Combination Products Summit 2026

Product Development, Quality Control & Regulatory Compliance

May 27-28, 2026, Providence, RI Marriott Downtown

Featuring Lessons Learned and Case Studies from Industry Experts

Sriram Natarajan
Sr. Manager
Johnson & Johnson

John Barr Weiner
Former Director
FDA/Barr Consulting

Ajit D'Souza
Exec. Director
Eli Lilly & Co.

Nicholas Zampa
Director, CPs
Alnylam Pharmaceuticals

Khaudeja Bano
Global Head, Device Quality
Genentech/Roche

Fady Khalla
Director
Merck

Sasha Smiljanic
Director, Systems Eng.
Eli Lilly & Co.

Mehul Desai
SVP
Enable Injections

Susan Neadle
President
CP Consulting Svcs.

Fubin Wu
Co-founder
GessNet

Jonathan Amaya-Hodges
Consulting Director
Suttons Creek

Pooja Rana
Sr. Regulatory Affairs
Intellectt Inc.

Maria Rodriguez
User Researcher
Medtronic

Chuck Ventura
CEO & Founder
Ventura Solutions

Asmita Khanolkar
Senior Director
SMC Ltd.

Casey Medina
President
Studio SE, Ltd.

Karolina Snajdarova
Regulatory Affairs Manager
Ypsomed AG

Jhumi Jain
Regulatory Affairs Consultant
Combination Products Consulting Services LLC

Tara Bates
Sr. HF Specialist
Emergo by UL

Erin Davis
Research Director, HF
Emergo by UL

Michael Maust, Jr.
Lab Manager
Noxilizer

And Comprehensive Coverage On:

- **Digital Transformation of Combination Product Development: From Segmented Documentation and Siloed Engineering to Structured Data and Integrated Systems**
- **Decoupled, Not Disconnected: Accelerating Combination Products the Right Way**
- **Challenges in Combination Product Development and Lifecycle Management: Navigating Convergence Risk**
- **The Regulatory Landscape of Digital Health and Combination Products**
- **Combination Products for a Circular Economy**
- **Mapping Regulatory Strategies for Combination Products in the US, EU, and Asia**
- **Strategies for Streamlining Clinical Development Programs for Drug-Device Combination Products**
- **Current & Future Trends in Drug Delivery Device Development**
- **Opportunities and Challenges for the Combination Products Sector**
- **From Complexity to Clarity: Lessons Learned Preparing HF Validation for a Robotic System**
- **Driving Extreme Value: A Model-based Approach to System Development**
- **Bringing Clarity to Combination Products Risk Management**
- **Navigating Two Distinct Ecosystems Essential for Combination Products and Drug Delivery Devices in Pharma On-body Delivery Systems & the 2 mL Myth**
- **Integrating "End-to-End" (E2E) Manufacturing Strategies for the Growing Demand of Combination Products**
- **Best Practices for Developing Use-related Risk Analyses**
- **And More!**

With Representation From:

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

Pharma Ed's Combination Products Summit 2026 is Sponsored by:

Silver Sponsors

NOXILIZER™

Ventura SOLUTIONS

SGS
When you need to be sure

Event Sponsors & Partners

GessNet
Advance medical product safety engineering

Oliver DESIGN

West

YPSOMED
SELFCARE SOLUTIONS

ON drugDELIVERY

PHARMACIRCLE

Drug Development & Delivery

Wednesday, May 27, 2026

7:15 *Complimentary Breakfast & Registration Check-in*

8:10 *Chairperson Susan Neadle's Welcome and Opening Remarks*

The Landscape of Delivery Devices: Challenges and Opportunities

8:15 **Conference Keynote: Latest Trends in Drug Delivery Device Development**

Ajit D'Souza, Executive Director, Drug Delivery & Devices, Eli Lilly & Co.

