PharmaED RESOURCES, Inc.

Combination Products Summit 2025

Product Development, Quality, Safety, & Regulatory Compliance

May 12-13, 2025, Philadelphia PA

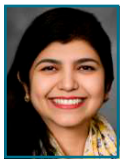
Featuring Lessons Learned & Case Studies from Industry Experts

Doug Mead
Founder
CP Pathways

Heather Guerin
Global Regulatory Dir.
Novartis

Alie Jahangir
Head of Quality, CP
Biogen

Rumi Young
Dir. Regulatory
Novo Nordisk



Khaudeja Bano
Global Head, VP Device Quality
Genentech

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

Sara Waxberg McNew
CSO
Design Science

Susan Neadle
President
CP Consulting Svcs.

Jennifer Riter
VP Analytical Svcs.
Kindeva Drug Delivery

Kinsuk Shah
Sr. AD, CP
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Cindy Tritton
Sr. Engineer
Biogen

Lauren Richards
Principal Regulatory Specialist
West Pharmaceutical Svcs.

Teresita Pileggi
Principal Human Factors Eng.

Chuck Ventura
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Fubin Wu
Co-founder
GessNet

Stefanie Stark
Head, Regulatory Affairs
Ypsomed AG

Jianxiu Zhao
Sr. Manager
Terumo Medical Solutions

James McCaw
Assoc. Scientist
Merck

Karl Hoelper
Director
CCL Healthcare

Ingo Waschulewski
Gerresheimer

And Comprehensive Coverage On:

- Implications of New FDA Guidances for Combination Products—Essential Drug Delivery Outputs (EDDOs) and Use Related Risk Analyses (URRAs)
- A Path to Approval—The Regulatory Journey of a Combination Product
- Using AI to Aid in Device Development and Regulatory Submissions
- Global strategies for Accelerating Drug Delivery Systems Submission Processes—Navigating US, EU, and China Regulatory Landscapes
- Bringing Clarity to Combination Products Risk Management
- Container Closure Integrity Testing of Devices/Combination Products
- Combination Product Platform Development—Considerations & Strategic Approaches
- Developing a Portfolio of Devices for a Single Marketed Product—Evaluating Risks, Benefits & Opportunities for Harmonization
- Implementing a Combination Product Library to Drive Standardization, Consistency, Efficiency, and Continuous Improvement
- Advancing Intrathecal and Intracerebral Ventricular Drug Delivery for CNS Disorders
- Integrating ICH Q9 and ISO 14971 to Optimize Risk Management for Combination Products
- Human factors and your product development process (HF isn't just Summative Testing)
- Material Qualification and Control for Combination Products
- Best Practices for Developing Use-related Risk Analyses
- And More!

With Representation From:

West · Lilly · Genentech (A Member of the Roche Group) · Novartis · novo nordisk · Biogen · Merck (Be well) · Boehringer Ingelheim · YPSOMED (Selfcare Solutions)

gerresheimer · Combination Products Consulting Services LLC · TERUMO Medical Care Solutions · Kindeva · GessNet (Advance medical product safety engineering) · Design Science (Usability starts here.) · CCL · RQM+ (The Plus is the People)

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Drug Development & Delivery

Monday, May 12, 2025

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

8:10 *Chairperson Alie Jahangir's Welcome and Opening Remarks*

Regulatory Spotlight—Recent FDA Guidances on EDDOs & URRAs, Implications for Industry

8:15 **Implications of New FDA Guidances for Combination Products—Essential Drug Delivery Outputs (EDDOs) and Use Related Risk Analyses (URRAs)**

Rumi Young, Director of Regulatory Policy, Novo Nordisk

As the pharmaceutical industry witnesses a surge in combination products, the FDA has responded by issuing guidance to clarify expectations and potentially streamline development efforts. Recent draft guidances, on Essential Drug Delivery Outputs (EDDO) and Use Related Risk Analyses (URRA), specifically target drug delivery combination products, focusing on Biologics License Applications (BLAs) and New Drug Applications (NDAs). The proposed EDDO framework leverages design control principles to address expectations for pre-market applications, INDs, and post-approval submissions, while the URRA guidance provides a methodology for determining the need for human factors validation studies. Given the release of these pivotal guidance documents, industry has raised questions regarding practical applications to product development as well as potential opportunities for regulatory flexibility. This session aims to provide clarity on these new regulatory policies and their real-world applications.

