

Pre-filled Syringes & Injection Devices 2025

Exploring the Future of Parenteral Combination Products

December 9-10, 2025, Sheraton La Jolla, CA

Featuring Lessons Learned and Case Studies from Industry Experts:



Subhi Saadeh
Sr. Manager
Gilead Sciences



James Wabby
Head, Global Regulatory
AbbVie



Alie Jahangir
Head of Quality, CP
Biogen



Nohreen Villanueva
Sr. Manager
J&J Innovative Medicine



Khaudeja Bano
Global Director, QA
Roche/Genentech



Sasha Smiljanic
Dir. Systems Eng.
Eli Lilly & Co.



Sahab Babaee
Assoc. Director
Sanofi



Sabiha Shirol
Assoc. Director
Alnylam Pharmaceuticals



Susan Neadle
President
CP Consulting Svcs.



Jennifer Riter
VP Analytical Svcs.
Kindeva Drug Delivery



Natalie Abts
Head, HF Engineering
Roche/Genentech



Katie Curtis
Sr. Manager, HF
Design Science.



Rhea Sirkar
CP Engineer
Alnylam Pharmaceuticals



Christian Lavarreda
Bus. Strategy & Dev.
Syntegon



Fubin Wu
Co-founder
GessNet



Reto Falk
Dir. Business Dev.
Ypsomed AG



Rylie Urbanski
Tech. Dev. Engineer
ZebraSci



Michael Maust
Laboratory Manager
Noxizer



Paul Reyland
Sales Director
CCL Healthcare

And Comprehensive Coverage On:

- **Keynote: Exploring the Future of Parenteral Combination Products—Prefilled Syringes and Injection Devices**
- **Complaint Insights Supporting Lifecycle and Risk Strategy**
- **Implications of New FDA Guidances for Combination Products—Essential Drug Delivery Outputs (EDDOs) and Use Related Risk Analyses (URRAs)**
- **Quality in the Crosshairs: Managing QA Complexity in Combination Products**
- **Quantifying Early Liftoff in Autoinjectors: Insights from Formative and Simulated Use Studies**
- **A Proactive Human Factors Approach to Address Risk for Standalone Drug Products**
- **Foundational Final Assembly Design Practices for Scalable Injectable Device Manufacturing**
- **Major Trends in the Market for Self-injection: Obesity and Large Volume Injections**
- **Device-enabled Innovative Strategies for Overcoming Delivery Challenges of High-Concentration Suspensions and Lyophilized Formulations**
- **Bringing Clarity to Combination Products Risk Management**
- **Combination Product Platform Development—Considerations & Strategic Approaches**
- **A Holistic Approach to Combination Products**
- **Challenges in The Combination Products Space: Language Barriers, Misaligned Processes, and Culture**
- **Advancing Intrathecal and Intracerebral Ventricular Drug Delivery for CNS Disorders**
- **Right-Sizing Human Factors Activities: A Risk-Based Approach**
- **Nitrogen Dioxide Sterilization, the leading alternative to EO**
- **From Layers to Particles: Deep Learning for Silicone & SvP Characterization**
- **And More!**

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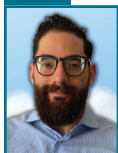
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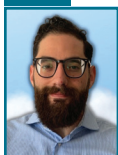


Event Sponsors:



Tuesday, December 9, 2025**7:00** Complimentary Breakfast & Registration Check-in**8:10** Co-Chairperson Subhi Saadeh's Welcome and Opening Remarks*Subhi Saadeh, Associate Director, MDCP, Gilead Sciences***Conference Keynote—The Future of Combination Products****8:15** Exploring the Future of Parenteral Combination Products—Prefilled Syringes and Injection Devices*James Wabby, Head, Global Regulatory Affairs—Emerging Technologies & Combination Products; & Volwiler Senior Research Fellow, AbbVie*