Platform autoinjectors streamline development across multiple drugs, largevolume injectors enable home administration of higherdose biologics, and interventional delivery systems provide targeted access to hardtoreach tissues. Together they expand therapeutic possibilities by improving usability, enabling complex formulations, and supporting precise, localized delivery for advanced medicines.

8:55 **Decoupled, Not Disconnected: Accelerating Combination Products the Right Way**

Nicholas Zampa, Director, Combination Products Development, Alnylam Pharmaceuticals

This presentation outlines a pragmatic operating model for advancing drug–device combination products efficiently under accelerated timelines while maintaining GMP discipline and patient safety. This approach contrasts with two common but suboptimal extremes. (1) Integration obsession: tightly coupled co-development models, where constant alignment and cross-endorsement slow progress and constrain agility; and (2) Siloed: fully siloed drug and device development, which creates late-stage integration risk and interface failures. Instead, we propose a structured parallel development model that preserves critical integration touchpoints while enabling drug product (DP) and device teams to move independently where appropriate.

9:35 *Mid-morning Coffee & Networking Break*

10:05 **2026 and Beyond: Opportunities and Challenges for the Combination Products Sector**

John "Barr" Weiner, Former Associate Director, Office of Combination Products, FDA, & Founder, Barr Consulting, LLP

It's been an unusual period for FDA, but just how different and how much may it matter to your products and prospects? What may it mean for combination products developmental planning, market access and post market control expectations? Leveraging his leadership perspective while at FDA and his learnings from work with regulated entities since, John "Barr" Weiner will discuss challenges and opportunities of the current context for products already in the pipeline and for driving more efficient, predictable policies and practices going forward.

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

10:45 **Driving Extreme Value with a Model-based Approach to System Development**

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

Model-Based Systems Engineering (MBSE) delivers significant value when adopted broadly across product-development teams, enabling shared understanding and early alignment on system behavior. Using a representative On-Body Delivery System (OBDS) with user-interface and connected-device features, this presentation describes how simple behavioral models—such as finite state machines and activity diagrams—help teams expose modes, interactions, and exception paths that are often missed in document-only development. By breaking down core modeling elements and illustrating their intent, we demonstrate how behaviors naturally translate into clear, concise requirements and verification artifacts using structured mechanisms.

The analysis further shows how each modeled behavior drives specific functional, interface, and fault-handling requirements, along with traceable test cases that accelerate verification planning. This approach preserves clarity while strengthening traceability. Equipping product teams with these MBSE skills creates a scalable capability that enhances requirement quality, reduces development risk, and improves cross-functional collaboration across complex device programs.

11:30 **Digital Transformation of Combination Product Development: From Segmented Documentation and Siloed Engineering to Structured Data and Integrated Systems**

Fady Khalla, Director, Device Systems—Risk Management, Merck, & Fubin Wu, President & Co-founder, GessNet

Combination Product development is often managed through manual fragmented documents and disconnected tools across pharma, device, quality, and regulatory teams. This document-centric approach drives duplicated effort, inconsistent interpretation of critical information, limited traceability, and slow change-impact assessment—reducing the ability to reuse platform knowledge and increasing late-stage rework.

This presentation aims to share an example of a digital transformation journey of combination product development from segmented documentation to a structured data foundation supported by integrated lifecycle workflows. We summarize the common pre-transformation challenges and present practical solutions, including selection criteria for digital solution, a fit-for-purpose data model that links intended use, user needs, requirements, risk controls, and verification/validation evidence; robust configuration management and impact analysis; compliant approvals and audit trails; governed reuse through digital libraries; and interoperability with enterprise systems.

The discussion further emphasizes how the selection of appropriate tools and strategic implementation partnerships can enhance consistency, efficiency, and predictability across a Combination Product portfolio. By standardizing templates and terminology, developing approved digital libraries, and deploying reusable content tailored for new products, organizations can streamline platform development, accelerate derivative creation, minimize traceability-related rework, and improve submission readiness. Ultimately, this approach fosters a repeatable development system that strengthens cross-functional alignment, expedites decision-making, and advances lifecycle management for complex combination product portfolios.