8:55 **Essential Drug Delivery Output (EDDO) is the new Essential Performance Requirement (EPR)**

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

Critical Issues—AI, Device Development & Regulatory Submissions

9:35 **Regulatory Submissions for Drug-Device Combination Products: Telling the Story**

Heather Guerin, Global Program Regulatory Director, Medical Devices, Novartis

In this session, we will unravel the complexities of regulatory submissions for drug-led drug-device combination products. This talk will guide you through the essential elements of device-related content for a comprehensive combination product submission, including key guidelines, best practices, and country and regional differences, ensuring that your documentation meets the expectations of health authorities worldwide. Gain insights into integrating device and drug information, addressing common challenges, and the importance of telling a compelling story. Learn how to present comprehensive data effectively to health authority reviewers, paving the way for successful commercial approvals. This talk is not just for regulatory professionals; anyone with responsibility to combination product development will benefit from this discussion of strategic approaches to combination product submissions.

10:15 *Networking Coffee Break*

10:45 **Using AI to Aid in Device Development and Regulatory Submissions**

Doug Mead, President & Principal, CP Pathways, LLC

GenAI search programs are an important tool for researching regulatory expectations. The Drugs@FDA database includes review memos, correspondence, and labeling information for all drugs approved by CDER. These can provide valuable insights into the information companies submit and what the FDA ultimately requires for approval of a specific product. FDA documents can include very specific content about design verification testing, human factors study results, stability, quality, and many other topics. After assessing this content, combination product companies will be best prepared to develop delivery device testing plans and their justifications that may reduce regulatory risks for their product. Examples of search results illustrating FDA expectations and policies will be presented.

11:25 **Global Strategies for Accelerating Drug Delivery Systems Submission Processes Through Platform Technologies: A Device Manufacturer's Perspective on Navigating US, EU, And China Regulatory Landscapes**

Stefanie Stark, Head of Regulatory Affairs—Delivery Systems, Ypsomed AG

As the pharmaceutical industry increasingly adopts platform technologies to accelerate for e.g. development programs, clinical trials and submission processes, the role of medical device manufacturers in providing device constituent parts is more critical than ever. Platform devices offer opportunities to streamline development timelines, reduce costs, and enhance compatibility across multiple drug products. However, navigating the regulatory landscapes in key markets such as the US, EU, and China presents unique challenges and opportunities for device manufacturers. Key topics to be covered include:

- The role of device constituent parts in platform technologies
- Navigating the regulatory landscape in major markets
- Developing a design space for a platform device constituent
- Building successful pharma partnerships

12:05 ***Complimentary Lunch, sponsored by***

CCL

1:05 **Advancing Patient Safety & Supply Chain Efficiency with RFID**

Karl Hoelper, Director of Smart Packaging and New Product Innovation, CCL Healthcare and Specialty Worldwide

As the demand for injectable prefilled syringes (PFS) and auto-injectors grows—driven by biologics, self-administration trends, and patient-centric healthcare—ensuring safety, authenticity, and traceability is more critical than ever. RFID technology presents a game-changing opportunity to enhance patient safety, improve supply chain efficiency, and combat counterfeiting in this high-value sector.

Key Discussion Points:

- Enhancing Product Authentication & Anti-Counterfeiting: How RFID-enabled syringes and auto-injectors ensure real-time verification and protect against falsified medications
- Supply Chain Optimization: Improving inventory tracking, cold chain management, and expiration monitoring with RFID integration
- Patient Safety & Adherence: Leveraging RFID for smart medication adherence, dose tracking, and connected healthcare applications
- Regulatory & Industry Considerations: Meeting serialization, UDI, and compliance requirements in the evolving healthcare landscape
- Implementation & Innovation: Overcoming material and signal challenges in metal-containing drug delivery devices

Technology Spotlight—Key Considerations for Novel Device & Platform Development

1:30 **Beyond Conventional Routes: Advancing Intrathecal and Intracerebral Ventricular Drug Delivery for CNS Disorders**

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

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

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

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

2:10 **Developing a Portfolio of Devices for a Single Marketed Product—Evaluating Risks, Benefits & Opportunities for Harmonization**

Kinsuk Shah, Senior AD, Combination Product Steward, Boehringer Ingelheim

What are the early-stage hurdles and challenges to developing two or three presentation variants of a single product? This talk will outline those challenges and suggest how to overcome them through attention to the following aspects of design input:

- Impact on Human Factors, user needs, and device-related design inputs – leveraging key requirements for all devices
- Identifying a Risk Management approach from market complaints and characteristics, in order to mitigate cross-device impact
- Patient-centricity and feedback: Asking and answering, "Which device is right for me?"

