www.pfs-injectables.com

October 1-3, 2024
Boston, MA

FREE TO ATTEND FOR DRUG DEVELOPERS & ACADEMICS

14th Annual

Injectables Summit

Developing High-Quality Combination Devices through Design & Engineering Excellence

Turbocharging Injectable Device-Drug Compatibility, Prioritizing Design Engineering for Peak Performance & Patient Centricity

Expert Speakers Include

Li-Chun Tsou
Director, Global Device Engineering & Technologies, Global MSAT - Drug Delivery & Aseptic Technology
GSK

Richard Braga
SRM/CDMO Lead – Devices and Combination Products
Takeda

Chanaka Amarasinghe
Associate Scientific Director
Bristol Myers Squibb

Michelle Horhota Broggi
Group Leader – Senior Principal Scientist
Pfizer

Henrik Bengtsson
Senior Innovation Manager
Novo Nordisk

Claus Geiger
Global Medical Device Project Leader
Sanofi

2024 Partners

serina · enable injections · DATWYLER · IMA AUTOMATION Flawless Assembly · WuXi AppTec · West

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Welcome to the 14th Injectables Summit

As the demand for at-home patient care, high-volume injectables, and evolving regulations continues to rise, with **Teva**'s LAI EU approval for schizophrenia and **AbbVie** LAI deal **Medincell** for $1.9b, innovation is crucial for drug developers to create high-quality products. Challenges in optimal device design and chronic disease treatments underscore the need for sharing critical technical insights and peer-to-peer learning for actionable takeaways.

Returning for its 14th year, the **Injectables Summit** stands as the premier gathering of *80+ industry experts*, singularly committed to optimizing the journey of biopharma's injectable device development. From seamless drug-product device integration to meticulous validation and verification processes, we showcase state-of-the-art devices and intricate long-acting, high-volume formulations, all with a steadfast focus on prioritizing patient usability.

Spark conversations with experts amongst **Johnson & Johnson**, **Takeda**, **Regeneron** and more with 3-days of packed content spanning *Device Design*, *Engineering*, *Integration* and more this October. Be part of the discussion to get inspired by innovations in novel devices, high volume drugs for reduced frequency of administration, minimizing costs and enhancing patient centricity with accelerated timelines.

Here's What Our Attendees Have to Say:

"The collaboration with peers in the industry, was enhanced by the speed networking and roundtable discussions"

Previous Attendee, **Gilead**

"It was an incredible experience to be exposed to educational content"

Previous Attendee, **Regeneron Pharmaceuticals**

5 HIGHLIGHTS YOU CAN'T MISS:

Overcome delivery challenges of complex formulations, such as high volume, high viscosity injectables with **Johson & Johson**, **Alnylam**, **Merck** and **Pfizer** to ensure maximal efficacy and patient-centric design

Capitalize on drug-device integration and maximize compatibility early on through fostered collaboration with human factors, drug product and device engineering teams with an interactive panel from **Bristol Myers Squibb**, **Sanofi**, **Moderna** and **Johson & Johson**

Make smart decisions when developing injectable products at large scale, navigating challenges with supply and availability to ensure production continues to meet demand with **Novo Nordisk**

Master innovation and user-centric design with human factor engineering on a range of therapeutic indications from oncology to diabetes to neurology with **Sanofi** to ensure all patient population needs are met

Integrate next generation AI in combination products development with **Clearside Medical**, where automation models and predictive performance can enhance injectable pipelines beyond the traditional

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EXPERT SPEAKER PANEL

14th Annual Injectables Summit

October 1-3, 2024 | Boston, MA

Bharat Arora
Director, Global Quality
Moderna

Chanaka Amarasinghe
Associate Scientific Director
Bristol Myers Squibb

Cherry Wan
Senior Director of Engineering
Clearside Biomedical

Claus Geiger
Global Medical Device Project Leader
Sanofi

Henrik Bengtsson
Senior Innovation Manager
Novo Nordisk

Heydy Andolz
Advisor Engineer
Eli Lilly and Company

Hiten Gutka
Senior Principal Scientist
Bristol Myers Squibb

Jamie Tsung
Director
Alnylam

John Dinka
Pharma/Bio, Combo Drug Product Process Operations
Independent Expert

Joyce Zhao
Director, Combination Product Device Development
Takeda

Leilei Zhang
Associate Principal Scientist
Merck

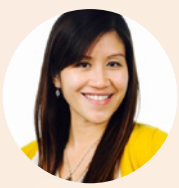
Li-Chun Tsou
Director, Global Device Engineering & Technologies, Global MSAT - Drug Delivery & Aseptic Technology
GSK