12:15 ***Complimentary Networking Lunch***

Regulatory Spotlight

1:20 **Mapping Regulatory Strategies for Combination Products in the US, EU, and Asia**

Pooja Rana, Senior Regulatory Affairs Specialist – Intellectt Inc.

Combination products present distinct regulatory challenges because they combine components that are typically governed under different regulatory frameworks and often reviewed by separate authorities. This multi-jurisdictional oversight introduces complexity in regulatory strategy, policy interpretation, and submission coordination. Variations in regional pathways for each constituent part can affect every phase of the product lifecycle -from preclinical development and clinical evaluation to marketing authorization, manufacturing controls, safety reporting, promotional compliance, and post-approval change management.

This presentation delivers a strategic framework for navigating global regulatory pathways for combination products across the United States, European Union, and key Asian markets. It will highlight critical considerations for pathway selection, regulatory alignment, integrated risk management, and lifecycle planning, alongside practical approaches for coordinating cross- functional teams and optimizing documentation. Attendees will gain actionable insights to anticipate regulatory expectations, reduce approval delays, and build globally scalable regulatory strategies that support efficient development, successful submissions, and sustained compliance.

2:00 **The Regulatory Landscape of Digital Health and Combination Products**

Jhumi Jain, Regulatory Affairs Consultant, Combination Product Consulting Services, LLC

Digital health technologies are increasingly integrated with medicines and drug–device combination products, reshaping both therapeutic delivery and regulatory oversight. This session examines the evolving regulatory landscape governing connected devices, software applications, and AI-enabled functions used in conjunction with medicinal products. Key topics include regulatory classification, when digital components may qualify as medical devices or software as a medical device (SaMD), and how such functionality may create or modify a combination product designation. Global regulatory considerations—intended use, claims, quality systems, cybersecurity, data governance, and AI lifecycle management—are addressed to equip attendees with practical insight for navigating approval pathways.

2:40 ***Afternoon Networking Break***

Critical Issues—Identifying the Right Organizational Practices for Combination Product Success

3:10 **Modeling a "Company within a Company:" Navigating Two Distinct Ecosystems Essential for Combination Products and Drug Delivery Devices in Pharma**

Khaudeja Bano, Global Head, Device Quality, Genentech, a Member of the Roche Group

The framework for developing drug delivery devices within an established pharmaceutical company differs fundamentally from traditional drug development. While the pharmaceutical industry is rooted in well-defined clinical and chemical pathways, developing combination products requires an agile, engineering-centric approach often described as managing a "company within a company."

This session will explore the complexities of navigating these two entirely different ecosystems. We will examine the critical integration of people, processes, and technology, highlighting how organizations can harmonize device engineering cycles with drug development timelines. Most importantly, we will discuss the fundamental shift in mindset required to bridge these worlds, ensuring that both the therapeutic and the delivery mechanism are developed with equal precision to meet regulatory standards and patient needs.

Key takeaways will include:

- Strategies for integrating device-specific quality systems within a traditional pharma infrastructure.

- Methods for aligning cross-functional teams across engineering and clinical disciplines.

- Frameworks for managing the unique lifecycle and technology requirements of drug delivery systems.

3:50 **Challenges in Combination Product Development and Lifecycle Management: Navigating Convergence Risk**

Susan Neadle, Founder & Principal, Combination Products Consulting Services, LLC

Combination products rarely fail because teams cannot integrate a drug, device, or biologic technically. They struggle because organizations underestimate the systemic friction created when regulatory regimes, development paradigms, quality systems, and corporate cultures collide.

This session reframes combination product complexity as a convergence risk problem. From classification ambiguity and cross-jurisdictional interpretation gaps to misaligned governance models and fragmented supplier ecosystems, the most consequential obstacles often emerge at the interfaces—between disciplines, processes, and timelines. Drawing on recurring patterns observed across programs, this talk highlights why legacy single-modality operating models are insufficient for hybrid products. Attendees will leave with a sharper understanding of where combination product programs typically destabilize—and why tailored governance, integrated quality strategies, and proactive lifecycle planning are not optional, but essential.

