Conbination products Seminar2026 Japan Program with Summary

Seminar theme ：Next-Generation Combination Products for the Era of Diversifying Modalities: Addressing New Delivery Technologies and Requirements

The Purpose of this seminar:

In recent years, drug modalities have diversified and increased in volume, including antibody therapeutics, GLP-1 receptor agonists, and subcutaneous absorption-enhancing enzymes. This trend necessitates new design requirements and technological innovations. Particularly as the potential for home-based cancer treatment expands, key issues include practical implementation challenges and ensuring ease of use for patients and healthcare professionals. To address these needs, novel delivery technologies such as high-volume self-administration devices and intranasal/inhalation delivery devices are advancing, offering unprecedented treatment options.

Meanwhile, combination products, by their nature of integrating pharmaceuticals and medical devices, must comply with multiple specifications, standards, and regulatory requirements. They also introduce additional demands, such as human factors and quality requirements. Precisely because these products were born to realize patient-centered care, they face such high expectations and complex requirements.

Furthermore, diverse combination products, including autoinjectors, are being launched, and integration with digital health and smart devices is advancing. However, not all technologies are accepted by the market, necessitating technology selection and value creation based on environmental trends and needs.

This seminar aims to provide an opportunity to discuss what combination products will be required for new modalities and delivery technologies expected to emerge in the future, while also considering how to optimize them from regulatory, technical, and

usability perspectives. We will do this by first surveying the current state of response to existing modalities.

Program

Sep. 16, 2026, on Wednesday

Opening Speech　Mr. Eiji Watanabe (PDA Japan　Chapter)

Session A: Development of Dosage Forms and Formulations Corresponding to Modalities

Moderator: Mr.Yusuke Hyakkan（Takeda Pharmaceutical Co.ltd.）

9:30-10:10 A-1 Next-generation prefilled syringes that achieve higher volume, higher viscosity, and co-administration formulations

Lecturer: Dr.Mitsuru Takahashi　（Nippon Becton Dickinson）

Summary: Prefilled syringe (PFS) formulations are used in many therapeutic drugs and vaccines, such as autoimmune diseases, to promote home treatment and reduce the burden on healthcare professionals. In recent years, the number of PFS formulations has increased, and there is a trend towards higher volume and viscosity of drugs in biopharmaceuticals, as well as the need for co-administration to combine two or more drug effects and drug solutions to be administered at the same time.
In this presentation, we will introduce our cutting-edge prefilled syringe products and technologies as next-generation new dosing devices, especially the 5.5mL syringe and BD Dual-Injection Valve & Syringe System.

10:10-10:50　A-2　Optimizing injectability of high-viscosity biologics in next-generation syringe-based autoinjectors

Lecturer: Mr.Norbert Jung（Ypsomed）,Mr. Alessandro Morandotti （Stevanato Group）

Summary: Autoinjectors (AIs) integrated with prefilled syringes remain a preferred option for single-dose subcutaneous delivery, supporting the shift from hospital-based treatment to patient self-administration. Historically, most AI platforms were developed around 1 mL long syringes; however, today's higher-concentration biologics often require larger-volume containers (e.g., 2.25 mL), with emerging interest in higher volumes (5.5mL) and higher-viscosity formulations, creating new injectability and integration challenges. As product complexity grows, tight alignment between formulation, container, and delivery device becomes essential. Next-generation combination products must broaden their design space to maintain consistent performance against these evolving technical requirements. In a collaborative study, Stevanato Group and Ypsomed investigate key drivers of injectability through two complementary experiments. The first evaluates the combined effect of increasing formulation viscosity and reducing needle length. The second examines how siliconization technology (sprayed-on versus cross-linked) influences force evolution over time, using accelerated aging to capture changes in performance. This system-level approach helps guide component selection, reduces development risk, and supports robust, patient-centric autoinjector solutions tailored to next-generation therapeutic modalities.

