

PharmaED RESOURCES, Inc.

Pre-filled Syringes & Injection Devices 2026

Exploring the Future of Parenteral Combination Products

December 2-3, 2026, Sheraton La Jolla, CA

Featuring Lessons Learned & Case Studies from Industry Experts:



Subhi Saadeh
Founder & Principal
Combinate



Pujitha Gourabathini
Manager, QA
BD



James Wabby
Head, Global Regulatory
AbbVie



Brian Neely
Chemist
FDA-CDER
(pending approval)



Bruce Lau
Sr. Manager
AbbVie



Nohreen Villanueva
Sr. Manager
Johnson & Johnson



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



Robin Hwang
Principal
RCP Consulting Corp.



Mitch Bardenwerper
Dir. Business Dev.
SCHOTT Pharma



Katherine Huffer
Sr. Manager, Reg. Affairs
West Pharmaceutical Services



Jennifer Riter
VP Analytical Svcs.
DDL



Mehul Desai
SVP
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Fubin Wu
Co-founder
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Margaret Gerthoffer
Technical Expert
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David Karvani
Sr. Director, Bus. Dev.
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Casey Medina
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Madison Laskowski
HF Engineer
Design Science



Xian Cao
Technical Lead
BA Sciences



Samantha Kennedy
Project Manager
Noxilizer, Inc.



Amy Hill
Reg. Project Mngr.
West Pharmaceutical Svcs.



Jace MacKellar
Bus. Dev. Manager
SCHOTT Pharma

And Comprehensive Coverage On:

- **Keynote: Beyond the Syringe—Injection Systems are Becoming Platforms as the Innovation Frontier Has Arrived**
- **FDA-CDER Quality Assessment of Drug-Device Combination Products**
- **Complaint Insights Supporting Lifecycle and Risk Strategy**
- **Safety Assurance Cases as a Framework for Usability Engineering in Software as Medical Devices (SaMD) and Combination Products**
- **Building End-to-End Traceability Across Design Controls, Risk Management, BOMs, and Regulatory Submissions**
- **Scaling On-Body Delivery Systems from Induction to Maintenance: Effective Supplier Development**
- **Driving Extreme Value: A Model-based Approach to System Development**
- **The 2 mL Myth: How Subcutaneous Volume Misconceptions Constrain Drug Development and Delivery**
- **Accelerating a Wearable Combination Product Through Integrated Device Support**
- **Designing the Platform for Confidence: Performance Verification and Human Factors Validation**
- **Applying ISO 24971-3 to Combination Product Risk Management**
- **Enabling Unbiased Container Selection: Large-Volume IV & SC Drug Delivery Solutions**
- **Decoding the Performance and Functional Testing of Needle-Based Injection Systems**
- **Impact of Potential PFAS Restrictions for Pharmaceutical Packaging**
- **Analytical Strategies for Dimethyl Sulfoxide Extracts in a Simulated-Use Study for Pre-Filled Syringes**
- **Human Factors Strategy for Injection Devices**

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LET'S COMBINATE DRUGS + DEVICES

Wednesday, December 2, 2026

7:00 *Complimentary Breakfast & Registration Check-in*

7:55 *Co-Chairperson Subhi Saadeh's Welcome and Opening Remarks*



Conference Keynote

8:00 **Beyond the Syringe—Injection Systems are Becoming Platforms as the Innovation Frontier Has Arrived**



James Wabby, MTOPRA, Head, Global Regulatory Affairs—Emerging Technologies & Combination Products; & Volwiler Senior Research Fellow, AbbVie

Injection system platforms 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. The industry must carefully evaluate the trade-offs transitioning from a single component to a system integration platform, which involves creating a new device fully tailored to a specific therapy, and platform-based solutions, which leverages predefined components and development frameworks that can be adapted to a medicinal product's characteristics.

Critical Issues—Risk Management Across the Product Lifecycle

8:40 **Complaint Insights Supporting Lifecycle and Risk Strategy**



Nohreen Villanueva, Senior Manager, Product Quality Vigilance—Combination Products, Johnson & Johnson

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.

9:20 **Advancing Combination Product Lifecycle Management: Building End-to-End Traceability Across Design Controls, Risk Management, BOMs, and Regulatory Submissions**



Fubin Wu, Co-founder & President, GessNet

Combination product lifecycle management requires teams to keep design controls, risk management, product configuration, V&V, and regulatory submissions aligned as the product evolves. In practice, these activities are often managed in separate documents and systems, making change impact difficult to assess and maintain consistently.