Combination products are emerging as innovative medical products due to their contribution to advancing medical care and are thus expected to have major impact in the coming years. Future technologies are most appealing to patients with ongoing medical conditions that require consistent treatment with daily injections or weekly procedures and unmet medical needs. Prefilled formats, particularly prefilled syringes (PFS), consistently help lower preparation errors and administration mishaps versus vial and syringe workflows. Parallel trends in self-injection, from insulin to biologics, shift care from clinics toward home settings, improving autonomy when designs are usable and safe. Overall, the successful development of combination products will require great collaboration within the industry to overcome partnerships, regulatory, clinical, and technical challenges.

Critical Issues—Product QA & PMS Lifecycle Strategies**8:55** Quality in the Crosshairs: Managing QA Complexity in Combination Products*Subhi Saadeh, Associate Director, MDCP, Gilead Sciences*

Quality assurance in combination products goes far beyond meeting regulatory requirements. As these products integrate drugs, devices, and biologics, QA teams face unique operational and technical challenges that stem from the complexity of cross-domain collaboration. This session explores non-regulatory hurdles such as harmonizing quality systems, managing documentation across diverse formats, coordinating change control across functional silos, and ensuring supplier quality in a fragmented ecosystem. Through practical examples and lessons learned from internal audits and quality events, attendees will gain actionable strategies

to improve system integration, enhance traceability, and foster a culture of quality that thrives in the hybrid world of combination products.

9:35 Complaint Insights Supporting Lifecycle and Risk Strategy*Nohreen Villanueva, Senior Manager of Product Quality Vigilance for Combination Products, Johnson & Johnson Innovative Medicine*

For combination products, complaint data offers a valuable source of real-world user input and customer feedback that is essential for proactive risk management and post-market surveillance (PMS). By incorporating this data early in the product lifecycle, manufacturers can better identify safety signals, usability concerns, and opportunities for improvement. These insights not only support regulatory compliance and enhance patient safety, but also inform new product development and guide targeted product enhancements. When used strategically, complaint handling shifts from a reactive compliance activity to a proactive driver of innovation, continuous improvement, and customer-focused design.

10:15 Networking Coffee Break**Critical Issues—Re-visioning Organizational Culture & Practices for Success in the Combination Product Space****10:45** A Holistic Approach to Combination Products*Khaudeja Bano, VP, Global Head of Device Quality, Roche/Genentech*

The global combination product ecosystem is constantly evolving, requiring our industry to keep pace with rapid changes and new developments. This presentation will delve into the challenges and best practices for establishing a robust infrastructure for combination products. We will define what is implicated in an end-to-end (E2E) or holistic approach to the pre-filled syringe (PFS) as a combination product lifecycle. Furthermore, we will explore current challenges and discuss effective mitigations for successful implementation within a pharmaceutical setting, focusing on the critical pillars of People, Process, and Technology.

11:25 Challenges in the Combination Products Space: Language Barriers, Misaligned Processes, and Culture*Susan W. Needle, Founder & Principal, Combination Products Consulting Services LLC*

Design, development and post-market lifecycle management of combination products bring a wide array of technical hurdles. Contending with these from a technical perspective is the focus of many standards, guidance documents and regulations. Less tangible barriers exist that combination product professionals face, often unknowingly. These include distinctly different interpretations of

common vocabulary used by pharma and device “worlds,” misaligned processes, and cultural challenges. All of these clash when the worlds collide as we integrate drugs, biologics and devices. This presentation will bring visibility to these challenges, and propose practices to overcome them.

12:05

Complimentary Lunch, sponsored by



1:15

Safeguarding Every Step of the Patient Journey



Paul Reyland, Sales Director, Western US, CCL Healthcare

Imagine a world where medicine is not only delivered, but trusted, protected, and truly connected to the people it serves. Smart packaging acts as the silent guardian of the pharmaceutical supply chain—ensuring authenticity, transparency, and safety from factory floor to patients home. Yet its greatest impact could begin once the product reaches the patient. Here, intelligent packaging has the potential to become more than a container: a bridge to future innovations such as adaptive AI health coaching—tools designed to guide, encourage, and learn alongside individuals to improve their outcomes. Together, these advances don't just safeguard products and brands—they safeguard lives, pointing toward a future of healthcare defined by confidence, connection, and empowerment at every step.

