SYMPOSIUM 2026 UTRECHT

Combination Products Programme

Monday 19 October 2026 – Tuesday 20 October 2026

Beatrix Building, Royal Jaarbeurs, Utrecht, The Netherlands

Please note, the programme may be subject to change.

Monday 19 October 2026 – DAY 1

Time	Session
11:00-12:00	**Registration**
12:00–12:10	**Welcome Speech**
	Speakers • Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden
12:10-13:40	**CP1 – Combo Group: Aligning Regulatory Practice for Combination Products**
	As combination products become increasingly more prevalent and complex, regulatory integration between medicinal and device frameworks is becoming critical. These products can experience many challenges in getting to market. The formation of the COMBination products Operational group (COMBO) is a significant step towards strengthening coordination across the EU regulatory framework with regards to this rapidly developing area, involving experts from the EMA, Commission, Medicines Competent Authorities, Device Authorities and Notified Bodies. Two distinct streams MD and IVD will explore solutions on identified issues to clarify and streamline processes and scope of activities under the current frameworks. Priority topics for MD include consultation for ancillary substances, Notified Body opinion and co-packaged devices & labelling. For IVD priority topics include distinction CDs vs IVDs and CDx consultation. This session will explore the challenges the COMBO group aims to address and the progress the group has made since its inception in October 2025.
	Session Leaders • Christelle Bouygues, Senior Regulatory Affairs Officer, EMA, The Netherlands
	Speakers coming soon...
13:40–14:40	**Lunch Break**
14:40–16:00	**CP2 – Global Approaches to Combination Products**
	Whilst combination products present unique regulatory challenges, much like other medicinal products and medical devices, they are subject to divergent pathways across different jurisdictions. As global innovation accelerates, understanding the requirements of each region to develop robust global strategies is key for professionals working in this space. This session will compare regulatory pathways and classification approaches for combination products across major global jurisdictions (including Europe and USA) and identify best practices for regulatory strategy. The session will also provide the latest regional updates and explore what each sector can learn from the others regarding regulatory frameworks for combination products.
	Session Leaders • Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden
	Speakers will include... • Barr Weiner, Consultant (Former Director, FDA Global Operations), Barr Consulting LLC, United States of America
16:00–16:40	**Networking Break**
16:40–18:00	**CP3 – Maintaining Post-Market Compliance for Combination Products**
	Combination products operate within a complex post-market environment, in which marketing authorisation holders and manufacturers must ensure coherent, compliant and safety monitoring systems. This session will explore how pharmacovigilance and post-market surveillance (PMS) requirements intersect for drug-device combinations, providing insights on what is expected and how to practically implement robust systems. along with case studies from industry experts.

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	Session Leaders • Ronald Boumans, Strategic Consultant, Boumans Regulatory Consulting B.V., The Netherlands
	Speakers will include... • Jan Bart Hak, Director MedTech Regulatory Sciences, ProPharma, The Netherlands
18:00–18:05	**Closing Speech**

End of Day 1

Tuesday 20 September 2026 – DAY 2

Time	Session
08:55–09:00	**Welcome to Day 2**
09:00–10:20	**CP4 – Effectively Managing Changes to Drug-Device Combination Products**
	Managing lifecycle changes for combination products in Europe presents distinct regulatory and operational challenges due to the dual oversight of medicinal product and medical device frameworks. Variations to the marketing authorisation may intersect with significant change assessments under the Medical Device Regulation (MDR), requiring coordination between competent authorities, notified bodies, and manufacturers. This session will examine how to plan and implement complex changes to drug-device combinations, such as device design modifications. It will explore regulatory classification of changes, documentation expectations, timelines, and strategies for aligning variation procedures with device conformity assessment requirements. Practical case studies will highlight common pitfalls, including misalignment of change control systems, impact assessments for primary mode of action, and maintaining CE certification during medicinal variations. Attendees will gain insights into proactive lifecycle planning, cross-functional governance, and maintaining compliance while supporting innovation and supply continuity.
	Session Leaders • Janine Jamieson, Editor, European IPQ, Sweden
	Speakers will include... • Louise Place, Senior Director CMC Regulatory Affairs Devices, GSK, United Kingdom
10:20–11:00	**Networking Break**
11:00–12:20	**CP5 – Combination Products of the Future**
	The convergence of new technologies, such as cell therapy, is redefining the landscape of combination products. Advanced therapy medicinal products (ATMPs), including engineered cell therapies, increasingly rely on specialised delivery systems, digital monitoring tools and companion devices. These new types of products raise plenty of complex regulatory questions, such as around classification, conformity assessments and long-term follow-up requirements. This session will have innovators who are working on such new technologies, and they how have addressed the regulatory challenges with these products. The session will also have a representative from a national competent authority on how authorities are supporting the advent of these new technologies.
	Session Leaders • Margareth Jorvid, Chief Executive Officer, Methra Uppsala, Sweden
	Speakers will include... • Ilona Reischl, Assessor, AGES, Austria • James Wabby, Vice President, Head of Regulatory Strategy: Combination Products and Emerging Medical Technologies, AbbVie, United States of America

End of the Combination Products Symposium