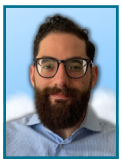
PharmaED RESOURCES, Inc.

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:

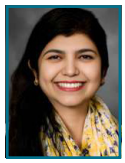


Subhi Saadeh
Founder & Principal
Let's Combinate BioWorks

James Wabby
Head, Global Regulatory
AbbVie

Alie Jahangir
Head of Quality, CP
Biogen

Natalie Abts
Head, HF Engineering
Roche/Genentech



Khaudeja Bano
Global Director, QA
Roche/Genentech

Susan Neadle
President
CP Consulting Svcs.

Sahab Babaee
Assoc. Director
Sanofi

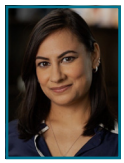
Sabiha Shirol
Assoc. Director
Alnylam Pharmaceuticals

Pujitha Gourabathini
Quality Assurance Manager
BD

Jennifer Riter
VP Analytical Svcs.
Kindeva Drug Delivery

Reto Falk
Dir. Business Dev.
Ypsomed AG

Christy Sadtler
Human Factors Engineer
Design Science.



Rhea Sirkar
CP Engineer
Alnylam Pharmaceuticals

Christian Lavarreda
Bus. Strategy & Dev.
Syntegon

Rylie Urbanski
Tech. Dev. Engineer
ZebraSci

Michael Maust
Laboratory Manager
Noxilizer

Paul Reyland
Sales Director
CCL Healthcare

Jerzy Wojcik
VP, Regulatory Affairs
EdgeOne Medical

Ali Yuksel
US Director
Moon Pharma USA

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!**

With Representation From:

GILEAD · BD (Advancing the world of health) · Roche / Genentech (A Member of the Roche Group) · ZEBRASCI (Combination Product Experts, a BD company) · Biogen · abbvie · SANOFI · Alnylam Pharmaceuticals · YPSOMED SELFCARE SOLUTIONS · Combination Products Consulting Services LLC · SYNTEGON PROCESSING & PACKAGING · Kindeva · MOON SOTRUN · DESIGN SCIENCE (Usability starts here.) · NOXILIZER · CCL · EdgeOne medical

Contact: Kim Hubbard | khubbard@pharmaedresources.com or call (217) 721-5774

Pharma Ed's Pre-filled Syringes & Injection Devices 2025 is Sponsored by:

ZEBRASCI
Combination Product Experts
a BD company

MOON SOTRUN®

CCL

NOXILIZER™

EdgeOne medical

Event Sponsors:

KERN LIEBERS

amcor

GessNET
Advance medical product safety engineering

SHL MEDICAL

element

Ventura SOLUTIONS

SMITHERS
ACCURATE DATA • ON TIME • HIGH TOUCH

SYNTEGON
PROCESSING & PACKAGING

ON drugDELIVERY

Drug Development & Delivery

Tuesday, December 9, 2025

7:00 Complimentary Breakfast & Registration Check-in

8:10 **Co-Chairperson Subhi Saadeh's Welcome and Opening Remarks**

Subhi Saadeh, Founder & Principal, Let's Combinate BioWorks

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, Founder & Principal, Let's Combinate BioWorks

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.

Regulatory Spotlight—Implications of New FDA Guidances for Parenteral Products

9:35 **Essential Drug Delivery Output (EDDO) is the New Essential Performance Requirement (EPR)**

Jennifer Riter, VP of Analytical & Development Services, Kindeva Drug Delivery, & Susan W. Neadle, 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.

10:20 *Networking Coffee Break*

Critical Issues—Re-visioning Organizational Culture & Practices for Success in the Combination Product Space

10:50 **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.

11:30 **Challenges in the Combination Products Space: Language Barriers, Misaligned Processes, and Culture**

Susan W. Neadle, 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.

12:10 ***Complimentary Lunch, sponsored by***

CCL

1:20 **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.

Device Options for Treating Obesity with Incretins: Balancing Patient Preference, Sustainability, and Cost

1:40 **Device Options for Treating Obesity with Incretins: Balancing Patient Preference, Sustainability, and Cost**

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

2:20 ***Afternoon Networking Break, Sponsored by***

EdgeOne medical

2:50 **Control Strategy Integration for Combination Products: The Role of Device Development and Specialized Support**

Jerzy Wojcik, Vice President, Regulatory Affairs and Quality Assurance Services

In today's complex and evolving landscape of combination products, earlier and integrated alignment between device development activities to define the drug control strategy is becoming critical to clinical and commercial success. Pharmaceutical leaders are increasingly recognizing the value of integrating device-related considerations into FDA interactions, particularly Type-B and Type-C Meetings, which can lead to greater regulatory clarity and more robust alignment with agency expectations. This session will explore the technical and regulatory foundations of an effective control strategy and highlight how early device considerations strengthen that foundation. We'll also demonstrate how this proactive approach enhances risk management, improves preparedness for regulatory engagement, and ultimately reduces the risk to your overall drug development program.

Technology Spotlight—Overcoming Common Challenges in Autoinjectors

3:10 **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 injec-

tion 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.

Panel Discussion

3:50 **PFS & Injection Devices—Challenges and Opportunities**

Moderator: Subhi Saadeh, Founder & Principal, Let's Combinate BioWorks

Panelists:
James Wabby, AbbVie
Khaudeja Bano, Roche/Genentech
Sahab Babaee, Sanofi

Discussants:
The Audience

4:30 **Beyond the Bubble: How Filling Process Control and Headspace Strategy Cut False Rejects in AVI**

Ali Yuksel, US Director of Operations, Moon Pharma USA

High false reject rates (FRR) in automated visual inspection (AVI) are often misdiagnosed as an inspection problem when they are, in fact, a filling process problem. Bubbles entrained during filling are frequently misclassified as particulates, and even advanced AI classifiers are challenged by defects masking particles. This presentation explores the upstream solution: how a precisely controlled filling curve (ramp, soak, deceleration) can prevent bubble formation at the source.

