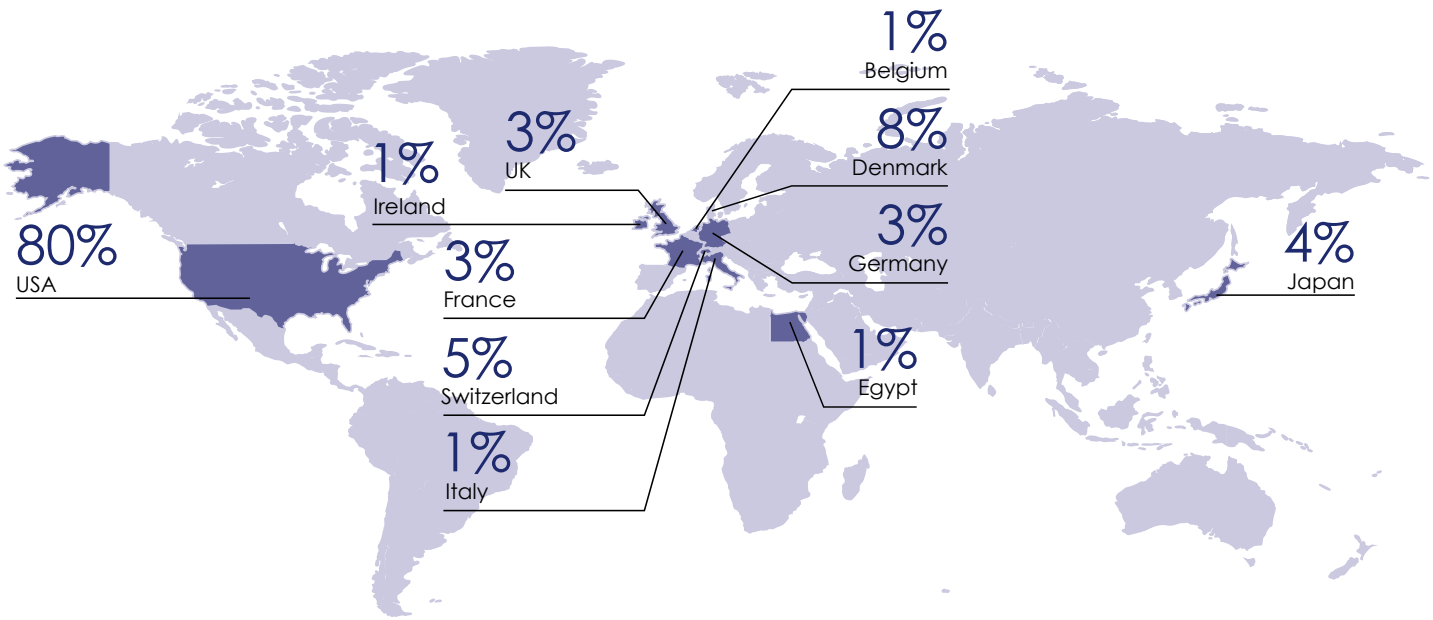
**Cambridge Design Partnership** is an end-to-end innovation partner. We build breakthrough products and services – from insight to ideas, prototypes to production. Our Drug Delivery sector focus on injection systems including auto injectors, pen injectors, wearable (OBDS) devices and infusion pumps, as well as Digital Health applications including connected drug delivery devices, diagnostics/biomarker devices, app development and cloud services.

www.cambridge-design.com

# Audience breakdown

## Geo breakdown of the PFS East Coast Portfolio

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**Michael Fraser | Head of Strategic Partnerships**
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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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**www.pfsamericas-connect.com**

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| Our Reference | P-453 |
|---|---|

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## VENUE Courtyard by Marriott Boston Downtown, MA, USA

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**EARLY BIRD DISCOUNT**

- ☐ **Book by 31st May to receive $400 off the conference price**
- ☐ **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 |
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| I cannot attend but would like to Purchase access to the following Document Portal | Price | |
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| ☐ Access to the conference documentation on the Document Portal | **£699.00** | **+ VAT** |

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VAT at 20% is charged on the attendance fees for all delegates. VAT is also charged on Document portal and literature distribution for all UK customers and for those EU Customers not supplying a registration number for their own country here

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