Day One Roundtable Discussion

4:30 **The Future of Combination Product Platform Development**

Moderator:

Susan Neadle, CP Consulting Services

Panelists:

Khaudeja Bano, Genentech/Roche

Ajit D'Souza, Eli Lilly & Co.

Fady Khalla, Merck

Sasha Smiljanic, Eli Lilly & Co.

John Barr Weiner, Former FDA/Barr Consulting, LLC

Discussants:

The Audience

5:05 ***Close of Day One***

Thursday, May 28, 2026

7:15 ***Complimentary Breakfast, Sponsored by***

Ventura SOLUTIONS

8:15 **Bridging the Gap—Navigating the Transition from Clinical Development to Commercial Launch**

Chuck Ventura, CEO & Founder, Ventura Solutions

Abstract Coming Soon

Technology Spotlight—OBDS & Larger Volume Delivery

8.55 **On-body Delivery Systems & the 2 mL Myth: How Subcutaneous Volume Misconceptions Are Constraining Drug Delivery and Development**

Mehul Desai, SVP, Global Medical Affairs & Advocacy, Enable Injections, Inc.

This presentation will focus on how On-body Delivery Systems (OBDS) can help overcome common delivery and development problems for Combination Products. Key themes and takeaways include:

- **Identify how misconceptions about subcutaneous volume limits have impacted drug development decisions**
- **Analyze survey and clinical evidence from nurses, pharmacists, and patients on the administration challenges created by current large-volume subcutaneous delivery methods**
- **Evaluate how OBDS address these challenges with drug delivery and development**

9:35 **Combination Devices for a Circular Economy**

Sriram Natarajan, Senior Manager, Johnson & Johnson

Abstract Coming Soon

10:05 ***Morning Networking & Coffee Break***

Spotlight on Human Factors Engineering in Drug/Device Development

10:35 **From Complexity to Clarity: Lessons Learned Preparing HF Validation for a Robotic System**

Maria Rodriguez, User Researcher, Medtronic

Abstract Coming Soon

11:15 **Latest Trends in Regulatory Feedback on Human Factors Engineering (HFE) Submissions for Combination Products**

Erin Davis, Research Director, Human Factors R&D, Emergo by UL, & Tara Bates, Senior Human Factors Specialist, Emergo by UL

Regulatory expectations for combination products are rapidly evolving, and Human Factors Engineering (HFE) has become a key area of scrutiny in global submissions. This presentation will highlight the most common themes emerging from recent regulatory feedback, including challenges in defining critical tasks, ensuring representative user groups, aligning risk analyses with IFUs, and designing training and usability test methods that appropriately reflect real-world use.

Attendees will learn practical strategies for performing and documenting HFE activities, as well as tips for anticipating regulator concerns to minimize review cycles. The presentation offers actionable guidance to help manufacturers strengthen submission quality and support the development of safe and effective combination products.

11:55 **Noxilizer Presentation**

Michael Maust, Jr., Laboratory Manager for Customer Projects, Noxilizer, Inc

Abstract Coming Soon

12:15 ***Complimentary Lunch, Sponsored by***

NOXILIZER™

1:20 **Post-Market Design Changes for Drug/Device Combination Products**

Jonathan Amaya-Hodges, Consulting Director, Suttons Creek, A BlueRidge Life Sciences Company

The combination product journey doesn't end upon regulatory approval, and in many ways it is just getting started as the team must now focus on ensuring continuous supply to the patient population now relying on the product. This goal becomes more challenging with inevitable changes to the combination product, both planned

and unplanned. When such design changes occur to the device constituent part, assessments must follow the primary mode of action framework (i.e. drug regulations and guidance for single-entity drug delivery combination products), while also considering data from the device perspective – which has a very different change process. And, all of this must consider what information has been submitted to which regulatory authorities, and where in those filings the data reside.