Furthermore, we will analyze the critical impact of product design on inspection strategy. We will discuss why traditional motion-based (spin/brake) inspection has its challenges in no-headspace syringes and how particle-to-sidewall adhesion (due to siliconization) necessitates a shift to a static, cosmetic-style inspection.

5:00 ***Happy Hour Mixer, Sponsored by***

MOON SOTRUN®

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***

ZEBRASCI Combination Product Experts a BD company

8:25 **Co-chairperson Alie Jahangir's Welcome & Opening Remarks**

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

8:30 **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 prefillable 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.

Critical Issues—Spotlight on Human Factors in Design Engineering

9:10 **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.

9:50

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

Christy Sadtler, Human Factors Engineer, 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.

10:30 ***Mid-morning Coffee & Networking Break***

11:00

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

Early liftoff—defined as premature removal of an autoinjector from the injection site before dose delivery is complete—poses a critical compromise to medical care. This presentation explores a systematic approach to quantifying early liftoff behavior using data from formative and simulated use studies. By integrating human factors engineering principles with device performance analytics, we identify key contributors to early liftoff, including user-device interface design, instructional clarity, and behavioral cues during injection.

A novel injection pad platform was employed during this study to capture real-time metrics such as device hold force, hold time, and injection duration. These quantitative parameters provide deeper insight into user interaction patterns and enable precise identification of early liftoff events. Notably, early liftoff becomes especially critical when dose frequency is low (two to four times a year), as each injection represents a significant therapeutic opportunity—making missed or incomplete doses more impactful to treatment efficacy.

The analysis leverages observational data, timing metrics, and user feedback to characterize liftoff patterns across diverse user populations including patient surrogates and lay caregivers. Insights gained inform risk mitigation strategies, design refinements, and training interventions aimed at improving injection success rates. This work underscores the importance of early-stage usability testing and advanced data capture in predicting real-world use challenges.

11:40 ***Complimentary Lunch, Sponsored by***

NOXILIZER™

12:50

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.

1:10 **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.

Spotlight on Drug Device Strategy—Making a Safety Assurance Case for Reusable Platforms

1:50 **Leveraging Safety Assurance Cases to Enable Reuse in Drug-Device Combination Products**

Pujitha Gourabathini, Quality Assurance Manager, BD

In drug–device combination product development, building a new delivery system for each drug is not practical. Reuse of approved device platforms across drugs and markets offers major benefits—efficiency, consistency, and continuous improvement. Yet in practice, moving a system to a new drug or adapting it for a specific country often feels like starting over.

The missing piece is a structured, evidence-backed narrative that supports reuse. This session introduces the Safety Assurance Case method as a solution. By organizing prior knowledge into a clear, graphical argument, assurance cases enable:

· Build a Safety Assurance Case that anchors platform safety claims and provides reusable evidence across multiple drug-device variants.

· Make proactive change decisions by cascading impacts through the assurance case, enabling rapid adaptation while maintaining regulatory and safety confidence.

· Traceable reuse across products and submissions

· Clear definition of platform boundaries (context, assumption etc.) and variant-specific changes

· Efficient adaptation to regional requirements

We'll illustrate how assurance cases can turn prior approvals into reusable assets, supporting faster development with regulatory clarity. Attendees will learn practical ways to apply this method to drug-device platform technologies, making reuse a confident, justifiable strategy.

2:35 ***Close of Program***

PharmaED RESOURCES, Inc.

PharmaEd Resources, Inc. • 2810 Robeson Park Drive • Champaign, IL 61822

About Your Destination.

La Jolla, California, has enchanted generations of travelers. Follow in their footsteps and embark on an adventure like no other with a stay at Sheraton La Jolla Hotel. Famous attractions like Torrey Pines Golf Course, the San Diego Zoo, Balboa Park, LEGOLAND and the USS Midway are all nearby. Visit celebrated academic institutions such as Birch Aquarium and the University of California San Diego. Our La Jolla hotel also places you near local restaurants, breweries, distilleries and shops. If you prefer to relax at our hotel, we offer an oasis filled with palm trees, manicured gardens, cascading waterfalls and tranquil koi ponds. Stay fit in our hotel gym and heated outdoor pool. At night, savor tasty cuisine, inventive cocktails and live entertainment at our two on-site restaurants before you retire to your peaceful accommodations. See why La Jolla is called the "Jewel of San Diego."

Registration Information

Register for the conference using one of three options:
Online: www.pharmaedresources.com **Phone:** (217) 721-5774
Mail: 2810 Robeson Park Drive, Champaign, IL 61822

Please Complete the Following

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

ADDRESS: _____

CITY: _____ STATE: _____

ZIP: _____ COUNTRY CODE: _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

E-MAIL: _____

VENUE INFORMATION:

Dates:	December 9-10, 2025
Venue:	Sheraton La Jolla
Venue Address:	3299 Holiday Court La Jolla CA 92037
Venue Phone:	(858) 453-5500

Please register me for:

Pre-filled Syringes & Injection Devices 2025

Standard Registration	$1,895
Early Bird Registration (by October 21st)	$1,695
Call for government, academic, or non-profit rate	

PAYMENT METHOD

CREDIT CARD REGISTRATION:

☐ CREDIT CARD ☐ VISA ☐ MASTERCARD ☐ AMEX

NAME: _____

CARD #: _____

EXPIRATION: ____ / ____

SIGNATURE: _____

BILLING ADDRESS: _____

CHECK REGISTRATION:

To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

PURCHASE ORDER #:

PLEASE NOTE:

PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.