10:50-11:05 Exhibitors' presentations
11:15-11:45 Exhibition break

11:45-12:25 A-3 Designing Drug Delivery Systems for Context: Case Studies in Lyophilized Drug Delivery and Microliter-Scale Dose Delivery

Lecturer Mr. Markus Bauss (SHL Medical）＆Mr. Nils Ronquist (SHL Medical）

Summary： The development of novel drug delivery systems is highly context-driven, aiming to meet the needs of both the drug product and its end user. As advanced therapeutics introduce challenges which may relate to stability, dosing precision, and usability, device design must align with clinical constraints for healthcare professional-led administration and practical constraints for patient-led use. This presentation highlights two case studies: a dual-chamber device for lyophilized formulations, enabling on-demand reconstitution while preserving stability and supporting intuitive use; and a micro-dosing technology delivering precise microliter-scale volumes without altering established clinical workflows. Together, these examples demonstrate how context driven design, integrating formulation requirements, engineering solutions, and user considerations, enables effective and adoptable drug delivery innovations

Session B: Session B Educational Lecture （The Global Landscape of the Healthcare Environment and the Diversifying Modalities）

Moderator: Ms. Michiyo Morikawa (CM Plus）

13:40-14:40 B-1 "The Future is Delivery"
—How the Modality Revolution Is Transforming CMC and Medical Devices—

Lecturer: Mr. Norikazu EIKI (Eiki consultants）

Summary: The value of a pharmaceutical product depends significantly not only on *what* is created but also on *how* it is delivered to patients. This presentation provides an overview of the diversification of modalities and the evolution of drug delivery. It explores how innovations in routes of administration, devices, and manufacturing technologies can enhance patient value and product competitiveness, ultimately strengthening drug discovery capabilities. The Future is Delivery.

Session C: Development of Dosage Forms and Formulations Corresponding to Modalities-2

Moderator：Dr.Shiuhei Mieda (Daiichi Sankyo Co.Ltd.)

14:40-15:20 C-1　Design Considerations for Next Generation Delivery of Oligonucleotide Therapeutics

- Focus on High Concentration SC Formulations and Direct CNS Administration （IT admin.）

Lecturer：Ms.Fumiko Koizumi, Dr. Tomoya Takenaka（Takeda Pharmaceutical Co.ltd.）

Summary: In recent years, diversification and dose escalation of pharmaceutical modalities, including monoclonal antibodies and oligonucleotide therapeutics, have driven increasing demand for advanced drug delivery technologies to improve patient convenience. In particular, subcutaneous (SC) administration and direct delivery to the central nervous system (CNS) via intrathecal (IT) or intracerebroventricular (ICV) routes are gaining importance. This presentation provides an overview of formulation challenges associated with the transition from intravenous (IV) to SC administration and high-concentration oligonucleotide products, as well as emerging trends in IT delivery devices such as implantable IT ports for CNS indications. From the perspectives of patients and healthcare professionals, key technical and usability considerations are discussed. Finally, future challenges and optimization strategies for combination product development, encompassing drug formulation and device design are explored.

15:20-15:35　Exhibitors' presentations

15:35-16:05 Exhibition break

16:05-16:45 C-2 Development of a Subcutaneous Drug Product for Lecanemab

Lecturer：Ms.Naomi Sakuramoto（Eisai Co., Ltd ）

Summary：This presentation describes the CMC strategy and the technical issues

addressed in the development of a subcutaneous auto-injector formulation of lecanemab. Because the injectable volume is limited for subcutaneous administration, development of a high-concentration formulation was a key requirement. A protein concentration of 200 mg/mL was achieved while controlling both viscosity increase and protein aggregation. In addition, through optimization of the syringe and auto-injector design, quality requirements were met while also achieving shorter injection time and simple, comfortable usability. Furthermore, to ensure the quality of the product as a combination product, basic performance requirements were defined and human factors studies were conducted. The knowledge gained through this development is expected to be useful for future development of subcutaneous formulations of biologic drugs.