This presentation introduces an end-to-end traceability approach that connects product performance and usability to risks, requirements, design definitions, BOMs, V&V evidence, and regulatory submissions.

Using a practical combination product example, the session will show how changes to components, materials, suppliers, or specifications can be traced across the product lifecycle to identify potential impacts on design, risk, verification evidence, and regulatory content.

10:00 *Networking Coffee Break*

Regulatory Update

10:30 **Quality Assessment of Drug-Device Combination Products**



Brian Neely, Regulatory Scientific Reviewer, FDA-CDER

Abstract Coming Soon

Regulatory Spotlight: FDA's New Draft Guidance on Essential Drug Delivery Performance Characteristics (EDDCs)

11:10 **From EDDOs to EDDCs: What FDA's Revised Draft Guidance Means for Drug Delivery Devices and Combination Products**



Subhi Saadeh, Founder & Principal, Combinate

FDA's revised draft guidance on Essential Drug Delivery Performance Characteristics (EDDCs) introduces important changes to how manufacturers identify, evaluate, and control critical aspects of drug delivery performance. This presentation will explore what changed from the 2024 draft, including updated expectations for identifying EDDCs, design verification and validation, performance testing, and control strategies. Using examples from prefilled syringes, autoinjectors, and other drug delivery systems, we'll discuss the practical implications for product development, regulatory sub-

missions, manufacturing, and lifecycle management. The session will also examine areas where questions remain and opportunities for industry feedback before the guidance is finalized.

11:50 **The Impact of ISO 11040-8:2026 on Terminal Sterilization of Prefilled Syringes: Evaluating Plunger Stopper Movement and Sterile Barrier Integrity**



Samantha Kennedy, Project Manager, Noxilizer, Inc.

The second edition of ISO 11040-8, published in 2026, introduces new considerations for finished prefilled syringes, including the assessment of unintended plunger stopper movement. For combination products undergoing terminal sterilization, pressure changes during processing may affect stopper position, the sterile barrier zone, and potential pathways for sterilant interaction with the drug product. This presentation examines pressure-driven stopper displacement across four syringe designs using measured travel and a headspace-based model and distinguishes sterile barrier integrity from chemical ingress. Attendees will gain a practical framework for incorporating pressure-related stopper movement into prefilled syringe design assessments and sterilization strategy selection, while identifying areas where further product-specific testing may be necessary.

12:10 *Complimentary Lunch, Sponsored by*

Noxilizer™

Technology Spotlight—Next-gen Large Volume SC Delivery

1:20 **The 2 mL Myth: How Subcutaneous Volume Misconceptions Constrain Drug Development and Delivery**



Mehul Desai, Senior Vice President of Global Medical Affairs, Enable Injections, Inc

A persistent belief in the biopharmaceutical industry holds that subcutaneous (SC) administration is limited to 2-3 mL without a permeation enhancer, despite large-volume SC (LVSC) products being on the market for over two decades. This presentation examines the origins, prevalence, and downstream consequences of this misconception using data from four surveys of 378 pharmaceutical experts across formulation, CMC, clinical development, medical affairs, and portfolio strategy.

Findings show the misconception is deeply rooted: respondents gave nearly identical volume estimates for bolus injection and SC infusion, and cited familiarity with commercialized small-volume biologics, rather than primary data, as their main source of knowledge. The consequences are measurable. Approximately 91% of drug development respondents had been involved in projects where a candidate was deprioritized or abandoned due to challenges achieving small SC volumes, and 69% of formulation experts reported clinical trial or launch delays tied to high-concentration formulation issues. Co-formulation with permeation enhancers carries an estimated 40-45% drug incompatibility rate at feasibility, per expert experience.

2:00 **Challenges & Opportunities of Large-V olume Subcutaneous Injections (LVSC) - Facts and Myths of LVSC**



Robin Hwang, Principal, ICP Consulting Corp.

High-Volume (HV) subcutaneous (SC) therapies are increasingly prevalent in competitive injectable marketplace. There are many myths in HV SC injections which are not supported by facts. This talk will cover some myths and facts of HV SC injections with and without recombinant hyaluronidase (rHuPH20). Clinical data and case studies will be provided to bust some major myths of LVSC injections.