2:50 ***Afternoon Networking Break***

Spotlight on Large Volume Injection Devices

3:20 **Patient's Perspective on Large Volume Subcutaneous Drug Delivery**

Cindy Tritton, Project Lead, Senior Engineer III, Technical Development, Biogen

This presentation will provide an overview of current challenges faced by delivery devices in delivering larger volumes. Key topics to be covered include:

- Current landscape of devices and industry direction for large volume injectors
- Patient tolerance and user acceptability of large-volume injectables
- Emerging trends and patient preference shaping the future of large-volume subcutaneous drug delivery

4:00 **An MBSE Approach to Integrating Design Inputs, Design Outputs, and Risk Management Through SysML Architecture**

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

As Combination Products and medical devices grow in complexity, ensuring clear traceability between design inputs, design outputs, and risk management activities becomes increasingly critical. Regulations and development process requires us to identify design outputs that are essential to proper functioning, ideally by linking back to design inputs. Achieving this linkage effectively can be challenging, as it requires the right level of granularity to support and to simplify future change control activities. The application of a SysML based architecture can be used in a model-based system engineering environment to deliver integrated design inputs, design outputs, and risk management.

Day One Roundtable Discussion

4:40 **Combination Product Development—Avoiding Regulatory Hang-ups**




Moderator: Alie Jahangir, Biogen

Panelists:

Doug Mead, CP Pathways

Sasha Smiljanic, Eli Lilly & Co.

Cindy Tritton, Biogen

Discussants:

The Audience

5:10 ***Happy Hour Mixer***

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

Tuesday, May 13, 2025

7:00 ***Complimentary Breakfast, Sponsored by***

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

Critical Issues—Risk Management in an Evolving Combination Product Landscape

8:15 **Bringing Clarity to Combination Products Risk Management**

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

In the evolving landscape of medical devices and pharmaceuticals, combination products—those that integrate drugs, devices, and/or biological products—present unique challenges and opportunities in risk management. This presentation delves into the complexities of managing risks associated with combination products, emphasizing the importance of a comprehensive and integrated approach. We will explore the regulatory framework governing combination products, highlight-

ing key guidelines from agencies such as the FDA and EMA. The presentation will cover risk assessment methodologies, tailored to the specific needs of combination products. Additionally, we will discuss the critical role of cross-functional teams in identifying and mitigating risks throughout the product lifecycle, from design and development to post-market surveillance. Case studies will illustrate best practices and common pitfalls, providing practical insights for effective risk management. By the end of this presentation, attendees will gain a deeper understanding of the regulatory requirements, risk assessment tools, and collaborative strategies essential for ensuring the safety and efficacy of combination products.

8.55 **Integrating ICH Q9 and ISO 14971 to Optimize Risk Management for Combination Products**

Chuck Ventura, CEO and Founder of Ventura Solutions

Effective combination product development relies on managing risks for both the device and drug/biologic constituents. ICH Q9, a guidance for pharmaceutical quality risk management, and ISO 14971, a standard for medical device risk management, are both critical to these processes. While these frameworks share similarities and differences, their approaches often lead to siloed efforts between pharmaceutical and device teams. This fragmentation results in inefficiencies, duplicate work, project delays, compliance risks, and potential increased user and patient risk.

This presentation focuses on an integrated solution that builds on the principles of both ICH Q9 and ISO 14971 to address the challenges of managing risks across the entire combination product. It proposes an integrated risk process that incorporates methodologies such as Use Related Risk Analysis (URRA), process failure mode and effects analysis (PFMEA), design failure mode and effects analysis (DFMEA), and a System Level Risk Assessment. This approach facilitates one comprehensive combination product risk assessment, capturing device and drug specific risks, and those arising from their interactions.

Through practical strategies and real-world examples, it will be demonstrated how an integrated device and drug risk process can ensure consistent risk evaluation, improve cross-functional collaboration, and align with regulatory expectations. By adopting this approach, organizations can enhance compliance, reduce inefficiencies, and accelerate product development timelines, all while prioritizing patient and user safety.

Actionable insights for professionals in the combination products industry will be provided to help optimize risk management practices and adapt to evolving regulatory and market demands.

9:35 ***Morning Networking & Coffee Break***

10:05 **TBA**

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

Abstract Coming Soon

Technology Spotlight—Standardizing Data for Optimized CP Development & Lifecycle Management

10:45 **Implementing a Combination Product Library to Drive Standardization, Consistency, Efficiency, and Continuous Improvement**

Fubin Wu, President & Founder, GessNet

The development of drug-device combination products requires a structured and systematic approach to managing risks, requirements, and regulatory compliance across multiple disciplines. A Combination Product Library provides a strategic solution by centralizing pre-approved templates, standardized datasets, and lifecycle-managed information, including hazards, harms, requirements, test protocols, and other critical elements.