Critical Issues—Spotlight on Human Factors in Design Engineering

1:35

A Proactive Human Factors Approach to Address Risk for Standalone Drug Products



Natalie Abts, Head of Human Factors Engineering, Device and Packaging Development, Genentech

Human factors application and regulation in the healthcare space has evolved substantially in the past 15 years, and has largely focused on medical devices and combination products. However, this often means that use-related risk for standalone drug products can be overlooked. Additionally, for drugs administered only by healthcare providers and not self-administered in the home setting, there is a persistent mindset that human factors work is not necessary and that healthcare professionals can adapt to any situation to use a product successfully. Failure by manufacturers to perform due diligence at the development stages subsequently passes risk along to the users, who are often working in stressful, unpredictable environments. Through demonstration of a successful case study of applying human factors to the user interface of a standalone drug product, this presentation will demonstrate the importance of human factors even when not strictly required by health authorities, and will also identify critical inputs for determining the scale of human factors work and normalizing it with stakeholders that may have little exposure to human factors science.

2:15

Right-Sizing Human Factors Activities: A Risk-Based Approach



Katie Curtis, Senior Human Factors Manager, Design Science, Inc.

Human factors (HF) are a critical element of combination product development, traditionally culminating in an HF validation study to demonstrate safe and effective use. But did you know that HF validation may not be required for every FDA submission?

In recent years, the FDA has issued two draft guidance documents promoting a risk-based approach to HF, encouraging manufacturers to scale their efforts based on the product's design, intended use, and use-related risk profile. In some cases, the FDA acknowledges that HF validation testing may be unnecessary if supported by a robust, well-justified rationale—allowing for submission of an abbreviated HF file.

This presentation will explore the core principles behind scalable HF programs and offer practical strategies to “right-size” HF activities through realistic case studies that demonstrate when HF validation data may—or may not—be required.

An effective HF program doesn't have to be one-size-fits-all. As this presentation will show, investing in targeted front-end HF activities is key to regulatory success—whether submitting a full validation report or a streamlined HF file. A well-executed, risk-based HF strategy can reduce development costs, accelerate FDA review timelines, and help bring safe, effective products to patients faster.

2:55

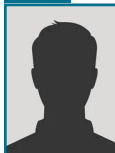
Afternoon Networking Break, Sponsored by



3:25

EdgeOne Medical Presentation

TBD



Abstract Coming Soon

3:45

Foundational Final Assembly Design Practices for Scalable Injectable Device Manufacturing



Christian Lavarreda, Director of Business Development for Processing Technology, Syntegon

Achieving scalable, high-quality injectable device manufacturing requires more than just automation—it demands a human-centered approach. This presentation explores how

optimized operator workflows, achieved through the application of user experience (UX) design and modular frameworks, are fundamental to successful tech transfer and seamless scale-up in the final assembly of injection devices. We present a case study on the configuration of a modular platform for the final assembly of any three-component auto-injectors and four-component pens, demonstrating how this approach to workflow optimization enhances not only ease of use but also product quality and manufacturing efficiency. Attendees will gain insights into how these foundational design principles drive efficiency, enhance quality, and enable seamless scale-up in injectable device manufacturing.

Panel Discussion

4:25

PFS & Injection Devices—Challenges and Opportunities

Moderator: *Subhi Saadeh, Associate Director, MDCP, Gilead Sciences*

Panelists:

James Wabby, AbbVie

Khaudeja Bano, Roche/Genentech

Sahab Babae, Sanofi

Discussants:

The Audience

5:00

Happy Hour Mixer

Join your colleagues in the hotel bar to relax, unwind, and informally network. Complimentary appetizers provided.