2:40 *Afternoon Networking Break, sponsored by*

SCHOTT PHARMA

3:10 **Enabling Unbiased Container Selection: Large-Volume IV & SC Drug Delivery Solutions**



Mitch Bardenwerper, Senior Business Development Manager—Polymer Solutions, & Jace MacKellar, Business Development Manager, SCHOTT Pharma USA



As biologics progress along their lifecycle, the transition from vial-based formats to advanced pre-filled systems becomes critical to enable patient-centric delivery and lifecycle value optimization. As the shift from intravenous to subcutaneous delivery accelerates, large-volume subcutaneous (LVSC) biologics are redefining requirements for primary packaging. Enabling volumes beyond traditional limits demands solutions that ensure drug stability, patient safety, and seamless device integration. SCHOTT Pharma addresses this need with advanced, ready-to-use (RTU) platform innovations, expanding both glass and polymer portfolios across syringes and cartridges.

Designed for sensitive biologics and high-viscosity formulations, they combine low extractables, optimized silicone technology, and high break resistance with tight tolerances. Co-developed with leading device partners and aligned with standard fill-and-finish line requirements, these next-generation systems give pharmaceutical companies a decisive competitive edge—minimizing

development risk, accelerating time-to-market, and enabling reliable scale-up of LVSC therapies.

Technology Spotlight — Combination Products in a Digital Age: Perspectives from System Engineering

3:50 **Bringing Task Analysis and System Behavior into One Model: An MBSE Approach for Combination Products**





Sasha Smiljanic, Director — Systems Engineering, Eli Lilly & Co., and Casey Medina, President, Studio SE, Ltd

Usability engineering under IEC 62366-1 relies on task analysis to identify user tasks and potential use errors. Systems engineering relies on behavior modelling to specify how the device responds. In practice these two activities sit in separate silos, use different tools, and are performed by different disciplines with limited overlap.

This presentation describes an MBSE approach using SysML that brings both activities into a single, simulatable model. Activity diagrams capture user tasks. Finite state machines capture system behavior, including GIU, LEDs, sound, and others.

Because the model is simulatable, three things become possible: formative studies can run against the model before any UI is built; multimodal is formalized as one source of truth for the design team; and testable UI requirements are derived directly from the model.

We walk through a worked example of combination product development and discuss what works, what doesn't, and what teams need to make this approach practical.

Roundtable Discussion

4:30 **The Future of SC Platform Development**

Moderator:
Subhi Saadeh, Combinate

Panelists:

James Wabby, AbbVie

Bruce Lau, AbbVie

Sasha Smiljanic, Eli Lilly & Co.

Mehul Desai, Enable Injections, Inc.

Discussants:

The Audience

5:05 *Happy Hour Mixer, Sponsored by*

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

Thursday, December 3, 2026

7:30 *Complimentary Breakfast, Sponsored by*

Ventura SOLUTIONS

Spotlight on Wearable Injectors — Challenges & Opportunities

8:30 **From Concept to Clinic in Four Months: Accelerating a Wearable Combination Product Through Integrated Device Support**



David Karvani, Senior Director Business Development & Strategic Partnerships, Ventura Solutions

Getting a novel wearable combination product from development into clinical trials is rarely a straight line, and compressed timelines only raise the stakes. This session presents a case study of how one pharma company moved a wearable drug delivery device into clinic within four months, supported by integrated device engineering, regulatory submission readiness, updated quality management processes, and a clear device roadmap built to align technical, regulatory, and business priorities. Attendees will come away with a practical model for embedding device engineering expertise directly into a sponsor's development team, lessons learned on running regulatory submissions and QMS work in parallel with device development rather than sequentially, and an approach to building a device roadmap that keeps clinical, regulatory, and commercial stakeholders aligned under time pressure.

9:10 **The Secret Sauce to Scaling On-Body Delivery Systems from Induction to Maintenance: Effective Supplier Development**



Bruce Lau, Senior Manager, R&D Quality, AbbVie

On-body delivery systems (OBDS) let patients self-administer across a full dosing range—from high-volume induction to lower-volume maintenance—with a consistent experience, home convenience, and fewer use errors. But scaling one platform across multiple dose volumes raises the bar for design control rigor, adding precious time to trials and market entry. The secret sauce: partnering with a supplier built on a true platform approach, one that scales design control discipline as needs evolve. For a $1B/year OBDS drug, that's $3.8M a day—time is of the essence.