This presentation will help disentangle the concepts involved in postmarket changes, discuss global implications of such changes, and review some case studies to better understand how to assess and manage common types of changes. After attending, one should have a better idea of where to look and how to manage the process of assessing and implementing postmarket design changes.

Manufacturing Spotlight—Improving Strategies from Clinic to Launch

2:00

Strategies for Streamlining Clinical Development Programs for Drug-Device Combination Products

Karolina Snajdarova, Regulatory Affairs Manager - Delivery Systems, Ypsomed AG

The pharmaceutical competitive landscape is continuously evolving. Streamlining clinical development programs for drug-device combination products requires more than optimized study design—it demands early, integrated collaboration and strong partnerships among all parties involved in the ecosystem.

Device manufacturers and their device platform technologies and pre-configurated products play a critical role in reducing complexity during development and accelerating time to clinic. However, the role of device manufacturers extends beyond "hardware" supply only. Tailored service offerings, such as regulatory affairs expertise and documentation, contribute significantly to accelerated clinical development timelines and streamline the interface between pharmaceutical companies and device partners.

Regulatory affairs is a key element, not only seen as a traditional compliance function, but as a strategic partner that guides early decisions, shapes development pathways and supports effective processes and documentation strategy. Early regulatory involvement ensures alignment with global expectations, facilitates the definition of device- versus drug-driven requirements, and enables successful interactions with health authorities.

From the perspective of a device manufacturer, this presentation will elaborate on how the combination of platform technologies, regulatory expertise, and additional value-added services enables faster and more reliable pathways to the clinic/market for drug-device combination products.

2:40

Integrating "End-to-End" (E2E) Manufacturing Strategies for the Growing Demand of Combination Products

Asmita Khanolkar, Senior Director, SMC Ltd.

As healthcare trends continue to move forward towards in-home treatments, the need for self-administration and patient-centric delivery solutions becomes crucial for patient therapy management. Delivery devices are being developed that enable a variety of presentations to be administered for complex therapies over a range of indications, formulation types, delivery needs and patient populations. This combined requirement for optimized drug delivery solutions and patient experience is driving the growth of drug-device combination products and the urgency for agility and speed towards developing enabling drug-device delivery solutions for successful clinical results. Bringing these solutions to the clinic requires robust CMC and manufacturing strategies, flexibility to support adaptive manufacturing and iterative drug-device development strategies towards an integrated approach for a path from development to clinic to launch. The presentation will focus on key strategies for developing drug-device combination products from early development through clinic and launch. The presentation will cover considerations across drug formulations, device and manufacturing technologies relevant for today's novel therapeutic landscape.

3:20 ***Close of Program***

PharmaED RESOURCES, Inc.

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

About Your Destination.

The Providence Marriott Downtown is located in the heart of Capital Hill offering 351 luxurious guestrooms, five suites, complimentary WIFI, an exclusive Concierge Lounge, new lobby and over 11,000 square feet of newly renovated function space and dedicated catering services. Our recreational amenities include connecting indoor/outdoor pools, heated whirlpool spa and Club Pace Fitness Center as well as AQUA; Providence's only poolside lounge. The Bluefin Grille is our award-winning restaurant offering breakfast, lunch and dinner featuring innovative seafood specialties and popular American fare. Complimentary parking and shuttle service throughout the city.

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:	May 27-28, 2026
Venue:	Providence Marriott Downtown
Venue Address:	1 Orms St. Providence, RI 02904
Venue Phone:	(401) 272-2400

Please register me for:

Combination Products Summit 2026

Standard Registration	**$1,695**
Early Bird Registration (by April 15th)	**$1,495**
Call for government, academic, or non-profit rate	

PAYMENT METHOD

CREDIT CARD REGISTRATION:

c CREDIT CARD c VISA c MASTERCARD c 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.