Wednesday, December 10, 2025

7:15

Complimentary Breakfast, Sponsored by



8:10

Co-chairperson Alie Jahangir's Welcome & Opening Remarks



Alie Jahangir, PhD, Global Head of Quality for Device and Combination Products, Biogen

8:15

From Layers to Particles: Deep Learning for Silicone & SvP Characterization



Rylie Urbanski, Technology Development Engineer, ZebraSci

Drug-device interactions can lead to various challenges and failure modes in biologic drug-device combination products, potentially impacting drug stability, efficacy,

and patient safety. BD offers a suite of advanced characterization techniques to address the challenges posed by drug-device interactions in prefilled syringes (PFS). Combining advanced surface analytics with deep learning, BD can provide actionable insights into silicone layer behavior and subvisible particle (SvP) formation. Using techniques like Quartz Crystal Microbalance with Dissipation (QCM-D), Interfacial Tension, and Water Contact Angle (WCA), silicone surfaces and drug interactions can be characterized with precision.

To take this analysis to the next level, BD has developed a deep learning model in collaboration with leading academic institutions and technology partners to achieve over 98% accuracy in classifying subvisible particles, including silicone oil droplets, protein aggregates, and air bubbles. This enables early risk detection, supports regulatory readiness, and may accelerate and de-risk development timelines. Our solution bridges the gap between formulation science and device engineering, empowering our pharma partners to make more informed and faster decisions in the development of their injectable biologic-device combination products.

Regulatory Spotlight—Implications of New FDA Guidances for Parenteral Products

8:55

Essential Drug Delivery Output (EDDO) is the New Essential Performance Requirement (EPR)



Jennifer Riter, VP of Analytical & Development Services, Kindeva Drug Delivery, & Susan W. Needle, Founder & Principal, Combination Products Consulting Services LLC



In June 2024, the FDA released a draft guidance “Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products” to provide better clarity and definition around what was previously known as Essential Performance Requirements (EPRs). The guidance describes FDA’s current thinking and recommendations related to the device design outputs that are essential for establishing and assessing drug delivery performance. The guidance includes devices and combination products that include device constituent parts that are intended for delivery of a human drug and biologics. In the presentation we will navigate the draft guidance and discuss the recommended approach to identifying EDDOs, examples of EDDOs for specific types of devices, and the information and data related to EDDOs that are provided in an application.

Technology Spotlight—A Systems Engineering Perspective

9:35

TBA

**Sasha Smiljanic, Director, Systems Engineering, Eli Lilly & Co.**

Abstract Coming Soon

10:15

Mid-morning Coffee & Networking Break

10:45

Beyond Conventional Routes: Advancing Intrathecal and Intracerebral Ventricular Drug Delivery for CNS Disorders**Alie Jahangir, PhD, Global Head of Quality for Device and Combination Products, Biogen**

Intrathecal (IT) and Intracerebroventricular (ICV) drug delivery are promising methods for treating Central Nervous System (CNS) disorders by delivering therapeutics directly to the spinal fluid or brain ventricles bypassing the Blood Brain Barrier (BBB). These techniques provide potential solutions for challenging conditions such as chronic pain, neurodegenerative diseases, and brain tumors.

Despite their potential, several challenges remain including infection risks, the need for precise device placement and complications associated with long term implantation. Furthermore, the specialized procedures required for these treatments, along with high associated costs, limit accessibility for many patients. However, significant opportunities through innovation exists. Advances in device technology, such as more precise delivery mechanisms and biocompatible biomaterials, coupled with targeted therapies, offer the potential to enhance patient outcomes while reducing side effects.

This presentation will explore these underutilized drug delivery routes and focus on emerging technologies that aim to address these challenges. By developing more efficient, patient centric delivery systems and targeting difficult to reach area of brain, we can further enhance the safety efficacy and accessibility of CNS treatments, ultimately improving patient care on a global scale.

