

Combination Products Summit 2025

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.



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



Nicholas Zampa
Director, CPs
Alnylam Pharmaceuticals



Pooja Rana
Sr. Regulatory Affairs
Intellect Inc.



Maria Rodriguez
User Researcher
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SMC Ltd.



Casey Medina
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Studio SE, Ltd.



Karolina Snajdarova
Regulatory Affairs Manager
Ypsomed AG



Jhumi Jain
Regulatory Affairs Manager
Vena Medical



Jonathan Amaya-Hodges
Consulting Director
Suttons Creek



Erin Davis
Research Director, HF
Emergo by UL

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:



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Wednesday, May 27, 2026

7:15 Complimentary Breakfast & Registration Check-in

8:10 Chairperson Susan Needle'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, large-volume injectors enable home administration of higher-dose biologics, and interventional delivery systems provide targeted access to hard-to-reach 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

Critical Issues—Identifying the Right Organizational Practices for Combination Product Success: Three Perspectives from Industry

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



John "Barr" Weiner, Former Director, Office of Global Operations, 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.

10:45 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 is fundamentally different from traditional drug development. This session will explore how to navigate these two entirely different ecosystems, focusing on the integration of people, processes, and technology—and most importantly, the shift in mindset required to succeed.

11:25 Challenges in Combination Product Development and Lifecycle Management: Navigating Convergence Risk



Susan Needle, 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 leg-

acy 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.

12:05 *Complimentary Networking Lunch*

Regulatory Spotlight

1:10 **Mapping Regulatory Strategies for Combination Products in the US, EU, and Asia**



Pooja Rana, Senior Regulatory Affairs Specialist – Intellect 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.

1:50 **The Regulatory Landscape of Digital Health and Combination Products**



Jhumi Jain, Regulatory Affairs Support, Vena Medical

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 sys-

tems, cybersecurity, data governance, and AI lifecycle management—are addressed to equip attendees with practical insight for navigating approval pathways.

2:30 *Afternoon Networking Break*

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

3:00 **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.

Abstract Coming Soon



3:45 **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.

Day One Roundtable Discussion

4:30

The Future of Combination Product Platform Development

Moderator:

Susan Needle, 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



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

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

TBA



Abstract Coming Soon

12:15 Complimentary Lunch, Sponsored by



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



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

Abstract Coming Soon

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-configured 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



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



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