Critical Issues—Usability Engineering in SaMDs & Combination Products

9:50 **Safety Assurance Cases as a Framework for Usability Engineering in Software as Medical Devices (SaMD) and Combination Products**



Pujitha Gourabathini, Manager, QA & Risk Management, BD

Software as Medical Devices (SaMD) and Drug-delivery combination products present unique usability engineering challenges due to their iterative release cycles and frequent configuration changes. Traditional usability validation approaches often require extensive re-testing, even when only minor user-interface modifications are introduced. This can lead to inefficiencies, redundant studies, and the risk of overlooking critical changes.

Safety Assurance Cases (SACs) offer a structured, evidence-based framework to address these challenges. By integrating usability engineering deliverables (such as task analyses, uFMEAs, usability risk-related assessments (URRAs), and human factors validation testing) into a SAC, organizations can systematically identify which usability data can be leveraged across versions and which elements require re-evaluation. This approach enables targeted validation, ensuring that new or modified features are appropriately flagged while preserving confidence in previously validated configurations.

For combination products, where usability risks span both device and drug delivery interfaces, SACs provide additional value by harmonizing evidence across domains. The result is a scalable, transparent methodology that reduces unnecessary duplication, strengthens regulatory justification, and enhances patient safety. This presentation will demonstrate how SACs can be applied to usability engineering in SaMD and combination products, highlighting their role in efficient lifecycle management and risk-based validation.

10:30 *Mid-morning Networking Break, Sponsored by*

West

11:00 **Designing the Platform for Confidence: Performance Verification and Human Factors Validation**





Katherine Huffer, Senior Manager, Regulatory Affairs, and Amy Hill, Regulatory Project Manager, West Pharmaceutical Services

Platform drug delivery devices offer the potential to support multiple combination product development programs through a common technology platform. Platform technologies provide an opportunity to reduce the development burden for combination products and may result in a faster time to market. However, developing a robust platform requires balancing diverse product and user requirements while maintaining flexibility for future product pipeline needs. This presentation proposes an integrated science and risk-based development framework for platform drug delivery devices, centered on the establishment of a design space. The framework emphasizes early consideration of target device pipeline, commercial requirements, and human factors inputs; theoretical modeling to inform design decisions, design space characterization, risk-based verification methods to demonstrate platform robustness across defined boundaries and human factors design validation to confirm that representative intended users can safely and effectively use the platform device across intended use scenarios. The proposed framework demonstrates how scientific understanding, risk management and human factors engineering can be leveraged to create versatile and sustainable platform device architectures capable of supporting evolving portfolio needs while reducing development risk and complexity.

11:40 **Reading Between the Lines: Human Factors Strategy for Injection Devices**



Maddy Laskowski, Human Factors Engineer, Design Science

2026 has been a significant year for human factors, with new and revised FDA guidance reinforcing a risk-based approach to human factors evaluation and the information expected in regulatory submissions. At the same time, advances in technology, the expansion of at-home treatment, and the use of similar device platforms across different products and indications are creating increasingly nuanced human factors questions. How should manufacturers determine the right combination of activities to support an injection device?

Use-related risk analyses, comparative analyses, comparative use human factors (CUHF) studies, and human factors validation studies are addressed across different

FDA guidance documents and regulatory frameworks, making it challenging to understand how they fit together in practice. Yet these activities can be complementary and highly cross-cutting. For example, comparative analyses may help establish whether a device is sufficiently similar to an on-market device to support forgoing human factors validation testing, while CUHF studies may incorporate traditional human factors validation study techniques to provide evidence regarding both the cause and impact of specific device differences.

Using injection device case studies, this presentation will go beyond individual guidance recommendations to explore how these approaches can be integrated into a proportionate, risk-based strategy while avoiding unnecessary or duplicative activities.