11:25

Nitrogen Dioxide Sterilization, the leading alternative to EO**Michael Maust, Laboratory Manager for Customer Projects, Noxilizer, Inc.**

Key Points:

- Providing an overview of Sterilization options for single use drug device combination products.

- Outlining key considerations for evaluating sterilization options for your specific product needs.

- Introduction to NO2 sterilization and the benefits of this method in comparison to EO and VHP.

11:45

Complimentary Lunch, Sponsored by**Technology Spotlight—Overcoming Common Challenges in Autoinjectors**

12:55

Device-enabled Innovative Strategies for Overcoming Delivery Challenges of High-Concentration Suspensions and Lyophilized Formulations**Sahab Babaee, PhD, Associate Director, Targeted Delivery, New Device Technology Strategy & Innovation, Sanofi**

Biologics constitute a growing portion of the pharmaceutical market. Lyophilization (freeze-drying) has been employed to enhance biologics' long-term stability by removing water through multiple freezing and drying cycles, ensuring they remain stable and effective throughout their shelf life. However, the administration of lyophilized drug and vaccine formulations can be limited due to their greater propensity for needle occlusion (clogging) in existing parenteral injection systems. Here, we first identify some of the key root causes of particle jamming and needle occlusion. Then, we present an experimental approach to fully characterize the transient injection behavior of particle solutions, enabling quantification of clogging risk in suspensions and lyophilized formulations. Finally, we introduce a modeling framework applicable to a broad class of spring-driven autoinjectors with dual-chamber cartridges for lyophilized drug delivery, supporting informed device selection through simulation-led technical due diligence.

1:35

Quantifying Early Liftoff in Autoinjectors: Insights from Formative and Simulated Use Studies**Sabiha Shirol, Associate Director of Combination Products Development, Alnylam Pharmaceuticals, & Rhea Sirkar, Combination Products Engineer, Alnylam Pharmaceuticals**

Abstract Coming Soon



2:15

Afternoon Break

2:30

Platform-Based Combination Products: Maximizing Reuse, Minimizing Rework



Fubin Wu, President & Founder, GessNet

Moving an approved autoinjector to a new drug shouldn't feel like starting over. The missing piece is a well-governed platform - a versioned, end-to-end digital baseline that every variant inherits and traces. This talk shows how to define a platform as a single, auditable thread linking the Quality Target Product Profile (QTPP), Design Inputs, Critical Quality Attributes (CQAs), System Design Outputs (EDDOs), Design Outputs (specs/drawings/procedures), and the bill of materials (BOM), with verification and risk information integrated. Product variants add only product-specific setpoints; the system then triggers targeted impact analysis - no new structures to rebuild - so changes and their effects are clear, explicit, and defensible.

Attendees will learn how to:

- Structure a platform baseline with clean traceability across Quality by Design (QbD), design controls, and risk management - enabling rapid changes while ensuring safety and effectiveness.
- Manage the DHF efficiently by keeping a stable platform core and lightweight product addenda, minimizing duplication while meeting regulatory expectations.
- Make proactive change decisions and cascade impacts automatically across the platform and its variants.

3:10

Major Trends in the Market for Self-injection: Obesity and Large Volume Injections



Reto Falk, Director, Account & Business Development, Ypsomed AG

This presentation will review the latest trends in the market for GLP1s and its trajectory moving forward. How will increased competition in this sector shape the evolution of delivery and care in the not-too-distant future? For example, what role will digital health tools play? Personalized medicine? What is the impact of "lifestyle" companies (e.g., Weight Watchers and other similar companies now also supplying GLP1s through compounding pharmacies) entering the market? Key takeaways include:

- The self-injection device market today and tomorrow
- How is the market for large volume injections developing
- Decoding the obesity revolution

3:45

Close of Program



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