This presentation will explore how manufacturers can establish and implement a Combination Product Library to:

- Enhance Standardization & Consistency – Reduce variability in risk assessments, design requirements, and test protocols by leveraging structured, pre-approved templates and datasets.
- Improve Efficiency – Minimize redundant work through validated data reuse, accelerating product development, risk management, and regulatory submissions.
- Enable Continuous Improvement – Maintain an evolving repository that integrates lessons learned, post-market insights, and regulatory updates to drive ongoing product enhancements.
- Support Lifecycle Management – Ensure traceability and controlled updates to critical data sets** across the combination product lifecycle, from early development through commercialization and post-market phases.

Real-world case studies will illustrate how a Combination Product Library can be effectively built and maintained. Attendees will gain practical insights into best practices for implementing and optimizing a scalable and governance-driven library, unlocking its full benefits.

11:25 **Designing an Autoinjector That Pushes the Limits of Viscosity and Volume**

Ingo Waschulewski, Senior Sales and Business Development Manager, Gerresheimer

Formulating liquid drugs such as biopharmaceuticals for SC delivery can result in high viscosity or larger volume. The design of standard PFS-based autoinjectors means they can struggle with such challenging formulations. A new approach is needed to go beyond the previous limits without compromising performance or patient acceptance. This presentation outlines the current market situation, and how a novel cartridge-based concept with innovative needle design has been developed and proven to quickly and effectively deliver higher viscosities and larger volume.

11:50 ***Complimentary Lunch, Sponsored by***

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Spotlight on Human Factors

12:55 **Beyond Validation: Unlocking the Full Potential of Human Factors Engineering**

Sara Waxberg McNew, CSO, Design Science, & Teresita Pileggi, Principal Human Factors Engineer, Design Science

Human factors engineering (HFE) has often been thought of as applying to validation activities, as summative studies are frequently required for medical devices and combination products to submit to regulatory bodies. However, it is still an ongoing effort to promote industry recognition that HFE can be utilized for additional assessments throughout the product development process beyond summative studies.

Throughout the phases of product development, additional opportunities to incorporate HFE activities provide supplemental assurance that medical products have been both designed correctly to meet their design inputs and for the correct intended use(s). As outlined in TIR59, HFE is most impactful if incorporated iteratively throughout the entirety of the product development lifecycle and not viewed as a "checkbox activity" at the end of validation to be able to submit to regulatory bodies. This presentation will highlight some overlooked areas of opportunity to integrate HFE assessments and techniques to not only design safe and effective products but maximize user satisfaction and reduce development costs as well.

1:35 **Integration of Primary Container Solutions with CDMO Services for Biotech Parenteral Drugs**

Dr. Jianxiu Zhao, Senior Technology Development Manager, Terumo Medical Care Solutions—Pharmaceutical Solutions Division

Integrating primary container solutions with CDMO capabilities offers a seamless and cohesive pathway to the development of combination drug products. In this presentation, we will explore Terumo's unique capabilities to combine its primary packaging design and manufacturing with fill & finish, device assembly, and secondary packaging. This integration offers biopharmaceutical companies a streamlined solution from early development to commercial launch. By leveraging these combined capabilities, companies can enhance efficiency, shorten time-to-market, and improve overall product quality and sustainability.

2:00 ***Afternoon Networking Break, Sponsored by***

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2:15 **Begin with the End in Mind: Defining a Pathway for Regulatory Success for Devices in Combination Products**

Lauren Richards, Principal Regulatory Affairs Specialist, West Pharmaceutical Services

This discussion centers on the essential elements of a successful regulatory submission package for combination products with spotlight on the device. It highlights the importance of achieving a 'right first time' submission. Furthermore, it emphasizes the critical role of collaboration between drug and device manufacturers to ensure compliance and streamline approval. Beginning with the end in mind, teams can better mitigate risks associated with the submission process and enhance the likelihood of approval.

Critical Issues—Container Closure Integrity Testing

2:55 **Introduction to Container Closure Integrity Testing of Devices/Combination Products**

James McCaw, Associate Principal Scientist, Device Development & Technology, Merck

This presentation will walk through USP <1207> and different CCI techniques available for container closure integrity testing. A focus will be on deterministic techniques and provide potential pitfalls when developing a method.

3:35 ***Close of Program***

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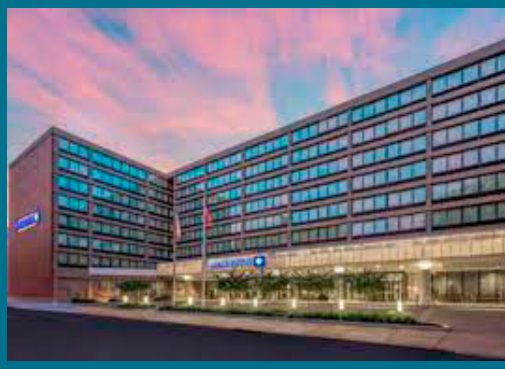

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