Lindsay Greczyn
Senior Device Development Engineer
Regeneron

Matthew Huddleston
Chief Technology Officer
Enable Injections

Michelle Horhota Broggi
Group Leader – Senior Principal Scientist
Pfizer

Michael Campbell
Senior Pharmacist
Johnson & Johnson



Shaoying Nikki Lee
Director of Clinical and Translational Science
Biora Therapeutics

Nirav Bhatt
Director, Device Engineering, Combination Products
AbbVie

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

Ramesh Kashi
Formerly Senior Scientific Director, Sterile Product Development
Independent Consultant

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EXPERT SPEAKER PANEL

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Randall Moreadith
Chief Development Officer
Serina Therapeutics

Richard Braga
SRM/CDMO Lead – Devices and Combination Products
Takeda

Sahab Babaee
Associate Principal Scientist - Program Lead & Device Innovation
Merck

PRE-CONFERENCE WORKSHOP DAY
TUESDAY, OCTOBER 1

14th Annual Injectables Summit
October 1-3, 2024 | Boston, MA

Workshop A — 9.00 - 11.30

Pioneering the Next Generation of Connected Devices & Digital Health to Transform Patient Adherence & Experience

In recent years, off the back of the COVID-19 pandemic, at-home patient care, and connectivity has become the norm, and this applies to self-administration and integration of connectivity in injectable devices. Now more than ever, patient centricity and adapting to these needs are ever-important. Delve into the transformative potential of connected devices in a world beyond diabetes management.

Join us in this interactive workshop to explore:

- Outlining the advantages of the use of real-time monitoring, feedback and intervention to maximize patient outcomes
- Exploring the competitive landscape for sterile injectable devices
- Understanding the strength and opportunity for connected devices
- Delving into the future outlook of drug delivery devices connected solutions to promote patient adherence and meet user needs
- Understanding human factors associated with evaluating a connected combination product
- Assessing human behavior when it comes to adding connectivity to the user interface and user experience

Leave this workshop equipped with an understanding of the direction of the future of connected devices beyond diabetes patients, and harness the full potential of connected injectables along the road to commercialization.

Workshop Leaders

Heydy Andolz
Advisor Engineer
Eli Lilly and Company

Li-Chun Tsou
Director, Global Device Engineering & Technologies, Global MSAT - Drug Delivery & Aseptic Technology
GSK

Workshop B — 12.30 - 3.00

Advancing Patient Centric Drug Products in High Concentration Formulations

With the drive for higher volume injectables, patient comfort and compliance must be addressed by minimizing injection pain and volume while maintaining dosage accuracy. Join this session to foster advancement of patient-centric drug products in high-concentration formulations for injectable combinations, enhancing therapeutic outcomes.

Join us as we delve into:

- Exploring considerations with formulation composition, dosage form design and primary packaging considerations
- Extrapolating learnings from commercial drug products and applying them for future perspectives
- Understanding the technical challenges such as stability, viscosity and volume limitations and exploring best options

Workshop Leader

Hiten Gutka
Senior Principal Scientist
Bristol Myers Squibb

CONFERENCE DAY ONE
WEDNESDAY, OCTOBER 2

14th Annual Injectables Summit
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8.30 **Morning Check-In & Light Breakfast**

Ramesh Kashi
Formerly Senior Scientific Director, Sterile Product Development
Independent Consultant

9.15 **Chair's Opening Remarks**

Prioritizing Drug Product-Device Integration for Seamless Transition

9.30 **Panel Discussion: Fostering Collaboration & Integration Between Formulation & Device Teams**

Join panelists who discuss how we can foster synergy between key stakeholders of injectable device development to optimize design, usability, and performance, ultimately enhancing user experiences and speed to market

- Aligning the goals and objectives of formulation and device teams to ensure a unified approach to product development
- Explore methods for setting shared priorities, establishing clear communication channels, and current challenges faced that act as barriers to seamless integration
- Weighing up: formulation characteristics, device characteristics and biocompatibility

Panelists:

Ramesh Kashi
Formerly Senior Scientific Director, Sterile Product Development
Independent Consultant

Claus Geiger
Global Medical Device Project Leader
Sanofi

Michael Campbell
Senior Pharmacist
Johnson & Johnson

Bharat Arora
Director, Global Quality
Moderna

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

Richard Braga
SRM/CDMO Lead – Devices & Combination Products
Takeda

10.15 **Navigating Early Integration Challenges in Combination Product Development**

- Establishing awareness and understanding the need for early engagement across teams
- Addressing risks and challenges before phase one for risk mitigation
- Preserving future combination product options by implementing strategies for flexibility in early formulation/combination product and device development