16:45-17:25 C-3 Formulation–Device Integration in Inhaled Drug Delivery: Optimizing Delivery for Respiratory Medicines

Lecturer：Dr.Mireia Puig-Sellart（Phillips Medisize）

Summary: Delivering drugs to the respiratory tract supports targeted treatment of disease and offers opportunities that may not be achievable through other routes of administration. However, these benefits are typically realized through close integration of drug properties, formulation strategy and delivery device selection. This presentation examines inhalation role within an integrated formulation and device development framework.
Illustrative case studies will be presented to highlight the important relationship between formulation-device interactions when delivering medicines to different areas of the respiratory tract. The first case study highlights liquid delivery to the lungs using a smart vibrating mesh nebulization approach. A second case study explores particle engineering strategies to produce respirable dry powders for complex biologic modalities. A final case study considers nasal delivery and highlights formulation approaches used to achieve successful deposition
Together, these examples demonstrate that early, product decision making, aligned across drug, formulation and device design, supports the successful development of emerging respiratory therapies.

Session D: Container Materials and Regulatory Compliance

Moderator：Ms. Brigitte Reutter-Haerle（Vetter Pharma ）

17:25-18:05　D-1　Elastomer Components and the Latest Regulatory Expectations: Meeting Global Standards（Pre-recorded lectures）

Lecturer：Dr. Ana Kuschel（West Pharmaceutical Services）

Summary：Global regulatory expectations for elastomer components in injectable packaging are rapidly evolving, with increased focus on material characterization, extractables and leachables data, and risk-based lifecycle management. This presentation reviews current requirements from USP, Ph. Eur., ISO, and ICH, and outlines practical approaches to demonstrating compliance through testing, documentation, and quality systems. It highlights how proactive alignment with global standards strengthens regulatory confidence, protects patient safety, and supports sustainable market access.

18:15-20:15　Mixer

Session E: Usability and Risk Management

Moderator：E-1　Mr. Eiji Watanabe (PDA Japan　Chapter),

E-2、E-3　　Mr. Shuichi Hatano (Shionogi & Co., Ltd.)

9:00-9:40　E-1　Usability Engineering Standard for Medical Devices (JIS T 62366-1) and its Application to Autoinjectors

Lecturer：Dr. Miyuki Shimizu（Medical Lab Partners）

Summary：Usability engineering process in the medical device development is not for improving user satisfaction or the product’s appearance; rather, it is for reducing the risks to an acceptable level, arising from use errors which occur when medical devices are used according to the instruction for use. Usability engineering process are conducted in accordance with the medical device usability engineering standard (JIS T 62366-1) and validate user interfaces, such as product display and instruction for uses.

In this presentation, the workflow and concepts of the usability engineering process will be discussed, as well as specific activities using an autoinjector as a case study.

9:40-10:20 E-2 Human Factors/Usability Engineering for Combination Products from a vendor's perspective
Lecturer：Dr. Ong Weiling（INTAGE Healthcare Inc.）

Summary：This presentation shares a vendor's practical perspective on applying Human Factors/Usability Engineering (HF/UE) to combination products as a risk-reduction process. We first review the essentials - formative vs. validation testing, critical tasks, and use error handling – and how HFE becomes pivotal when the users, user interfaces, and use environments interact. We will then briefly compare regulatory expectations across Japan, Korea, US, EU, and China, highlighting both the common backbone (deliverables and traceability) and typical points of divergence such as study intent, level of detail, IFU/labeling assumptions, and acceptance logic. We propose two main success factors: early planning with end-to-end traceability from critical tasks to risk analysis to study design, and validation study designs that are realistic, risk-focused, and defensible. These are illustrated with real project examples aligned with global standards. Common observed pitfalls conclude the session.