12:20 *Complimentary Lunch, Sponsored by*

DATWYLER

Spotlight on Packaging & Analytical Testing

1:30 **Impact of Potential PFAS Restrictions for Pharmaceutical Packaging**



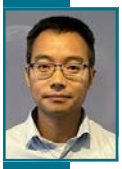
Margaret Gerthoffer, Technical & Scientific Expert, Datwyler

Since the publication of the original PFAS restriction proposal in 2023, the potential impact of a REACH restriction on fluoropolymers and related applications has remained significant for the pharmaceutical supply chain. In this time frame, two prevalent committees in REACH have been formed with respect to 1) the environmental risk of fluoropolymer use and 2) the risk to patients if a ban/restriction option is initiated for life-saving treatments, which is still in consultation. In the updated draft, these applications were associated with a proposed 18-month transition period and 12-year derogation to phase out the use of fluoropolymers. In addition to REACH, systems are being implemented throughout Canada and the state-level in the US to track PFAS related articles. Considering the well-established benefits of fluoropolymer coatings in the pharma industry, this talk will cover forward-facing actions that comply with regulations while also addressing the critical needs of patients receiving life-saving care.

Audience takeaways include:

- Review the importance of fluoropolymers as developed to date.
- Understand the difference between spray and film coating technologies; learn about the regulatory decisions evolving on different technology areas.
- Gain insight into future perspectives of the pharmaceutical industry on PFAS usage.

2:10 **Analytical Strategies for Dimethyl Sulfoxide Extracts in a Simulated-Use Study for Pre-Filled Syringes**



Xian Cao, PhD, Technical Lead, BA Sciences

Dimethyl sulfoxide (DMSO) can be used as a powerful organic extraction solvent in extractables and leachables (E&L) studies, particularly when dealing with aggressive drug product formulations. Its solvating power can mimic the extraction power of the drug product and generate a full extractables profile from the pre-filled syringes (PFS). However, the use of DMSO also introduces significant analytical hurdles such as high boiling point, viscosity and poor peak shape, ion suppression, incompatibility with direct gas chromatography injection, and severe chromatographic interferences during instrumental analyses if not properly addressed.

To overcome these limitations, this study developed analytical strategies tailored for the analyses of semi-volatiles, non-volatiles, and elemental impurities of complex DMSO extracts from PFS using gas chromatography-mass spectrometry (GC-MS), liquid chromatography-mass spectrometry (LC-MS), and inductively coupled plasma mass spectrometry (ICP-MS). Sample preparation techniques include controlled dilution into 2-propanol, aqueous-organic mixtures followed by liquid-liquid extraction (LLE), and matrix-matched diluent. The optimized methods yielded target compound recoveries of 96% - 112% for the organic analyses and elemental impurity recoveries of 87% - 96% for inorganic analysis.

This study establishes robust analytical strategies for analyzing DMSO extracts in a simulated use study of PFS.

2:50 **Decoding the Performance and Functional Testing of Needle-Based Injection Systems**



Jennifer L. Riter, Vice President, Analytical Testing Services, DDL, Inc

Needle-based injection systems — prefilled syringes, pen injectors, autoinjectors, and on-body delivery systems — sit at the intersection of drug product and device, and their test plans must answer to both. Sponsors routinely confront a fragmented standards landscape: ISO 11608 governs the system, ISO 11040 and ISO 7886/7864 the primary container and needle, ISO 80369-7 the fluid path connection, USP chapters the elastomeric and glass components and package integrity, and ASTM methods much of the aging, distribution, and package integrity work. Without a framework connecting them, programs risk redundant testing, gaps at the seams between standards, and sample sizes that cannot support the reliability claims a submission requires.

This presentation lays out a practical framework for building a defensible performance and functional test plan. We will work through the core functional attri-

butes—break-loose and extrusion force, dose accuracy, activation and cap removal forces, needle penetration and pull-out force, injection time, end-of-dose indication, safety feature performance, container closure integrity, and subvisible particulates—and map each to its governing method across ISO 11608-1 through -7, ISO 11040-4/-8, ISO 80369-7 and -20, ISO 23908, USP ⟨381⟩, ⟨382⟩, ⟨788⟩, and ⟨1207⟩, and ASTM F1980, D4169, F2338, and F3172.

Beyond method selection, the session addresses the decisions that most often drive review questions and repeat testing: worst-case sample and condition selection, conditioning and accelerated aging strategy, statistical rationale and sample size justification, and traceability from test results back to design inputs and ISO 14971 risk controls. Attendees will leave with a structured approach to scoping, sequencing, and defending a test plan for these systems.

3:30 *Close of Program*



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Venue Phone:	(858) 453-5500

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