Matthew Huddleston
Chief Technology Officer
Enable Injections

Randall Moreadith
Chief Development Officer
Serina Therapeutics

10.45 **Patient-enabled Therapy for Advanced Parkinson's Disease - A Case Study with Serina Therapeutics' SER-252 + Enable Injections' enFuse Wearable Drug Delivery Platform**

- SER-252 is a long-acting POZ-polymer conjugate of apomorphine, a potent dopamine agonist capable of treating the advanced stages of Parkinson's disease
- The enFuse Wearable Drug Delivery Platform allows for large volume administration (~ 25 mL) in the comfort of the patient's home, without the need for a healthcare provider to assist in delivery
- SER-252 + enFuse has entered IND-enabling studies and is on track to enter into a Phase I clinical trial in the 2H-2025

11.15 **Morning Break & Speed Networking**

Fuel up with a fresh cup of coffee while engaging in dynamic networking opportunities with leading industry professionals committed to driving innovation in injectable devices.

CONFERENCE DAY ONE
WEDNESDAY, OCTOBER 2

14th Annual Injectables Summit
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Advancements in Large Volume Formulations & High Viscosity Injectable Drug Delivery

Jamie Tsung
Director
Alnylam

12.15 **An Overview of the Development of Novel Formulations for Injectable Delivery**

- Elevating formulation development for subcutaneous RNA delivery to improve patient experience
- Addressing challenges associated with device interaction, such as container-drug incompatibility, leaching of container components, and formulation stability issues
- Understanding how patient-centred outcomes influenced the development of the formulation

Michael Campbell
Senior Pharmacist
Johnson & Johnson

12.45 **Roundtable Discussion: Exploring Innovations to Overcome Challenges With Viscosity of Biologics & Large Volume Drugs**

- Overcoming the challenges of biologic density with high-volume formulations
- Exploring new devices for flow rate options to maximize injection administration while minimizing site discomfort and tissue damage
- Developing primary containers to support higher-viscosity products for long-acting injectables

1.30 **Networking Lunch**

Sahab Babaee
Associate Principal Scientist - Program Lead & Device Innovation
Merck

2.30 **Navigating Through the Challenges of High-Volume, High-Viscosity Combination Products**

- Understanding formulation compatibility from intravenous to subcutaneous administration
- Characterizing and quantifying PAI associated with large volume and post-injection behaviours
- Delving into device design approaches and innovating combination products to reduce injection forces

Bharat Arora
Director, Global Quality
Moderna

3.00 **Heading Quality in Combination Product Development for Optimal Performance**

- Session details to be announced

4.00 **Afternoon Break & Poster Session**

Utilizing Cutting Edge Technologies, AI & Digitalization for Advanced Combination Product Development

Joyce Zhao
Director, Combination Product Device Development
Takeda

4.45 **Leveraging Digitalization & AI for Advanced Combination Product Development**

- Overview of digitalization strategy on combination product development and post-launch lifecycle management
- Enhancing predictive capabilities to enable accurate prediction of product performance
- Optimizing design control for effective verification processes beyond limitations of traditional methods

CONFERENCE DAY ONE
WEDNESDAY, OCTOBER 2

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Chanaka Amarasinghe
Associate Scientific Director
Bristol Myers Squibb

5.15 **Utilizing AI to Advance Next-Generation Combination Products & Improve Patient Outcomes**

- Establishing automation and modelling systems to ensure efficiency
- Understanding that models are only as good as the data that is provided for accuracy
- Striking the balance between modelling and data for regulators and confidence in submissions

Cherry Wan
Senior Director of Engineering
Clearside Biomedical

5.45 **Examining the Pros & Cons of a Platformed Approach for Injectables Development**

- Exploring how platformed approaches can offer standardized components, modular design, flexibility, scalability, streamlined development for consistent quality and cost efficiency
- Patients aren't platforms: understanding your patient populations
- Maximizing efficiency by distinguishing between common tasks and unique features, focusing efforts on areas requiring attention, optimizing development processes and timelines

Ramesh Kashi
Formerly Senior Scientific Director, Sterile Product Development
Independent Consultant

6.15 **Chair's Closing Remarks**

6.30 **End of Conference Day One**

Attending Companies Include:

ALEXION · Alnylam · Bristol Myers Squibb · CIVICA · CLEARSIDE BIOMEDICAL · DATWYLER
Lilly · enable injections · FRESENIUS KABI · GSK · Genentech · GILEAD
HASELMEIER · IMA AUTOMATION · Johnson & Johnson · Kira PHARMA · MERCK · MIKRON
novo nordisk · Pfizer · REGENERON · sanofi · Takeda · teva
Ventura SOLUTIONS · ViiV Healthcare · windgapmedical · WuXi AppTec