10:20-10:50　Exhibition break

10:50-11:30 E-3 Risk Management in Drug–Device Combination Products in Clinical Setting
Lecturer：Mr. Yasunori Nagano（Sanraku Hospital）

Summary：In this presentation, I address post-marketing safety surveillance of drug–device combination products, focusing on risks that arise from device operation in clinical settings and on how such risks should be managed. The presentation discusses appropriate approaches to risk management from the standpoint of real-world clinical

practice, particularly in situations where device handling contributes to safety concerns. In addition to presenting the research findings obtained to date, I incorporate insights and reflections drawn from clinical experience to examine the identification of safety signals and potential directions for risk minimization.

Session F: Utilizing IoT （Electronic Information）

Moderator：Mr. Kazuhisa Matsunaga (Astellas Pharma)

11:30-12:10 F-1 Smart Self-Injection: Enhancing Clinical Trial Efficiency and Commercial Care Coordination

Lecturer：Dr. Stefanie Seiler（YPSOMED）

Summary：Self-injectable therapies are becoming increasingly important due to the shift toward at-home care, an aging population, and the rise of injectable treatments. Consequently, self-injection devices are now commonly used in clinical trials to reduce site visits and patient burden. However, such clinical studies limit investigators' and sponsors' ability to oversee drug administration.

Smart injection devices help bridge this gap by capturing accurate, time-stamped, injection data and by tracking user errors. They enable real-time adherence monitoring and allow for immediate intervention to address the pain points with subcutaneous injection.

This presentation will share results from a user study simulating a clinical trial. The study examined the effect of a smart, connected accessory used with a standard autoinjector on operational efficiency and usability as compared to traditional manual documentation methods.

The session concludes with an outlook on the broader value of smart injection

technologies in commercial settings, particularly for improving care coordination and supporting better patient outcomes.

12:15－12:55 Lunch （luncheon seminar）Company：I.M.A. Industria Macchine Automatiche S.p.A.

12:55-13:25 Exhibition break

13:25-14:05 F-2 Toward the Implementation of Safe Medication Administration

Lecturer：Ms. Eriko Nemoto（Terumo）

In clinical settings, numerous medication errors have been reported during syringe pump–based drug administration, including incorrect setting of doses or units and selection of the wrong medication to be loaded into the pump.
To address these challenges, Terumo aims to enhance both medication safety and operational efficiency by utilizing IC tag–enabled prefilled syringes (PFS) in combination with RFID-enabled smart pumps. These technologies allow for automatic drug identification at the time of setup and the use of upper and lower dosing limiters to prevent administration errors.
Based on the current realities of medication administration in clinical practice, this lecture will demonstrate how these systems contribute to reducing medication errors and will provide perspectives for strengthening medication safety measures and improving administration processes.

SessionG: Process Design Methods

Moderator：Mr. Hiroaki Suzuki　(Vetter Pharma)

14:05-14:45　G-1　　From Clinical Manufacturing to Commercial Supply – Key Considerations and Lessons Learned

Lecturer：Dr. Armin Wilfinger（Vetter Pharma）

Summary：As demand for prefilled syringes and cartridges continues to grow—driven by high-value biologics, patient-centric delivery, and home-use requirements—the transition from vial-based clinical manufacturing to commercial prefilled systems introduces additional complexity.

This becomes even more challenging when managing *large volumes*, both in terms of increased bulk drug substance quantity and the higher fill volumes required for certain delivery formats. Within a Quality by Design (QbD) framework, early definition of critical parameters across the entire process chain is essential. This includes addressing both product- and process-related factors, especially during scale-up and development of the filling process: defining compounding strategies for large-volume batch sizes, selecting suitable pumping technologies for accurate dosing, and establishing robust stopper placement approaches. Understanding how fill volume, container geometry, and device requirements interact is essential to designing a robust process that ultimately delivers a product meeting all performance and quality expectations.

This presentation highlights these considerations and how a QbD-driven approach enables stable, scalable, and regulatory-compliant manufacturing processes.