CONFERENCE DAY TWO
THURSDAY, OCTOBER 3

14th Annual Injectables Summit
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8.30 **Morning Check-In & Light Breakfast**

9.20 **Chair's Opening Remarks**

Elevating Device Engineering & Human Factors for Patient Usability

Claus Geiger
Global Medical Device Project Leader
Sanofi

9.30 **Setting Out for a Patient-Centric Design**

- Defining medical requirements and transforming them into the injection device design
- Considerations for a user-friendly and safe use of the device when applying it to the everyday world
- Increasing significance of discussing human factors early on

Nirav Bhatt
Director, Device Engineering, Combination Products
AbbVie

10.00 **Mastering Innovation & User-Centric Design in Injectable Drug Development**

- Diving into the ongoing learning process of human factors and patient usability in injectable device design
- Sharing lessons learned across a variety of therapeutic indications across oncology, diabetes and neurology for tailored approaches
- Emphasizing the significance of user-centric approaches in enhancing patient satisfaction and treatment adherence

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10.00 **Partner Presentation: Datwyler**

- Session details to be confirmed

10.45 **Morning Break**
Enjoy a morning coffee while networking with industry experts

Navigating Quality & Manufacturing for the Injectables Landscape

Shaoying Nikki Lee
Director of Clinical and Translational Science
Biora Therapeutics

11.15 **Biojet: A novel device for Oral delivery of biologics**

- Oral delivery of biologics (Peptides, Antibodies and Nucleic acids) overcomes injection phobia and enables daily dosing
- BioJet enables needless delivery of biologics at doses similar to subcutaneous injections
- Liquid jet injection is an elegant, simple mechanical technology designed to be very cost-effective

Henrik Bengtsson
Senior Innovation Manager
Novo Nordisk

11.45 **Outlining How We Run External Innovation via The Bio Innovation HUB**

- Exploring problems we aim to solve in scalability, sustained release and new devices
- Delving into reconstitution devices as solutions
- Navigating the pros and cons of our approach

12.15 **Networking Lunch**

CONFERENCE DAY TWO
THURSDAY, OCTOBER 3

14th Annual Injectables Summit
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1.15 **Enhancing Combination Product Development: Navigating Challenges & Optimizing Interfaces**

Lindsay Greczyn
Senior Device Development Engineer
Regeneron

- Streamlining procedures to optimize approaches to enhance efficiency and effectiveness in combination product development interfaces
- Aligning project timelines and ensuring smooth coordination between design transfer and manufacturing activities
- Supporting manufacturability and process development efforts while meeting design history file requirements

2.00 **Roundtable Discussion: Navigating Fill-Finish & Future-Focused Device Manufacturing**

John Dinka
Pharma/Bio, Combo Drug Product Process Operations

- Explore the integration of RFID technology into container closures for real-time tracking and pedigree establishment while assessing the readiness of biopharma for these changes
- Examine the importance of collaboration between fill-finish vendors, pharmaceutical companies, and regulatory bodies
- Highlight the significance of quality assurance and supply chain management in ensuring product integrity and patient safety

2.45 **Afternoon Break**

Next Generation Injectable Devices, Their Development & Future Perspectives

3.15 **Forward Focus: Making Smart Decisions of Evaluating Pros & Cons When Selecting Devices**

Leilei Zhang
Associate Principal Scientist
Merck

- Performing a wholistic evaluation on whether we need devices and the considerations to take into account to make balanced and informed choices
- Exploring the considerations and weighing up the pros and cons of what device is needed and when: PFS vs autoinjector vs onbody injector and more
- Considering factors such as connectivity and advanced features, decision-makers can foster innovation in injectable device technology, leading to improved patient outcomes

3.45 **Chair's Closing Remarks**

4.00 **End of Conference**

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Datwyler - Innovation Partner

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IMA Automation North America designs and builds turn-key assembly and test systems for the medical device industry. Our engineered solutions support your assembly and test projects at every stage in the product life cycle. As part of the IMA Automation Group we offer local solutions for our global customers. From concept to prototyping, clinicals to commercialization, low to high volume production, we have the comprehensive experience and know-how to help you achieve your production goals

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OUR 2024 PARTNERS

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Drive Injectable Innovation - Partner With Us

Your Ultimate Platform to Foster New & Existing Collaborations With the Evolving Injectables Combination Product Field

As one of the longest-standing communities, the **14th Injectables Summit** will return to Boston this October to present a unique platform for **80+ Injectable Device, Design, Engineering, Integration** teams from biopharma to learn and advance their combination product development.

Biopharma companies are seeking partners who can understand their needs, collaborate effectively, and build long-term, trusted relationships. With evolving regulatory requirements and increasingly complex device designs, drug developers need support to confidently move forward.

They're looking for support in:

Devices and Components: Syringes, needles, infusion sets, and drug containers compatible with injectable products.

CMO Services: Contract manufacturing for injectable delivery devices, including injection molding, assembly, and packaging.

Testing and Validation: Ensuring reliable function, durability, and compatibility with products.

Digital and Connected Device Solutions: Technologies for data collection, monitoring, connectivity, and digital platforms for remote monitoring and adherence tracking.

Human Factors Engineering: Usability studies, ergonomic evaluations, and user interface design assessments.

Formulation and Excipient: Formulation development and stability testing to ensure product safety and effectiveness.

> "Very informative and educational"
>
> Senior Manager – Quality Engineering, **Johnson & Johnson**

Mark your calendars, and join us as a partner this October to:

Foster Existing and Forge New Connections in a setting that encourages collaboration, fosters intimate discussions and supports conversations, you won't find this elsewhere

Elevate Your Brand in a room with dedicated, focused, and like-minded individuals, the stage could be yours for the taking

Showcase Your Capabilities address biopharma frustrations with existing services and demonstrate how your solutions can overcome these challenges

LET'S TALK

Conner Robson-Wild
Partnerships Director
+1 617 455 4188
sponsor@hansonwade.com

Ready to Register?

3 Easy Ways To Book

https://pfs-injectables.com/take-part/register/

Tel: +1 617 455 4188

Email: info@hansonwade.com

1. **Build** your knowledge base and understanding with 3 days of in-depth technical insights to streamline your injectable combination product development
2. **Connect** with industry peers and forge new connections, to build lasting connections, complementary collaborations and seeking the best solution to your device requirements
3. **Discover** latest advancements and technologies from AI, to connected devices, to high viscosity devices from **Novo Nordisk**, **Takeda**, **Regeneron** and more

Drug Developer Pricing*	
Conference + 2 Workshops	FREE TO ATTEND
Conference + 1 Workshop	
Conference Only	
Academic Pricing*	
Conference + 2 Workshops	FREE TO ATTEND
Conference + 1 Workshop	
Conference Only	

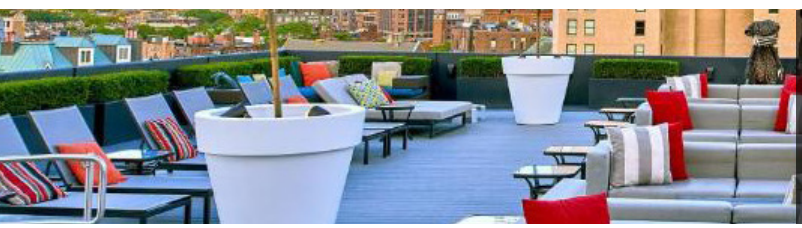
Solution Provider Pricing	Register & Pay By Friday, August 30	On the Door Price
Conference + 2 Workshops	$4,747	$5,097
Conference + 1 Workshop	$4,098	$4,398
Conference Only	$3,449	$3,699

*Eligibility criteria for a free pass states that your company must have a public drug pipeline or institution in academia, and not provide solutions or services for a fee to any other company. If eligibility criteria is not met, Hanson Wade retain the right to reject / cancel your registration.

Team Discounts*

- **10% discount – 3 Attendees**
- **15% discount – 4 Attendees**
- **20% discount – 5+ Attendees**

Make the most of **14th Injectables Summit** by attending with colleagues and registering your team. By attending as a group, you and your colleagues can make the most of the pre-conference workshops and networking sessions to ensure you leave with valuable connections and actionable insights.



VENUE

Revere Hotel Boston Common
200 Stuart St, Boston, MA 02116, United States
https://www.reverehotel.com

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

Changes to Conference & Agenda: Every reasonable effort will be made to adhere to the event programme as advertised. However, it may be necessary to alter the advertised content, speakers, date, timing, format and/or location of the event. We reserve the right to amend or cancel any event at any time. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities. Data Protection: The personal information shown and/or provided by you will be held in a database. It may be used to keep you up to date with developments in your industry. Sometimes your details may be obtained or made available to third parties for marketing purposes. If you do not wish your details to be used for this purpose, please write to: Database Manager, Hanson Wade, Eastcastle House, 27/28 Eastcastle Street, London, W1W 8DH