14:45-15:15: Exhibition break

15:15-15:55　G-2　Approaches to yield improvement in redundant filtration system

Lecturer：Mr.Taichi Hanada（Merck）

Summary：Combination products are increasingly required to be manufactured in a consistently stable manner due to the evolution of therapeutic approaches designed for self-administration, alongside the growing diversity in formulation characteristics. In this context, ensuring product yield in the final sterile filtration process remains one of

the critical challenges in the manufacturing of combination products. In general, redundant filtration is implemented in the final sterile filtration process as a risk mitigation measure against integrity test failures; however, this inevitably results in a more complex process, requiring careful consideration during both process development and operation. Even when the filtration system itself is appropriately designed, inadequate operational practices, such as pre-filtration flushing-related recovery operations or post-filtration product recovery steps, can lead to yield losses. This presentation introduces approaches to maximising yield from both process development and operational perspectives, using redundant filtration with single-use products as an example.

SessionH: Case Studies on Material Properties and Container Closer Integrity Testing

Moderator：Mr. Yoshiya Minakami （Chugai pharmaceutical）

15:55－16:35 H-1 Considerations for the Use of COC Cartridges in Combination Products for Emerging Drug Modalities

Lecturer：Mr.Christoph Zauner（Schott Pharma）

Summary：The rapid expansion of advanced drug modalities, including antibody therapeutics, GLP-1 receptor agonists, high-concentration biologics, and lipid-nanoparticle (LNP)–based formulations, has increased functional performance requirements for primary packaging in combination products. In parallel, the shift toward self-administration and home-based therapies has heightened the relevance of mechanical robustness, container–closure stability, and predictable performance under cold-chain and frozen storage conditions. Cyclic olefin copolymer (COC) cartridges have therefore been evaluated as an alternative to conventional glass containers, with particular focus on low-temperature use scenarios where brittle fracture of glass represents a handling risk.
Freeze-storage studies investigating siliconization behavior quantified extractable free

silicone under controlled conditions. At −20 °C, sprayed-on silicone systems exhibited approximately 24-fold higher levels of free silicone compared with cross-linked siliconized systems.
Formulation compatibility was assessed using LNPs as a sensitive model system. Comparative storage studies at −80 °C demonstrated comparable LNP particle size and polydispersity index (PDI) in polymer syringes and market-standard glass vials over multiple time points, while ToF-SIMS–based surface analysis indicated much lower LNP adsorption on polymer syringe surfaces, showing a major advantage.
From a device-integration perspective, reported glass cartridge internal-diameter tolerances are typically controlled at approximately ±0.09 mm (often treated as ±0.10 mm). Manufacturing capabilities as well as technical capability analysis show that polymer can substantially reduce diameter-driven variability, supporting more robust cartridge–stopper–device interfaces.

16:35-17:15 H-2 CCIT Strategies and Solutions for Combination Products

Lecturer：Dr. Wenliang Chen（Packaging Technologies & Inspection）

Summary: As drug-device combination systems and prefilled syringes (PFS) increase in complexity, this presentation examines advanced strategies for Container Closure Integrity Testing (CCIT) with a focus on ensuring sterility assurance and long-term product stability. Aligned with USP <1207> and current regulatory expectations, this session evaluates the applicability, sensitivity, and limitations of deterministic CCIT technologies across different stages of the product lifecycle. The presentation specific focus will be placed on micro-current HVLD for high-sensitivity integrity testing in liquid-filled PFS, helium leak detection for USP <382> compliance and component qualification, and vacuum decay as a robust, non-destructive, and scalable solution for routine batch release testing of combination products.

In general, the presentation will focus on few key points, which includes how to align CCIT method selection with product design, regulatory expectations, and lifecycle requirements to support robust container closure integrity strategies for combination products.

Session I: Q&A session

17:20-17:50 Q&A session Mr. Eiji Watanabe（PDA Japan Chapter）

17:50-18:00 Closing message Mr. Eiji Watanabe（PDA Japan Chapter）